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HEADS OF AGENCIES – CMDh

10 November

NEW - 11-13 November CMDh agenda

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
14/11/2025	PIP: EMEA-002554-PIP02-19 - paediatric investigation plan ilofexor	Updated
14/11/2025	PIP: EMEA-003521-PIP01-23 - paediatric investigation plan single-stranded 5' capped mRNA encoding the HAs of the influenza virus strains A/H1N1, A/H3N2, and B/Victoria and the N-terminal domain (NTD) and receptor binding domain (RBD) of the SARS-CoV-2 spike glycoprotein (mRNA-1083)	Updated
14/11/2025	Referral: Ipidacrine-containing medicinal products - referral ipidacrine	Updated
14/11/2025	Medicine: Comirnaty COVID-19 mRNA vaccine	Updated
14/11/2025	Medicine: Anagrelide Viartis (previously Anagrelide Mylan) anagrelide	Updated
14/11/2025	Medicine: Tukysat ucatinib	Updated

Date	Content	Status
14/11/2025	Medicine: Elucirem gadopiclenol	Updated
14/11/2025	Medicine: Ondexxya andexanet alfa	Updated
14/11/2025	Medicine: Plegridy peginterferon beta-1a	Updated
14/11/2025	Page: Veterinary limited markets	Updated
14/11/2025	Page: Incident management plan	Updated
14/11/2025	Medicine: Ranivisor anibizumab	Updated
14/11/2025	Medicine: Epruvy (previously Ranibizumab Midas) ranibizumab	Updated
14/11/2025	Event: PMS Product user interface (PUI) Training: Product data submission & bulk edit made easy	Updated
14/11/2025	Medicine: Kizfizo temozolomide	Updated
14/11/2025	Event: European Medicines Agency (EMA) and European Association for the Study of Diabetes (EASD) bilateral meeting	Updated
14/11/2025	Medicine: Alyftrek deutivacaftor / tezacaftor / vanzacaftor	Updated
14/11/2025	Referral: Tecovirimat SIGA - referral tecovirimat	Updated
14/11/2025	Medicine: Tysabri natalizumab	Updated
14/11/2025	Event: European Medicines Agency (EMA) and European Association of Urology (EAU) bilateral meeting	Updated
14/11/2025	Medicine: Enflonsia clesrovimab	Updated
14/11/2025	Medicine: Ohtuvayre ensifentrine	New
14/11/2025	Medicine: Insulin Aspart Injection insulin aspart	New

Date	Content	Status
14/11/2025	Medicine: Nurzigma pridopidine	Updated
14/11/2025	Post-authorisation: Xerava - opinion on variation to marketing authorisation eravacycline	New
14/11/2025	Medicine: Aqneursa L-acetylleucine	Updated
14/11/2025	Medicine: Hetlloz tasimelteon	Updated
14/11/2025	Medicine: Osqay denosumab	New
14/11/2025	Medicine: GalenVita germanium (68Ge) chloride; gallium (68Ga) chloride	New
14/11/2025	Medicine: Ondibta insulin glargine	New
14/11/2025	Medicine: Teizeild teplizumab	New
14/11/2025	Medicine: Dawnzera donidalorsen	New
14/11/2025	Medicine: Enzalutamide Accordpharma enzalutamide	New
14/11/2025	Medicine: Waskyra autologous CD34+ haematopoietic stem cells transduced ex vivo with a lentiviral vector encoding human Wiskott-Aldrich syndrome protein	New
14/11/2025	Medicine: Inluriyo imlunestrant	New
14/11/2025	Medicine: Teduglutide Viartis teduglutide	New
14/11/2025	Medicine: Rezurock Belumosudil	Updated
14/11/2025	News: First gene therapy to treat rare disease Wiskott-Aldrich syndrome	New

Date	Content	Status
14/11/2025	News: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 10-13 November 2025	New
14/11/2025	Post-authorisation: Koselugo - opinion on variation to marketing authorisation selumetinib	New
14/11/2025	Post-authorisation: Minjuvi - opinion on variation to marketing authorisation afasitamab	New
14/11/2025	Post-authorisation: Veyvondi - opinion on variation to marketing authorisation vonicog alfa	New
14/11/2025	Medicine: Juluca dolutegravir; rilpivirine	Updated
14/11/2025	Medicine: Dovato dolutegravir; lamivudine	Updated
14/11/2025	Event: European Medicines Agency and Transcelerate bilateral meeting	New
14/11/2025	Medicine: Zypadhera olanzapine	Updated
14/11/2025	News: First-in-class treatment to delay onset of type 1 diabetes	New
14/11/2025	Medicine: Tivicay dolutegravir	Updated
14/11/2025	Medicine: Triumeq abacavir; dolutegravir; lamivudine	Updated
14/11/2025	Page: Medicine shortage communications (MSC)	Updated
14/11/2025	Shortage: Bronchitol mannitol	New
14/11/2025	Document: Medicine shortage communication (MSC) : Bronchitol, 40 mg inhalation powder, hard capsules: ongoing shortage	New
14/11/2025	Page: Substance and product data management services	Updated
14/11/2025	Medicine: Zavicefta ceftazidime; avibactam	Updated
14/11/2025	Document: Minutes of the CVMP meeting 7-9 October 2025	New

Date	Content	Status
14/11/2025	Page: Assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in non-food-producing animal species - Scientific guideline	New
14/11/2025	Document: Concept paper for the development of a guideline on the assessment of the risk to public health from antimicrobial resistance due to the use of an antimicrobial veterinary medicinal product in non-food-producing animal species	New
14/11/2025	Page: Classification of a product as intended for a limited market and eligibility for authorisation under Article 23 of Regulation (EU) 2019/6 (Applications for limited markets)	Updated
14/11/2025	Document: Questions and answers on classification of a product as intended for a limited market according to Article 4(29) and/or eligibility for authorisation according to Article 23 (Applications for limited markets)	New
14/11/2025	Document: Substances considered as not falling within the scope of Regulation (EC) No. 470/2009, with regard to residues of veterinary medicinal products in foodstuffs of animal origin	Updated
13/11/2025	Event: Fifth Veterinary Big Data Stakeholder Forum	Updated
13/11/2025	PIP: EMEA-002815-PIP01-20 - paediatric investigation plan rozibafusp alfa	Updated
13/11/2025	Medicine: Mekinist trametinib	Updated
13/11/2025	Medicine: Afiveg aflibercept	Updated
13/11/2025	Medicine: Hefiya adalimumab	Updated
13/11/2025	Medicine: Hyrimoz adalimumab	Updated
13/11/2025	Page: ICH E21 guideline on inclusion of pregnant and breastfeeding individuals in clinical trials – Scientific guideline	Updated
13/11/2025	Event: Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) multistakeholder workshop on Patient Registries for Alzheimer's disease	Updated
13/11/2025	Document: Concept paper on new guidance on the clinical investigation of medicinal products for the treatment of idiopathic pulmonary fibrosis (IPF)	Updated
13/11/2025	Document: Concept paper on a paediatric update of the guideline on clinical investigation of medicinal products for the management of Crohn's disease	Updated

Date	Content	Status
13/11/2025	Document: Concept paper on a paediatric update on the guideline on the development of new medicinal products for the treatment of Ulcerative Colitis	Updated
13/11/2025	PIP: EMA-003156-PIP02-22 - paediatric investigation plan Efavaleukin alfa	Updated
13/11/2025	Document: Records of data processing activity for internal publication of appointments, transfers and departures	New
13/11/2025	Medicine: Sitagliptin / Metformin hydrochloride Accord sitagliptin; metformin hydrochloride	Updated
13/11/2025	Medicine: Dasatinib Accord Healthcare dasatinib	Updated
13/11/2025	Event: Workshop on the use of external controls for evidence generation in regulatory decision-making	Updated
13/11/2025	Medicine: Efient prasugrel	Updated
13/11/2025	Document: European medicines regulatory network incident management plan for medicines for human use	Updated
13/11/2025	Document: Draft guideline on non-inferiority and equivalence comparisons in clinical trials	New
13/11/2025	Page: Non-inferiority and equivalence comparisons in clinical trials - Scientific guideline	New
13/11/2025	Page: Non-inferiority and equivalence comparisons in clinical trials - Scientific guideline	Updated
13/11/2025	Page: Switching between superiority and non-inferiority - Scientific guideline	Updated
13/11/2025	Medicine: Janumet sitagliptin; metformin	Updated
13/11/2025	Document: Records of data processing activity for workstation ergonomics in the context of Health & Safety of staff and contractors	Updated
12/11/2025	PSUSA: PSUSA/00009145/202412 - periodic safety update report single assessment estradiol (17-beta) / progesterone	New
12/11/2025	Medicine: Tevimbra tislelizumab	Updated
12/11/2025	Medicine: Kisqali	Updated

Date	Content	Status
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12/11/2025	Medicine: Lutathera lutetium (177Lu) oxodotreotide	Updated
12/11/2025	Medicine: Iclusig ponatinib	Updated
12/11/2025	Medicine: Kaftrio ivacaftor; tezacaftor; elexacaftor	Updated
12/11/2025	Medicine: Eyluxvi aflibercept	Updated
12/11/2025	Event: HMA/EMA multi-stakeholder workshop on artificial intelligence (AI)	Updated
12/11/2025	Event: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	Updated
12/11/2025	Medicine: Glivec imatinib	Updated
12/11/2025	Document: EVVet3 EVWeb Production - Release notes	Updated
12/11/2025	Document: List of eligible industry stakeholder organisations	Updated
12/11/2025	Event: Fourth European Medicines Agency (EMA) and European Confederation of Pharmaceutical Entrepreneurs (EUCOPE) bilateral meeting	New
12/11/2025	Event: Fourth European Medicines Agency - Medtech Europe bilateral meeting	Updated
12/11/2025	Event: EMA Cancer Medicines Forum (CMF) meeting with industry stakeholders on cancer treatment optimisation	Updated
12/11/2025	Document: Highlights – Fourth EMA-Vaccines Europe bilateral meeting	New
11/11/2025	Document: Faecal microbiota transplantation EU-IN Horizon Scanning Report	Updated
11/11/2025	Medicine: Datopotamab deruxtecan Daiichi Sankyo datopotamab deruxtecan	Updated
11/11/2025	Medicine: Slenyto melatonin	Updated
11/11/2025	Medicine: Uzpruvo ustekinumab	Updated

Date	Content	Status
11/11/2025	Document: Agenda - PCWP/HCPWP and all eligible organisations meeting 2025	Updated
11/11/2025	Medicine: Norvir ritonavir	Updated
11/11/2025	Medicine: Bimervax COVID-19 Vaccine (recombinant, adjuvanted)	Updated
11/11/2025	Medicine: Roctavian valoctocogene roxaparvovec	Updated
11/11/2025	Shortage: Beriglobin human normal immunoglobulin	New
11/11/2025	Document: Medicine shortage communication (MSC) : Beriglobin (human normal immunoglobulin), 2 mL and 5 mL solution for injection in pre-filled syringe: supply shortage and cessation of marketing (discontinuation)	New
11/11/2025	Medicine: mResvia Respiratory syncytial virus mRNA vaccine (nucleoside modified)	Updated
11/11/2025	Document: Article 57 product data	Updated
11/11/2025	Document: Engineered living materials for in situ production of therapeutics - EU-IN Horizon Scanning Report	Updated
11/11/2025	Document: Nanotechnology-based medicinal products for human use EU-IN Horizon Scanning Report	Updated
11/11/2025	Event: Annual open meeting of the European Network of Paediatric Research at EMA (Enpr-EMA) November 2025	Updated
11/11/2025	Event: ACT EU multi-stakeholder platform annual meeting	Updated
11/11/2025	Page: Eligible patients and consumers organisations	Updated
11/11/2025	Document: Agenda - PDCO agenda of the 11-14 November 2025 meeting	New
10/11/2025	PIP: EMA-002713-PIP02-21-M02 - paediatric investigation plan etrasimod	Updated
10/11/2025	PIP: EMA-003152-PIP01-21 - paediatric investigation plan dolutegravir; HIV-1 Maturation Inhibitor (GSK3640254)	Updated
10/11/2025	PIP: EMA/PE/0000246904 - paediatric investigation plan cobolimab	Updated
10/11/2025	Medicine: Jakavi ruxolitinib	Updated

Date	Content	Status
10/11/2025	Medicine: Verquvo vericiguat	Updated
10/11/2025	Medicine: Tecovirimat SIGA tecovirimat monohydrate	Updated
10/11/2025	Medicine: Nemluvio nemolizumab	Updated
10/11/2025	Medicine: Sitagliptin SUN sitagliptin fumarate	Updated
10/11/2025	Event: European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties meeting with all eligible organisations - 2025	Updated
10/11/2025	Medicine: Aspaveli pegcetacoplan	Updated
10/11/2025	DHPC: Libtayo - direct healthcare professional communication (DHPC) cemiplimab	Updated
10/11/2025	Event: Quarterly System Demo - Q4 2025	New
10/11/2025	Medicine: Flixabi infliximab	Updated
10/11/2025	Document: Agenda - HMA/EMA Annual Data Forum 2025	Updated
10/11/2025	Page: Quality of medicines questions and answers: Part 1	Updated
10/11/2025	Medicine: Dectova zanamivir	Updated
10/11/2025	Document: Annex to agenda of the CHMP meeting 10-13 November 2025	New
10/11/2025	Document: Agenda of the CHMP meeting 10-13 November 2025	New
10/11/2025	Medicine: Oyavas bevacizumab	Updated
10/11/2025	Medicine: Rezdiffra resmetirom	Updated
10/11/2025	Document: Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2025	Updated
10/11/2025	Event: Medicine shortages: EMA public webinar putting patients first	Updated

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
13.11.2025	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien
10.11.2025	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 18.09.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Testosteron (alle Darreichungsformen, ausgenommen topische Anwendung) Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Testosteron (alle Darreichungsformen, ausgenommen topische Anwendung) 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 October 15th, 2025.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since November 10th, 2025.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeduropa updates will be presented quarterly.

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