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8 December

NEW - 9-11 December CMDh agenda

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
12/12/2025	**Document**: Minutes of the CVMP meeting 4-6 November 2025	New
12/12/2025	**Document**: Work plan for the Committee for Veterinary Medicinal Products (CVMP) Antimicrobials Working Party (AWP) 2026	New
12/12/2025	**Event**: HMA/EMA multi-stakeholder workshop on artificial intelligence (AI)	Updated
12/12/2025	**Document**: CTIS Simplification Task Force: topics for analysis	Updated
12/12/2025	**Event**: Clinical Trials Information System (CTIS) sponsor end user training programme - March 2026	New
12/12/2025	**Event**: 15th Industry Standing Group (ISG) meeting	Updated
12/12/2025	**Document**: Biomarkers in oncology indications approved in the EU: key facts	New
12/12/2025	**Event**: EMA multistakeholder workshop on supporting innovation in cardiovascular medicines and medical devices in the EU	New
12/12/2025	**Medicine**: Clopidogrel Viatris (previously Clopidogrel Taw Pharma) clopidogrel	Updated
12/12/2025	**Medicine**: Prialt ziconotide	Updated

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12/12/2025	**Medicine**: Synagis palivizumab	Updated
12/12/2025	**Medicine**: Azacitidine Mylan azacitidine	Updated
12/12/2025	**Medicine**: Libmyris adalimumab	Updated
12/12/2025	**Medicine**: Imaavy nipocalimab	Updated
12/12/2025	**News**: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 8-11 December 2025	New
12/12/2025	**News**: New medicine to treat non-muscle invasive bladder cancer	New
12/12/2025	**Medicine**: Ranluspec ranibizumab	New
12/12/2025	**Medicine**: Gotenfia golimumab	New
12/12/2025	**Medicine**: Exdensur depemokimab	New
12/12/2025	**Medicine**: Jelrix autologous cartilage-derived articular chondrocytes, in-vitro expanded	Updated
12/12/2025	**Medicine**: Aumseqa Aumolertinib	New
12/12/2025	**Medicine**: mNexspike COVID-19 mRNA vaccine	New
12/12/2025	**Medicine**: Blarcamesine Anavex blarcamesine	New
12/12/2025	**Medicine**: Myqorzo aficamten	New
12/12/2025	**Medicine**: Anktiva nogapendekin alfa inbakicept	New
12/12/2025	**Referral**: Melatomed and associated names - referral melatonin	New
12/12/2025	**Post-authorisation**: Dovprela (previously Pretomanid FGK) - opinion on variation to marketing authorisation pretomanid	New
12/12/2025	**Post-authorisation**: Elucirem - opinion on variation to marketing authorisation gadopiclenol	New
12/12/2025	**Post-authorisation**: Vueway - opinion on variation to marketing authorisationgadopiclenol	New

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12/12/2025	**Post-authorisation**: Nucala - opinion on variation to marketing authorisation mepolizumab	New
12/12/2025	**Post-authorisation**: Hetlioz - opinion on variation to marketing authorisation tasimelteon	New
12/12/2025	**Post-authorisation**: Uplizna - opinion on variation to marketing authorisation inebilizumab	New
12/12/2025	**Post-authorisation**: Mounjaro - opinion on variation to marketing authorisation tirzepatide	New
12/12/2025	**Post-authorisation**: Eylea - opinion on variation to marketing authorisation aflibercept	New
12/12/2025	**Post-authorisation**: Winrevair - opinion on variation to marketing authorisation sotatercept	New
12/12/2025	**Post-authorisation**: Arexvy - opinion on variation to marketing authorisation recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E	New
12/12/2025	**Post-authorisation**: Vfend - opinion on variation to marketing authorisation voriconazole	New
12/12/2025	**Post-authorisation**: Simponi - opinion on variation to marketing authorisation golimumab	New
12/12/2025	**Post-authorisation**: Recarbrio - opinion on variation to marketing authorisation imipenem; cilastatin; relebactam	New
12/12/2025	**Post-authorisation**: Aspaveli - opinion on variation to marketing authorisation pegcetacoplan	New
12/12/2025	**Medicine**: Prevymis letermovir	Updated
12/12/2025	**Event**: Fourth European Medicines Agency - Medtech Europe bilateral meeting	Updated
12/12/2025	**Page**: Clinical investigation of medicinal products in the treatment of patients with acute respiratory distress syndrome - Scientific guideline	Updated
12/12/2025	**Document**: Guideline on the clinical investigation of medicinal products in the treatment of patients with acute respiratory distress syndrome - Revision 2	New

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12/12/2025	**Document**: Checklist for the submission of day +5 translations for a post-opinion linguistic review - veterinary	Updated
12/12/2025	**Document**: HMPC meeting report on European Union herbal monographs, guidelines and other activities - 17-19 November 2025	New
12/12/2025	**Page**: Union list of critical medicines	Updated
12/12/2025	**Document**: Questions and answers on the Union list of critical medicines	Updated
12/12/2025	**Document**: Union list of critical medicines	New
12/12/2025	**Page**: ICH E22 General considerations for patient preference studies - Scientific guideline	New
12/12/2025	**Document**: ICH E22 Guideline on general considerations for patient preference studies - Step 2b	New
12/12/2025	**Document**: CVMP work plan 2026	New
12/12/2025	**Document**: Work plan for the Committee for Veterinary Medicinal Products (CVMP) Efficacy Working Party (EWP-V) 2026	New
12/12/2025	**Document**: Work plan for the Committee for Veterinary Medicinal Products (CVMP) Environmental Risk Assessment Working Party (ERAWP) 2026	New
12/12/2025	**Document**: Work plan for the CVMP Novel Therapies & Technologies Working Party (NTWP) 2026	New
12/12/2025	**Document**: Work plan for the Committee for Veterinary Medicinal Products (CVMP) Pharmacovigilance Working Party (PhVWP-V) 2026	New
12/12/2025	**Document**: Work plan for the European Sales and Use of Antimicrobials in veterinary medicine Working Group (ESUAvet WG) 2026	New
12/12/2025	**Document**: Work plan for the Committee for Veterinary Medicinal Products (CVMP) Safety Working Party (SWP-V) 2025	New
12/12/2025	**Document**: Checklist for the submission of Day 215 product information annexes for a post-opinion linguistic review (Word file)	Updated
12/12/2025	**Document**: Work plan for the Committee for Veterinary Medicinal Products (CVMP) Immunologicals Working Party (IWP) 2026	New
12/12/2025	**Document**: Work plan for the Committee for Veterinary Medicinal Products (CVMP) Scientific Advice Working Party (SAWP-V) for 2026	New
12/12/2025	**Page**: Stability testing for applications for variations to marketing authorisation - Scientific guideline	Updated
12/12/2025	**Document**: Guideline on stability testing for applications for variations to a marketing authorisation - Revision 3	New
11/12/2025	**Medicine**: Teriflunomide Viatris (previously Teriflunomide Mylan) teriflunomide	Updated
11/12/2025	**Medicine**: Darunavir Viatris (previously Darunavir Mylan)	Updated

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	darunavir	
11/12/2025	**Medicine**: Tobi Podhaler tobramycin	Updated
11/12/2025	**Medicine**: Afstyla lonoctocog alfa	Updated
11/12/2025	**Document**: Highlights - 20th EMA Industry Platform meeting on the operation of EU pharmacovigilance legislation meeting	New
11/12/2025	**Event**: New variations guidelines: webinar for marketing authorisation holders (human)	New
11/12/2025	**Medicine**: Pifeltro doravirine	Updated
11/12/2025	**Event**: Virtual live hands-on training course for clinical trials sponsors using EudraVigilance system - February 2026	New
11/12/2025	**Event**: Virtual live hands-on training course for clinical trials sponsors using EudraVigilance system - May 2026	New
11/12/2025	**Medicine**: Veyvondi vonicog alfa	Updated
11/12/2025	**Medicine**: Hyrimoz adalimumab	Updated
11/12/2025	**Medicine**: Hefiya adalimumab	Updated
11/12/2025	**News**: EMA welcomes political agreement on new EU pharmaceutical legislation	New
11/12/2025	**Medicine**: Mounjaro tirzepatide	Updated
11/12/2025	**Document**: Members of the Coordinating group of European network of paediatric research at the European Medicines Agency (Enpr-EMA)	Updated
11/12/2025	**Event**: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) – December 2025	Updated
11/12/2025	**Document**: Agenda – Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) (17 December 2025)	New
11/12/2025	**Document**: From laboratory to patients: How the safety of medicines is ensured in the European Union	Updated
11/12/2025	**Document**: Methodology European Specialised Expert Community (ESEC): Members	Updated
11/12/2025	**PSUSA**: PSUSA/00000177/202501 - periodic safety update report single assessment amlodipine / atorvastatin	New

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11/12/2025	**Document**: Methodology Working Party (MWP) interested parties meeting report, September 2025	New
11/12/2025	**Event**: First EMA/HMA multi-stakeholder forum on EudraVigilance and signal detection	Updated
11/12/2025	**Document**: Consolidated 3-year work plan for the Emergency Task Force (ETF)	Updated
11/12/2025	**DHPC**: Tranexamic acid - direct healthcare professional communication (DHPC) tranexamic acid	New
11/12/2025	**Page**: Questions and answers on post approval change management protocols - Scientific guideline	Updated
11/12/2025	**Document**: Questions and answers on post approval change management protocols (PACMP) - Revision 1	New
11/12/2025	**Event**: Mandatory use of ISO/ICH E2B(R3) Individual Case Safety Reporting inthe EU: Hands-on training course using the EudraVigilance System	New
11/12/2025	**Event**: Mandatory use of ISO/ICH E2B(R3) Individual Case Safety Reporting inthe EU: Hands-on training course using the EudraVigilance System	New
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11/12/2025	**Event**: Mandatory use of ISO/ICH E2B(R3) Individual Case Safety Reporting inthe EU: Hands-on training course using the EudraVigilance System	New
10/12/2025	**Page**: Guidance on good manufacturing practice and good distribution practice: Questions and answers	Updated
10/12/2025	**Page**: How to submit information on authorised and investigational medicines	Updated
10/12/2025	**Document**: Draft user manual for the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) user interface (XEVMPDweb)	New
10/12/2025	**PIP**: EMA/PE/0000183758 - paediatric investigation plan zimislecel	New

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10/12/2025	**PIP**: EMA/PE/0000183430 - paediatric investigation plan tralokinumab	Updated
10/12/2025	**PIP**: EMA/PE/0000183866 - paediatric investigation plan brexpiprazole	Updated
10/12/2025	**PIP**: EMA/PE/0000184400 - paediatric investigation plan dapagliflozin; eplerenone	New
10/12/2025	**PIP**: EMA/PE/0000183220 - paediatric investigation plan iclepertin	Updated
10/12/2025	**PIP**: EMEA-002944-PIP01-20 - paediatric investigation plan 2-[(4-{6-[(4-cyano-2-fluorobenzyl)oxy]pyridin-2-yl}piperidin-1-yl)methyl]-1-[(2S)-oxetan-2-ylmethyl]-1H-benzimidazole-6-carboxylic acid tris(hydroxymethyl)aminomethane salt (1:1) (PF-06882961)	Updated
10/12/2025	**PIP**: EMEA-003104-PIP02-22 - paediatric investigation plan Favezelimab; pembrolizumab	Updated
10/12/2025	**PIP**: EMEA-002979-PIP01-21 - paediatric investigation plan pamrevlumab	Updated
10/12/2025	**PIP**: EMEA-001613-PIP04-21 - paediatric investigation plan tezepelumab	Updated
10/12/2025	**PIP**: EMEA-001758-PIP01-15-M02 - paediatric investigation plan Lumicitabine	Updated
10/12/2025	**Medicine**: Aimovig erenumab	Updated
10/12/2025	**Medicine**: Livogiva teriparatide	Updated
10/12/2025	**Medicine**: Kovaltry octocog alfa	Updated
10/12/2025	**Medicine**: Libmeldy autologous CD34+ cells encoding ARSA gene	Updated
10/12/2025	**Medicine**: Eydenzelt aflibercept	Updated
10/12/2025	**Page**: Radiopharmaceuticals - Scientific guideline	Updated
10/12/2025	**Document**: Draft guideline on quality of radiopharmaceuticals - Revision 2	New
10/12/2025	**Event**: 20th industry stakeholder platform - operation of European Union (EU) pharmacovigilance	Updated
10/12/2025	**Event**: Annual open meeting of the European Network of Paediatric Research at EMA (Enpr-EMA) November 2025	Updated
10/12/2025	**Medicine**: Sirolimus TriviumVet sirolimus	New

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10/12/2025	**Document**: EMA procedural advice for medicinal products intended exclusively for markets outside the European Union in the context of co-operation with the World Health Organisation (WHO)	Updated
10/12/2025	**Event**: 2025 annual meeting of the members and Coordinating Group of the European network of paediatric research at the EMA (Enpr-EMA)	New
10/12/2025	**Document**: Minutes of the CAT meeting 8-9 October 2025	New
10/12/2025	**Document**: Minutes of the CAT meeting 10-12 September 2025	New
10/12/2025	**Page**: Union Product Database	Updated
10/12/2025	**Medicine**: Pandemic influenza vaccine H5N1 AstraZeneca (previously Pandemic influenza vaccine H5N1 Medimmune) pandemic influenza vaccine (H5N1) (live attenuated, nasal)	Updated
10/12/2025	**Medicine**: Rizmoic naldemedine	Updated
10/12/2025	**Medicine**: Libtayo cemiplimab	Updated
10/12/2025	**Document**: Article 57 product data	Updated
10/12/2025	**Medicine**: Esbriet pirfenidone	Updated
10/12/2025	**Medicine**: Cejemly sugemalimab	Updated
10/12/2025	**Page**: Medical devices	Updated
10/12/2025	**Page**: List of medicines under additional monitoring	Updated
10/12/2025	**Document**: List of medicinal products under additional monitoring	Updated
10/12/2025	**Document**: List of medicinal products under additional monitoring	Updated
09/12/2025	**Page**: Dextrans - Scientific guideline	Updated
09/12/2025	**PIP**: EMA/PE/0000182447 - paediatric investigation plan amlitelimab	Updated
09/12/2025	**PIP**: EMA/PE/0000183373 - paediatric investigation plan tadalafil; tamsulosin	New
09/12/2025	**PIP**: EMA/PE/0000183329 - paediatric investigation plan interleukin-23 receptor antagonist peptide	Updated
09/12/2025	**PIP**: EMA/PE/0000183137 - paediatric investigation plan encaleret	Updated
09/12/2025	**PIP**: EMA/PE/0000182808 - paediatric investigation plan zoliflodacin	Updated
09/12/2025	**PIP**: EMA/PE/0000183083 - paediatric investigation plan	New

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	(S)-(4-amino-1,3-dihydrofuro[3,4-c][1,7]naphthyridin-8-yl)(3-(4-(trifluoromethyl)phenyl)morpholino)methanone	
09/12/2025	**PIP**: EMA/PE/0000182525 - paediatric investigation plan modified messenger ribonucleic acid encoding individual patient-specific tumour neoantigens (V940/ mRNA-4157)	New
09/12/2025	**PIP**: EMA/PE/0000182462 - paediatric investigation plan bizalimogene ralaplasmid; mavilimogene ralaplasmid; rocakinogene sifuplasmid	New
09/12/2025	**PIP**: EMA/PE/0000182440 - paediatric investigation plan resiniferatoxin	New
09/12/2025	**Medicine**: Carbaglu carglumic acid	Updated
09/12/2025	**Page**: Cancer Medicines Forum	Updated
09/12/2025	**Document**: Mandate, objectives and rules of procedure for the Cancer Medicines Forum	New
09/12/2025	**Medicine**: Bimervax COVID-19 Vaccine (recombinant, adjuvanted)	Updated
09/12/2025	**Document**: Bimervax: Periodic safety update report assessment 30 September 2024 - 29 March 2025	New
09/12/2025	**Medicine**: Enzalutamide Viatris enzalutamide	Updated
09/12/2025	**Document**: Concept paper on the guideline revision on good pharmacogenomic practice	Updated
09/12/2025	**Medicine**: Loargys pegzilarginase	Updated
09/12/2025	**Event**: European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties meeting with all eligible organisations - 2025	Updated
09/12/2025	**Document**: Meeting summary - PCWP/HCPWP and all eligible organisations meeting 18 November 2025	New
09/12/2025	**Medicine**: Inbrija levodopa	Updated
09/12/2025	**Medicine**: Anzupgo delgocitinib	Updated
09/12/2025	**Medicine**: Gohibic vilobelimab	Updated
09/12/2025	**Document**: List of substances and products subject to worksharing for signal management	Updated
09/12/2025	**Page**: Combination Products Operational Group	Updated

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09/12/2025	**Document**: Combination Products Operational Group (COMBO) - Terms of reference	New
09/12/2025	**Medicine**: Kimmtrak tebentafusp	Updated
09/12/2025	**Medicine**: Opdivo nivolumab	Updated
09/12/2025	**Medicine**: Levetiracetam Accord levetiracetam	Updated
09/12/2025	**Medicine**: Dacogen decitabine	Updated
09/12/2025	**Document**: Consolidated 3-year rolling work plan for the Methodology Working Party 2026-2028	New
09/12/2025	**News**: New data on antimicrobials sales and use in animals in the EU	New
09/12/2025	**Page**: European Sales and Use of Antimicrobials for Veterinary Medicine (ESUAvet) annual surveillance reports	Updated
09/12/2025	**Document**: European sales and use of antimicrobials for veterinary medicine: Annual surveillance report for 2024	New
09/12/2025	**Document**: 3-year work plan for the joint CHMP/CVMP Quality Working Party 2026-2028	New
09/12/2025	**Document**: Consolidated 3-year rolling work plan for the Non-clinical domain 2026-2028	New
09/12/2025	**Event**: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	Updated
09/12/2025	**Page**: Questions and answers for biological medicinal products	Updated
09/12/2025	**Document**: New Approach Methodologies EU-IN Horizon Scanning Report	Updated
09/12/2025	**Document**: 3-year rolling work plan for the Biosimilar Medicinal Products Working Party 2026-2028	New
09/12/2025	**Document**: Alzheimer's disease EU-IN Horizon Scanning Report	Updated
09/12/2025	**Document**: 3-year work plan for the Biologics Working Party (BWP) 2026-2028	New
09/12/2025	**Medicine**: Aubagio teriflunomide	Updated
09/12/2025	**Page**: Development and manufacture of synthetic peptides - Scientific guideline	Updated
09/12/2025	**Document**: Guideline on the development and manufacture of synthetic peptides	New
09/12/2025	**Event**: 15th industry stakeholder platform on research and development support	Updated

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09/12/2025	**Medicine**: Eviplera emtricitabine; rilpivirine; tenofovir disoproxil	Updated
09/12/2025	**Medicine**: Abecma idecabtagene vicleucel	Updated
09/12/2025	**Medicine**: Kostaive zapomeran	Updated
09/12/2025	**PIP**: EMEA-003580-PIP01-24 - paediatric investigation plan 6'-([(1S,3S)-3-([5-(difluoromethoxy)-2-pyrimidinyl]amino)cyclopentyl]amino)-2H- [1,3'-bipyridin]-2-one (AZD0780)	New
09/12/2025	**PIP**: EMEA-003564-PIP01-23 - paediatric investigation plan olorofim	New
09/12/2025	**PIP**: EMEA-003558-PIP01-23 - paediatric investigation plan linaprazan glurate	New
09/12/2025	**PIP**: EMEA-003588-PIP01-24 - paediatric investigation plan 7-ethyl-10-hydroxy-camptothecin	New
09/12/2025	**PIP**: EMEA-003592-PIP01-24 - paediatric investigation plan gorilla adenovirus vector expressing HPV6 and HPV11 antigens (PRGN-2012)	New
09/12/2025	**PIP**: EMEA-003614-PIP01-24 - paediatric investigation plan diazoxide choline	New
09/12/2025	**Page**: European Surveillance of Veterinary Antimicrobial Consumption (ESVAC): 2009 - 2023	Updated
08/12/2025	**Document**: Agenda - PDCO agenda of the 9-12 December 2025 meeting	New
08/12/2025	**PIP**: EMEA-003556-PIP02-24 - paediatric investigation plan tulisokibart	New
08/12/2025	**PIP**: EMEA-003556-PIP01-23 - paediatric investigation plan tulisokibart	New
08/12/2025	**PIP**: EMEA-003506-PIP01-23 - paediatric investigation plan doruxapapogenum ralaplasmidum	New
08/12/2025	**PIP**: EMEA-002978-PIP02-24 - paediatric investigation plan trastuzumab deruxtecan	New
08/12/2025	**Herbal**: Carvi fructus - herbal medicinal product Caraway fruit	Updated
08/12/2025	**Herbal**: Carvi aetheroleum - herbal medicinal product Caraway oil	Updated
08/12/2025	**PIP**: EMA/PE/0000225184 - paediatric investigation plan nirmatrelvir; ritonavir	Updated
08/12/2025	**Herbal**: Althaeae radix - herbal medicinal product Marshmallow Root	Updated
08/12/2025	**Medicine**: Palforzia defatted powder of Arachis hypogaea L., semen (peanuts)	Updated
08/12/2025	**Medicine**: Tecartus brexucabtagene autoleucel	Updated
08/12/2025	**Medicine**: Yescarta axicabtagene ciloleucel	Updated
08/12/2025	**Medicine**: Caprelsa vandetanib	Updated
08/12/2025	**Document**: Medicine shortage communication (MSC): Insulin lispro Sanofi (insulin lispro 100 units/ml solution for injection in cartridge and pre-filled pen)	New

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08/12/2025	**Shortage**: Insulin lispro Sanofi insulin lispro	New
08/12/2025	**Medicine**: Neulasta pegfilgrastim	Updated
08/12/2025	**Medicine**: Zubsolv buprenorphine; naloxone	Updated
08/12/2025	**Medicine**: Symkevi tezacaftor; ivacaftor	Updated
08/12/2025	**Document**: Programme - Joint HMA/EMA multi-stakeholder workshop on Patient Registries December 2025	Updated
08/12/2025	**Document**: Medicinal products for human use: monthly figures - November 2025	New
08/12/2025	**Medicine**: Xermelo telotristat ethyl	Updated
08/12/2025	**Medicine**: Scemblix asciminib	Updated
08/12/2025	**Document**: Agenda - HMA/EMA Annual Data Forum 2025	Updated
08/12/2025	**Medicine**: Filspari sparsentan	Updated
08/12/2025	**Event**: Committee for Medicinal Products for Human Use (CHMP): 08-11 December 2025	Updated
08/12/2025	**Document**: Annex to agenda of the CHMP meeting 8-11 December 2025	New
08/12/2025	**Document**: Agenda of the CHMP meeting 8-11 December 2025	New
08/12/2025	**Document**: Classification of changes (tracked changes)	Updated
08/12/2025	**Document**: Classification of changes	Updated
08/12/2025	**Event**: EMA workshop: Non-clinical data for regulatory decision-making on the efficacy of medical countermeasures	Updated
08/12/2025	**Event**: Quarterly System Demo - Q4 2025	Updated
08/12/2025	**Page**: Union Product Database: release notes	Updated
08/12/2025	**Document**: Release notes - production release version 1.7.2544 - 5 December 2025 - Veterinary Medicinal Products Regulation: Union Product Database	New
08/12/2025	**Medicine**: Ebglyss lebrikizumab	Updated
08/12/2025	**Medicine**: Lyfnua gefapixant	Updated
08/12/2025	**Medicine**: Eucreas vildagliptin; metformin	Updated
08/12/2025	**PIP**: EMA/PE/0000224486 - paediatric investigation plan amlodipine; ramipril; rosuvastatin	New
08/12/2025	**PIP**: EMA/PE/0000224202 - paediatric investigation plan Dengue tetravalent vaccine (live, attenuated)	Updated
08/12/2025	**PIP**: EMA/PE/0000221803 - paediatric investigation plan betula pendula pollen extract	New
08/12/2025	**Document**: Product Management Service (PMS) roadmap	Updated
08/12/2025	**Page**: Scientific publications	Updated

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08/12/2025	**Event**: EMA/HMA annual data forum	Updated
08/12/2025	**Page**: Good pharmacogenomic practice - Scientific guideline	Updated
08/12/2025	**Page**: Substance and product data management services	Updated
08/12/2025	**Document**: Call for user acceptance testers for the read functionality in the Public Product Management Service (PMS) Application Programming Interface (API)	New
08/12/2025	**DHPC**: Remsima - direct healthcare professional communication (DHPC) infliximab	New

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
12.12.2025	**Oxbryta: Überprüfung des Nutzen-Risiko-Verhältnisses** Wirkstoff: Voxelotor Mit Veröffentlichung der Entscheidung der Europäischen Kommission am 09. Dezember 2025 wurde das Risikobewertungsverfahren zu Oxbryta (Voxelotor) abgeschlossen.
11.12.2025	**Rote-Hand-Brief zu intravenösen Tranexamsäure-Formulierungen: Schwerwiegende, einschließlich tödlich verlaufender, Nebenwirkungen aufgrund einer versehentlichen intrathekalen Verabreichung** Wirkstoff: Tranexamsäure Die Zulassungsinhaber informieren darüber, dass injizierbare Tranexamsäure-Formulierungen nur zur intravenösen Anwendung zugelassen sind.
10.12.2025	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 16.10.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Gabapentin** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Gabapentin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

Date	Title
09.12.2025	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 15.10.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Trimethoprim** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Trimethoprim infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
09.12.2025	**Informationen zu Einreichung und Genehmigung von Schulungsmaterial** Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien
08.12.2025	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 15.10.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Propylthiouracil** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Propylthiouracil infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
08.12.2025	**Sitzung (8. Dezember 2025 per Videokonferenz) – Kurzprotokoll** Sachverständigen-Ausschuss für Apothekenpflicht nach § 53 Absatz 1 AMG
08.12.2025	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 15.10.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Vancomycin** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Vancomycin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
11.12.2025	**Anzeigen von Medizinprodukten und In-vitro-Diagnostika** Die Anzeigen von Medizinprodukten und In-vitro-Diagnostika im Zusammenhang mit dem Inverkehrbringen und dem Sicherheitsbeauftragten sind noch bis zum 28. Mai 2026 über das DMIDS zu erfassen.
11.12.2025	**DiGA-Leitfaden (Stand: 10.12.2025, Version 3.6)** Das Fast-Track-Verfahren für digitale Gesundheitsanwendungen (DiGA) nach § 139e SGB V

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since November 28th, 2025.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.