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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
05/06/2026	Document: Report - HMA/EMA multi-stakeholder workshop on reporting and qualification of mechanistic models for regulatory assessment	New
05/06/2026	PSUSA: PSUSA/00000491/202506 - periodic safety update report single assessment calcifediol	New
05/06/2026	Medicine: Zarzio filgrastim	Updated
05/06/2026	Medicine: Ixchiq Chikungunya vaccine (live)	Updated
05/06/2026	Document: Member states contact points for translations review	Updated
05/06/2026	Medicine: Ebymect dapagliflozin; metformin	Updated
05/06/2026	Medicine: Xigduo dapagliflozin; metformin	Updated
05/06/2026	Document: Standard operating procedure for the preparation of ESUAvet annual reports	New

Date	Content	Status
05/06/2026	Medicine: Dasselta desloratadine	Updated
05/06/2026	Medicine: HyQvia human normal immunoglobulin	Updated
05/06/2026	Document: Member states contact points for review of national versions of the content of mobile scanning and other technologies	Updated
05/06/2026	Document: Checklist for the submission of Day 215 product information annexes for a post-opinion linguistic review (Word file)	Updated
05/06/2026	Document: Contact details of national competent authorities for requests of translation exemptions falling under Art. 63.3 of Directive 2001/83/EC and cases of shortages	Updated
05/06/2026	Document: Union Product Database (UPD) registration guide for UI and API users	Updated
05/06/2026	Document: Agenda - Clinical trials information system information day webinar	Updated
05/06/2026	Document: Agenda - Challenges in drug development, regulation and clinical practice in immune thrombocytopenia	Updated
05/06/2026	Medicine: CellCept mycophenolate mofetil	Updated
05/06/2026	Medicine: Opsumit macitentan	Updated
05/06/2026	Medicine: Tivdak tisotumab vedotin	Updated
05/06/2026	Medicine: Idacio adalimumab	Updated
05/06/2026	Medicine: Insulin Aspart Injection insulin aspart	Updated
05/06/2026	Document: Appendix 1: Acceptable intakes established for N-nitrosamines	Updated
04/06/2026	Document: Timetable: Safety referral (Article-20 and Article-31 pharmacovigilance)	Updated

Date	Content	Status
04/06/2026	Document: Timetable: Safety referral (Article 107i, urgent Union procedure)	Updated
04/06/2026	Document: Timetable: Non-safety referrals	Updated
04/06/2026	Medicine: Tegsedi inotersen	Updated
04/06/2026	Medicine: Nugalviq govorestat	Updated
04/06/2026	Orphan: EU/3/13/1153 - orphan designation for treatment of plasma-cell myeloma daratumumab	Updated
04/06/2026	Medicine: Rapamune sirolimus	Updated
04/06/2026	Medicine: Rotarix rotavirus vaccine, live	Updated
04/06/2026	PIP: EMA/PE/0000232781 - paediatric investigation plan lenacapavir sodium / islatravir	New
04/06/2026	PIP: EMA/PE/0000232771 - paediatric investigation plan tacrolimus	New
04/06/2026	PIP: EMA/PE/0000232769 - paediatric investigation plan pegozafermin	New
04/06/2026	Medicine: Enflonsia clesrovimab	Updated
04/06/2026	PIP: EMA/PE/0000232764 - paediatric investigation plan zasocitinib	New
04/06/2026	PIP: EMA/PE/0000232763 - paediatric investigation plan icotrokinra	New
04/06/2026	PIP: EMA/PE/0000232638 - paediatric investigation plan Ifinatamab deruxtecan	New
04/06/2026	PIP: EMA/PE/0000232759 - paediatric investigation plan telitacicept	New
04/06/2026	PIP: EMA/PE/0000232171 - paediatric investigation plan Botulinum toxin type A	New
04/06/2026	Page: Artificial intelligence	Updated
04/06/2026	Document: 2025 AI Observatory report	New
04/06/2026	Document: Standard operating procedure for the contribution to the 3-yearly JIACRA reports	New
04/06/2026	Page: Expert panel support for breakthrough medical devices: pilot programme	Updated

Date	Content	Status
04/06/2026	PIP: EMA/PE/0000230564 - paediatric investigation plan ezetimibe; rosuvastatin	New
04/06/2026	PIP: EMA/PE/0000230006 - paediatric investigation plan empagliflozin / sitagliptin	New
04/06/2026	PIP: EMA/PE/0000229841 - paediatric investigation plan itepekimab	New
04/06/2026	PIP: EMA/PE/0000227611 - paediatric investigation plan sacituzumab tirumotecan	New
04/06/2026	PIP: EMA/PE/0000183637 - paediatric investigation plan humanised afucosylated IgG1 monoclonal antibody against CCR8	New
04/06/2026	PIP: EMA/PE/0000232755 - paediatric investigation plan Dasiglucagon	New
03/06/2026	Document: PDCO minutes of the 21-24 April 2026 meeting	New
03/06/2026	PIP: EMA/PE/0000232765 - paediatric investigation plan sargramostim	New
03/06/2026	PSUSA: PSUSA/00010508/202509 - periodic safety update report single assessment metronidazole / neomycin / nystatin	New
03/06/2026	Medicine: Kostaive zapomeran	Updated
03/06/2026	Medicine: Ameluz 5-aminolevulinic acid hydrochloride	Updated
03/06/2026	Medicine: Xeplion paliperidone	Updated
03/06/2026	Medicine: Namuscla Mexiletine	Updated
03/06/2026	Page: Development of a reflection paper on the use of external controls for evidence generation in regulatory decision-making - Scientific guideline	Updated
03/06/2026	Shortage: Biltricide praziquantel	Updated
03/06/2026	Shortage: Insuman Basal and Comb 25 insulin human	Updated
03/06/2026	Shortage: Integrilin eptifibatide	Updated
03/06/2026	Shortage: Mimpara cinacalcet	Updated
03/06/2026	Document: Concept paper on the development of a reflection paper on the use of External controls for evidence generation in regulatory decision-making	New
03/06/2026	Medicine: Lynparza olaparib	Updated
03/06/2026	Medicine: Sotyktu deucravacitinib	Updated
03/06/2026	News: EMA, AMA and African regulatory authorities join forces on Ebola outbreak response	New
03/06/2026	Medicine: Sirturo bedaquiline	Updated
03/06/2026	Medicine: Vyndaqel tafamidis	Updated

Date	Content	Status
03/06/2026	Medicine: Nexium Control esomeprazole	Updated
03/06/2026	Page: Medicines for human use under evaluation	Updated
03/06/2026	Document: EMA's API general terms and conditions of use - Terms of use	Updated
03/06/2026	Event: Updates to industry contact management for authorisation products (IRIS)	New
02/06/2026	Referral: Tecovirimat SIGA - referral tecovirimat	Updated
02/06/2026	Medicine: Theralugand lutetium (177Lu) chloride	Updated
02/06/2026	Medicine: Orkambi lumacaftor; ivacaftor	Updated
02/06/2026	Document: Questions and answers on the refusal of a change to the marketing authorisation for Hetlioz (tasimelteon) (II-40)	Updated
02/06/2026	Page: Website outages and upgrades	Updated
02/06/2026	Medicine: Pazenir paclitaxel	Updated
02/06/2026	Medicine: Opdivo nivolumab	Updated
02/06/2026	Medicine: Zandoriah teriparatide	Updated
02/06/2026	Page: Languages on this website	Updated
02/06/2026	Document: Policy 84: Multilingualism on the EMA website and in external communications	Updated
02/06/2026	PIP: EMEA-001134-PIP01-11 - paediatric investigation plan chimeric monoclonal anti-Shiga toxin antibodies cαStx1 and cαStx2	Updated
02/06/2026	PSUSA: PSUSA/00001263/202507 - periodic safety update report single assessment escherichia coli lysate	New
02/06/2026	Medicine: Akynzeo netupitant; palonosetron	Updated
02/06/2026	Page: Frequently asked questions	Updated
02/06/2026	Event: European platform for regulatory science research meeting: June 2026	New
02/06/2026	Document: Data protection notice for legal entity and bank account validation regarding payments	Updated
02/06/2026	Document: Meeting summaries of the Immunisation and Vaccine Monitoring Advisory Board (IVMAB)	Updated
01/06/2026	Herbal: Lecithinum ex soya - herbal medicinal product Soya-bean lecithin	Updated

Date	Content	Status
01/06/2026	Medicine: Emadine emedastine	Updated
01/06/2026	Medicine: Jinarc tolvaptan	Updated
01/06/2026	Medicine: Capvaxive pneumococcal polysaccharide conjugate vaccine (21-valent)	Updated
01/06/2026	Medicine: Zepzelca lurbinectedin	Updated
01/06/2026	Medicine: Lopinavir/Ritonavir Viatriis (previously Ritonavir Mylan) lopinavir; ritonavir	Updated
01/06/2026	Medicine: Eurneffy epinephrine	Updated
01/06/2026	Document: New product information wording: extracts from PRAC recommendations on signals adopted at the 12-15 January 2026 PRAC	Updated
01/06/2026	Medicine: Abrysvo respiratory syncytial virus vaccine (bivalent, recombinant)	Updated
01/06/2026	Medicine: Nemluvio nemolizumab	Updated
01/06/2026	Medicine: Carvykti ciltacabtagene autoleucel	Updated
01/06/2026	Medicine: Imatinib Accord imatinib	Updated
01/06/2026	Document: Minutes - HMA-EMA joint Network Data Steering Group meeting - 15 April 2026	New
01/06/2026	Page: Combination Products Operational Group: agendas and highlight reports	Updated
01/06/2026	Medicine: Kapruvia difelikefalin	Updated
01/06/2026	Document: Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2026	Updated
01/06/2026	News: United for Health: EMA in WorldPride 2026	New

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
05.06.2026	Tecovirimat SIGA: Überprüfung der Wirksamkeit bei der Behandlung von Mpox Wirkstoff: Tecovirimat Der Durchführungsbeschluss der Kommission zu Tecovirimat SIGA wurde veröffentlicht.

Date	Title
02.06.2026	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since May 28th, 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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