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HEADS OF AGENCIES – CMDh

- No updates since October 27th, 2026.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
06/11/2026	**Medicine**: Rivaroxaban Viatris (previously Rivaroxaban Mylan)rivaroxaban	Updated
06/11/2026	**Medicine**: Yorvipathpalopegteriparatide	Updated
06/11/2026	**Medicine**: Aldurazymelaronidase	Updated
06/11/2026	**Medicine**: Bylvayodevixibat	Updated
06/11/2026	**Medicine**: ComirnatyCOVID-19 mRNA vaccine	Updated
06/11/2026	**Medicine**: Entyviovedolizumab	Updated
06/11/2026	**Medicine**: Lacosamide Accordlacosamide	Updated
06/11/2026	**Medicine**: Elapraseidursulfase	Updated
06/11/2026	**Medicine**: Neparvissacubitril; valsartan	Updated
06/11/2026	**Medicine**: Entrestosacubitril; valsartan	Updated
06/11/2026	**Document**: Medicine shortage communication (MSC): Emend (aprepitant, 80 mg hard capsules; 125 mg hard capsules; 125 mg powder for oral suspension): planned permanent marketing cessation (discontinuation)	New
06/11/2026	**Document**: Highlight report - Combination Products Operational Group (COMBO) - Medical Devices stream - October 2026	New
06/11/2026	**Post-authorisation**: Credelio - opinion on variation to marketing authorisationlotilaner	New
06/11/2026	**Medicine**: Nobivac PLUS DHPPi / Leptoscanine distemper, canine adenovirus, canine parainfluenza virus vaccine (live), canine parvovirus vaccine (live, recombinant) and canine leptospirosis vaccine (inactivated)	New

06/11/2026	**Medicine**: Credelio Quattrolotilaner; moxidectin; pyrantel; praziquantel	New
06/11/2026	**Medicine**: Laverdiaverdinexor	New
06/11/2026	**Medicine**: Scovellavelagliflozin	Updated
06/11/2026	**News**: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 3-5 November 2026	New
06/11/2026	**Shortage**: Emend	New
06/11/2026	**Medicine**: Galafoldmigalastat	Updated
06/11/2026	**Medicine**: Tecvayliteclistamab	Updated
06/11/2026	**Medicine**: Vabysmofaricimab	Updated
05/11/2026	**Event**: PMS Q&A Clinic on Product User Interface (PUI) and Application Programming Interface (API) – December 2026	Updated
05/11/2026	**PSUSA**: PSUSA/00009144/202603 - periodic safety update report single assessmentdiethylamine-salicylate / escin	New
05/11/2026	**Medicine**: Suboxonebuprenorphine; naloxone	Updated
05/11/2026	**Medicine**: Wayrilzrilzabrutinib	Updated
05/11/2026	**Medicine**: Voriconazole Accordvoriconazole	Updated
05/11/2026	**Medicine**: Cosentyxsecukinumab	Updated
05/11/2026	**Medicine**: Ogsiveonirogacestat	Updated
05/11/2026	**Medicine**: Jyselecafilgotinib	Updated
05/11/2026	**Page**: Templates for assessors	Updated
05/11/2026	**Document**: Assessment report for PSUSA NAPs	New
05/11/2026	**Document**: Assessment report for PSUSA CAPs	New
05/11/2026	**Page**: Nitrosamine impurities: guidance for marketing authorisation holders	Updated
05/11/2026	**Document**: Nitrosamines EMEA-H-A5(3)-1490 - Questions and answers for marketing authorisation holders / applicants on the CHMP Opinion for the Article 5(3) of Regulation (EC) No 726/2004 referral on nitrosamine impurities in human medicinal products	Updated
05/11/2026	**Event**: European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties meeting with all eligible organisations	Updated
05/11/2026	**PSUSA**: PSUSA/00001308/202603 - periodic safety update report single assessmentethinylestradiol / gestodene	New
05/11/2026	**Document**: Suboxone : EPAR - Scientific Discussion	Updated
05/11/2026	**Document**: Suboxone : EPAR - Procedural steps taken before authorisation	Updated
04/11/2026	**Document**: List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment	Updated
04/11/2026	**Document**: Ophthalmic devices - other - Notified Body 0123 - 12/01/2025 - Expert decision and opinion in the context of the clinical evaluation consultation procedure (CECP)	New
04/11/2026	**Document**: Resorbable filling and reconstruction devices - Notified Body 2797 - 08/05/2026 - Expert decision and opinion in the context of the clinical evaluation consultation procedure (CECP)	New
04/11/2026	**Event**: Sixth Veterinary Big Data Stakeholder Forum	Updated

04/11/2026	**Event**: Digitalisation and artificial Intelligence in pharmaceutical manufacturing: Quality Innovation Group (QIG) - Follow-up roundtable meeting	Updated
04/11/2026	**Event**: EudraGMDP Q&A clinic for public users	New
04/11/2026	**PIP**: EMA/PE/0000257220 - paediatric investigation planbempedoic acid; ezetimibe; atorvastatin	New
04/11/2026	**PIP**: EMA/PE/0000257216 - paediatric investigation planbempedoic acid; ezetimibe; atorvastatin	New
04/11/2026	**PIP**: EMA/PE/0000253356 - paediatric investigation planhumanised IgG1 monoclonal antibody against B7H4 receptor conjugated to N-((2R,10S)-10-benzyl-2-cyclopropyl-1-(((1S,9S)-9-ethyl-5-fluoro-9-hydroxy-4-methyl-10,13-dioxo-2,3,9,10,13,15-hexahydro-1H,12H-benzo[de]pyrano[3',4':6,7]indolizino[1,2-b]quinolin-1-yl)amino)-1,6,9,12,15-pentaoxo-3-oxa-5,8,11,14-tetraazahexadecan-16-yl)-6-(2,5-dioxo-2,5-dihydro-1H-pyrrol-1-yl)hexanamide	New
04/11/2026	**PIP**: EMA/PE/0000253047 - paediatric investigation planencaleret	Updated
04/11/2026	**PIP**: EMA/PE/0000252649 - paediatric investigation planinebilizumab	Updated
04/11/2026	**PIP**: EMA/PE/0000252572 - paediatric investigation planferumoxtran	Updated
04/11/2026	**PIP**: EMA/PE/0000249046 - paediatric investigation planGuselkumab	Updated
04/11/2026	**PIP**: EMA/PE/0000248697 - paediatric investigation planefzimfotase alfa	Updated
04/11/2026	**PIP**: EMA/PE/0000248263 - paediatric investigation planleniolisib phosphate	Updated
04/11/2026	**PIP**: EMA/PE/0000248063 - paediatric investigation planeslicarbazepine acetate	Updated
04/11/2026	**PIP**: EMA/PE/0000247449 - paediatric investigation planlucerastat	Updated
04/11/2026	**Medicine**: Sugammadex Mylansugammadex	Updated
04/11/2026	**Medicine**: Brukinsazanubrutinib	Updated
04/11/2026	**Medicine**: Xromihydroxycarbamide	Updated
04/11/2026	**Document**: Agenda of the CAT meeting 4-6 November 2026	New
04/11/2026	**Document**: Mandate, objectives and rules of procedure for the Scientific Advisory Groups (SAGs) and ad-hoc experts groups (AHEGs)	Updated
04/11/2026	**Document**: Agenda - HMA / EMA multistakeholder AI and Data forum: Build trustworthy AI on strong data foundations	Updated
04/11/2026	**Medicine**: Nylaspegpegfilgrastim	Updated
04/11/2026	**Page**: Plasma master file certificates	Updated
04/11/2026	**Medicine**: Eravacrabbit haemorrhagic disease vaccine (inactivated)	Updated
04/11/2026	**Document**: Agenda - Stakeholder meeting, November 2026	New
04/11/2026	**Page**: Portfolio and technology meetings	Updated
04/11/2026	**Page**: Eligible healthcare professionals' organisations	Updated
04/11/2026	**DHPC**: Respreeza - direct healthcare professional communication (DHPC)human alpha1-proteinase inhibitor	New
04/11/2026	**Page**: Union list of critical medicines	Updated

04/11/2026	**Document**: Union list of critical medicines - version 2.1 (revision 2)	Updated
04/11/2026	**Document**: Highlights - 21st industry stakeholder platform - operation of European Union (EU) pharmacovigilance	Updated
04/11/2026	**Document**: European Medicines Agency mid-year report 2026	New
03/11/2026	**Medicine**: Veanibek (previously Miglustat Gen.Orph)miglustat	Updated
03/11/2026	**Medicine**: Vlustozik (previously Ibuprofen Gen.Orph)ibuprofen	Updated
03/11/2026	**Medicine**: Bildyosdenosumab	Updated
03/11/2026	**Medicine**: Sycrestasenapine	Updated
03/11/2026	**Medicine**: Rozlytrekentrectinib	Updated
03/11/2026	**Medicine**: Otulfiustekinumab	Updated
03/11/2026	**Post-authorisation**: Truqap - withdrawal of application for variation to marketing authorisationcapivasertib	New
03/11/2026	**Medicine**: Zokinvylonafarnib	Updated
03/11/2026	**Medicine**: Rinvoqupadacitinib	Updated
03/11/2026	**Document**: Agenda of the COMP Meeting 3-5 November 2026	New
03/11/2026	**Medicine**: Liraglutide STADAliraglutide	Updated
03/11/2026	**Medicine**: Ablymicoliraglutide	Updated
03/11/2026	**Document**: Organisation chart: Task Forces	Updated
03/11/2026	**Document**: Agenda of the CVMP meeting 3-5 November 2026	New
03/11/2026	**Document**: Nitrosamine Implementation Oversight Group Terms of Reference	Updated
03/11/2026	**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
03/11/2026	**Document**: QRD Appendix V - Adverse-drug-reaction reporting details	Updated

NOTICE TO APPLICANTS

No updates since July 10th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Content
06.11.2026	Aktuelle Hinweise zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
05.11.2026	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 17.09.2026 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Alendronsäure Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Alendronsäure 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 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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