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HEADS OF AGENCIES – CMDh

No updates since May 27th, 2026.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
12/06/2026	Medicine: Zutectra human hepatitis B immunoglobulin	Updated
12/06/2026	Medicine: Emtricitabine/Tenofovir disoproxil Mylan emtricitabine; tenofovir disoproxil	Updated
12/06/2026	Document: Lonquex : EPAR - Public assessment report	Updated
12/06/2026	Medicine: Dimethyl fumarate Mylan dimethyl fumarate	Updated
12/06/2026	Medicine: Efavirenz/Emtricitabine/Tenofovir disoproxil Mylan efavirenz; emtricitabine; tenofovir disoproxil	Updated
12/06/2026	Document: Products Management Services (PMS) public API - Terms and conditions	New
12/06/2026	Medicine: Sugammadex Mylan sugammadex	Updated
12/06/2026	Medicine: Lenalidomide Mylan lenalidomide	Updated
12/06/2026	Medicine: Fulvestrant Mylan fulvestrant	Updated

Date	Content	Status
12/06/2026	Event: Regulatory Perspectives on Herbal Medicinal / Botanical Drug Product Development: Joint FDA / EMA Workshop	New
12/06/2026	Document: Regulatory Perspectives on Herbal Medicinal Botanical Drug Product Development - Joint FDA-EMA Workshop: Event agenda	New
12/06/2026	Document: Product Management Service (PMS) - Implementation of International Organization for Standardization (ISO) standards for Identification of Medicinal Products (IDMP) in Europe: Registration requirements to public PMS API (beta release) - Chapter 1, Annex B	New
12/06/2026	Document: Product Management Service (PMS) User Acceptance Testing (UAT) Application Programming Interface (API) registration process for industry - Chapter 1, Annex A	Updated
12/06/2026	Document: Products Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 1: Registration requirements for production environments	Updated
12/06/2026	Page: Substance and product data management services	Updated
12/06/2026	Medicine: Amlodipine / Valsartan Mylan amlodipine; valsartan	Updated
12/06/2026	News: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 8-11 June 2026	New
12/06/2026	Medicine: Fingolimod Mylan fingolimod	Updated
12/06/2026	Medicine: Deferasirox Mylan deferasirox	Updated
12/06/2026	Medicine: Azacitidine Mylan azacitidine	Updated
12/06/2026	Medicine: Fubelv etanercept	Updated
12/06/2026	Document: Product Management Service (PMS) public API - Frequently asked questions (FAQs)	New
12/06/2026	Medicine: Apremilast Accord apremilast	Updated

Date	Content	Status
12/06/2026	Event: Clinical Trials Information System (CTIS) bitesize talk: Annual safety report (ASR) new safety module	New
12/06/2026	PSUSA: PSUSA/00000892/202511 - periodic safety update report single assessment cyanocobalamin / folic acid, cyanocobalamin / folic acid / potassium iodide	New
12/06/2026	Medicine: Posaconazole Accord posaconazole	Updated
12/06/2026	Page: Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) meetings	Updated
12/06/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) – June 2026	New
12/06/2026	Shortage: Salbutamol inhalation products salbutamol	Updated
12/06/2026	Event: Product Management Service (PMS) public API beta release - Technical overview and live demo	New
12/06/2026	Medicine: LysaKare arginine; lysine	Updated
12/06/2026	Medicine: Anktiva nogapendekin alfa inbakicept	Updated
11/06/2026	PSUSA: PSUSA/00010217/202509 - periodic safety update report single assessment drospirenone / ethinylestradiol	New
11/06/2026	Medicine: Tenofovir disoproxil Zentiva tenofovir disoproxil	Updated
11/06/2026	Medicine: Teriflunomide Viatris (previously Teriflunomide Mylan) teriflunomide	Updated
11/06/2026	Post-authorisation: Pluvicto - withdrawal of application for variation to marketing authorisation lutetium (177Lu) vipivotide tetraxetan	Updated
11/06/2026	Medicine: Brineura cerliponase alfa	Updated
11/06/2026	Medicine: DuoPlavin clopidogrel; acetylsalicylic acid	Updated
11/06/2026	Medicine: Livtencity maribavir	Updated
11/06/2026	Medicine: Voxzogo vosoritide	Updated

Date	Content	Status
11/06/2026	Medicine: Qtern saxagliptin; dapagliflozin	Updated
11/06/2026	Event: 20th anniversary of European Medicines Agency's Patients' and Consumers' Working Party (PCWP)	Updated
11/06/2026	Event: Product Management Service (PMS) information day 2026	Updated
11/06/2026	Document: Process for the electronic submission of medicinal product information - Chapter 3	Updated
11/06/2026	Medicine: Winrevair sotatercept	Updated
11/06/2026	Document: European Medicines Agency's data protection notice for the EMA Account Management system	Updated
11/06/2026	Page: Annual reports and work programmes	Updated
11/06/2026	News: EMA's 2025 annual report shows strong approval numbers for human and veterinary medicines	New
11/06/2026	Medicine: Edistride dapagliflozin	Updated
11/06/2026	Medicine: Forxiga dapagliflozin	Updated
11/06/2026	Event: Shortage prevention plan (SPP) workshop	New
11/06/2026	Document: Change management activities delivery plan - HMA-EMA joint Big Data Steering Group	Updated
10/06/2026	Event: Managing product data quality in PMS: processes, known issues, current status and best practices	New
10/06/2026	PIP: EMA/PE/0000273488 - paediatric investigation plan rocatinlimab	Updated
10/06/2026	Medicine: Byannli (previously Paliperidone Janssen-Cilag International) paliperidone	Updated
10/06/2026	Medicine: Oczyesa octreotide	Updated
10/06/2026	Medicine: Vargatef nintedanib	Updated
10/06/2026	Medicine: Crysvita burosumab	Updated
10/06/2026	Medicine: Jemperli dostarlimab	Updated
10/06/2026	Medicine: Zejula niraparib	Updated
10/06/2026	Medicine: Slenyto melatonin	Updated
10/06/2026	Medicine: Upstaza eladocagene exuparvovec	Updated
10/06/2026	Event: Updates to industry contact management for authorisation products (IRIS)	Updated

Date	Content	Status
10/06/2026	Medicine: Bysumlog insulin lispro	Updated
10/06/2026	Document: List of eligible industry stakeholder organisations	Updated
10/06/2026	Page: Class III implantable devices and Class IIb medical devices intended to administer or remove medicinal products: expert panel opinions	Updated
10/06/2026	Document: EMA/HMA European platform for regulatory science research platform meeting – draft agenda	Updated
10/06/2026	Page: Real-world evidence	Updated
10/06/2026	Event: Cancer Medicines Forum: March 2026	New
10/06/2026	Event: Quarterly System Demo - Q2 2026	Updated
09/06/2026	Document: List of medicines currently in PRIME scheme	Updated
09/06/2026	Medicine: Ultomiris ravulizumab	Updated
09/06/2026	Medicine: Rinvoq upadacitinib	Updated
09/06/2026	Medicine: Dovprela (previously Pretomanid FGK) pretomanid	Updated
09/06/2026	Medicine: Tepkinly epcoritamab	Updated
09/06/2026	Medicine: Sarclisa isatuximab	Updated
09/06/2026	Medicine: Scintimun besilesomab	Updated
09/06/2026	Medicine: Neofordex dexamethasone	Updated
09/06/2026	Medicine: Kineret anakinra	Updated
09/06/2026	Medicine: Orphacol cholic acid	Updated
09/06/2026	Document: Records of data processing activity regarding EMA Account Management System (public)	New
09/06/2026	Event: Sixteenth industry stakeholder platform on research and development support	New
09/06/2026	Medicine: Efmody hydrocortisone	Updated
09/06/2026	Document: 2025-2028 Work plan for the Patients' and Consumers' Working Party (PCWP) and the Healthcare Professionals' Working Party (HCPWP)	New
09/06/2026	Medicine: Avtozma tocilizumab	Updated
09/06/2026	Document: Agenda - Clinical trials information system information day webinar	Updated

Date	Content	Status
09/06/2026	Document: Agenda - Challenges in drug development, regulation and clinical practice in immune thrombocytopenia	Updated
09/06/2026	Document: Appendix 1: Acceptable intakes established for N-nitrosamines	Updated
08/06/2026	Document: Agenda of the PRAC meeting 8-11 June 2026	New
08/06/2026	PIP: EMA-001563-PIP02-15-M01 - paediatric investigation plan ciprofloxacin hydrochloride	Updated
08/06/2026	Medicine: Omjjara mometinib	Updated
08/06/2026	Medicine: Yescarta axicabtagene ciloleucel	Updated
08/06/2026	Medicine: Alecensa alectinib	Updated
08/06/2026	Medicine: Vyjuvek beremagene geperpavec	Updated
08/06/2026	Medicine: Xolair omalizumab	Updated
08/06/2026	Document: Applications for new human medicines under evaluation: June 2026	New
08/06/2026	Page: Scientific publications	Updated
08/06/2026	Page: Ebola	Updated
08/06/2026	Document: Presentations - EnprEMA& ACT EU workshop on paediatric clinical trials	New
08/06/2026	Medicine: Fintepla fenfluramine	Updated
08/06/2026	Document: Data protection notice for legal entity and bank account validation regarding payments	Updated
08/06/2026	Medicine: Jentaduo linagliptin; metformin hydrochloride	Updated
08/06/2026	Document: Minutes of PRAC meeting on 7-10 April 2026	New

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
12.06.2026	Pharmacovigilance Risk Assessment Committee (PRAC) Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 08.06.-11.06.2026 behandelt wurden.

Date	Title
11.06.2026	Rote-Hand-Brief zu Evrysdi: Polytetrafluorethylen-Partikel (PTFE–Teflon) Wirkstoff: Risdiplam Die Firma Roche Registration GmbH und die Roche Pharma AG informieren über Beanstandungen über unlösliche Fremdpartikel in der zubereiteten Evrysdi 0,75 mg/ml Lösung zum Einnehmen.
10.06.2026	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
09.06.2026	Selbstauskunft zur Umsetzung der Anforderungen zum Schreiben in die elektronische Patientenakte/Authentisierung mittels der GesundheitsID gemäß § 4 Absatz 6, § 5 Absatz 10 sowie § 6a der Digitale Gesundheitsanwendungen-Verordnung (DiGAV) Selbstauskunft zur Umsetzung der Anforderungen zum Schreiben in die elektronische Patientenakte/Authentisierung mittels der GesundheitsID gemäß § 4 Absatz 6, § 5 Absatz 10 sowie § 6a der Digitale Gesundheitsanwendungen-Verordnung (DiGAV), Stand 05.06.2026

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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