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HEADS OF AGENCIES – CMDh

27 October

- UPDATE - 'Blue-box' requirements

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
30/10/2026	**PSUSA**: PSUSA/00002893/202602 - periodic safety update report single assessment tenoxicam	New
30/10/2026	**PSUSA**: PSUSA/00001532/202602 - periodic safety update report single assessment gliclazide	New
30/10/2026	**PSUSA**: PSUSA/00002152/202602 - periodic safety update report single assessment nicorandil	New
30/10/2026	**PSUSA**: PSUSA/00000230/202602 - periodic safety update report single assessment aprotinin	New
30/10/2026	**Medicine**: Hirobriz Breezhaler indacaterol	Updated
30/10/2026	**Orphan**: EU/3/14/1372 - orphan designation for treatment of microscopic polyangiitis (avacopan) (2R,3S)-2-(4-cyclopentylaminophenyl)-1-(2-fluoro-6-methylbenzoyl)piperidine-3-carboxylic acid(4-methyl-3-trifluoromethylphenyl)amNide	Updated
30/10/2026	**Orphan**: EU/3/14/1373 - orphan designation for treatment of granulomatosis with polyangiitis	Updated
30/10/2026	**Medicine**: Tavneos avacopan	Updated

30/10/2026	**Orphan**: EU/3/24/2973 - orphan designation for treatment of familial chylomicronaemia syndrome olezarsen sodium	Updated
30/10/2026	**Medicine**: Tryngolza olezarsen	Updated
30/10/2026	**Medicine**: Keytruda pembrolizumab	Updated
30/10/2026	**Document**: Programme of the 2026 annual meeting of the European network of paediatric research at EMA (EnprEMA)	Updated
30/10/2026	**Medicine**: Spikevax (previously COVID-19 Vaccine Moderna) COVID-19 mRNA vaccine	Updated
30/10/2026	**Medicine**: Lemtrada alemtuzumab	Updated
30/10/2026	**Medicine**: Oslif Breezhaler indacaterol	Updated
30/10/2026	**Document**: List of centrally authorised products with safety-related changes to the product information	Updated
30/10/2026	**PSUSA**: PSUSA/00000910/202603 - periodic safety update report single assessment cystine / pyridoxine hydrochloride	New
30/10/2026	**PSUSA**: PSUSA/00002174/202602 - periodic safety update report single assessment nitrofurantoin, nitrofurantoin / pyridoxine hydrochloride	New
30/10/2026	**PSUSA**: PSUSA/00001045/202603 - periodic safety update report single assessment diclofenac sodium / orphenadrine citrate	New
30/10/2026	**PSUSA**: PSUSA/00002486/202603 - periodic safety update report single assessment perchlorates	New
30/10/2026	**PSUSA**: PSUSA/00009277/202603 - periodic safety update report single assessment rabies vaccine	New
30/10/2026	**News**: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 26 - 29 October 2026	New
30/10/2026	**Referral**: Flupentixol/melitracen-containing medicinal products - referral flupentixol; melitracen	New
30/10/2026	**Page**: Reporting suspected side effects	New
30/10/2026	**Document**: Executive decision the contribution to travel and subsistence expenses for the candidate invited to attend a selection procedure	Updated
30/10/2026	**PSUSA**: PSUSA/00011098/202602 - periodic safety update report single assessment furazidine	New
30/10/2026	**PSUSA**: PSUSA/00000907/202603 - periodic safety update report single assessment cyproterone acetate / estradiol valerate	New
30/10/2026	**PSUSA**: PSUSA/00001316/202603 - periodic safety update report single assessment ethosuximide	New
30/10/2026	**Event**: 21st industry stakeholder platform - operation of European Union (EU) pharmacovigilance	Updated
30/10/2026	**PSUSA**: PSUSA/00001635/202602 - periodic safety update report single assessment human plasma (pooled and treated for virus inactivation)	New

30/10/2026	**Document**: List of industry subject matter experts and list of planned calls for industry subject matter experts	Updated
30/10/2026	**PSUSA**: PSUSA/00001099/202603 - periodic safety update report single assessment dimeticone / guaiazulene	New
30/10/2026	**Medicine**: Oxlumo lumasiran	Updated
30/10/2026	**Document**: Oslif Breezhaler : EPAR - Public assessment report	Updated
30/10/2026	**Document**: Oslif Breezhaler : EPAR - All Authorised presentations	Updated
30/10/2026	**Document**: Hirobriz Breezhaler : EPAR - All Authorised presentations	Updated
30/10/2026	**Document**: Hirobriz Breezhaler : EPAR - Public assessment report	Updated
29/10/2026	**Medicine**: Carvykti ciltacabtagene autoleucel	Updated
29/10/2026	**Medicine**: Qarziba (previously Dinutuximab beta EUSA and Dinutuximab beta Apeiron) dinutuximab beta	Updated
29/10/2026	**Medicine**: Opdivo nivolumab	Updated
29/10/2026	**Medicine**: Infanrix Hexa diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV), poliomyelitis (inactivated) (IPV) and Haemophilus influenzae type-b (Hib) conjugate vaccine (adsorbed)	Updated
29/10/2026	**Medicine**: Jubereq denosumab	Updated
29/10/2026	**Event**: Stakeholder Meeting on the transferable data exclusivity voucher (TDEV) for priority antimicrobials	New
29/10/2026	**Medicine**: mResvia respiratory syncytial virus mRNA vaccine	Updated
29/10/2026	**Medicine**: Dimethyl fumarate Mylan dimethyl fumarate	Updated
29/10/2026	**Medicine**: Ayvakyt avapritinib	Updated
29/10/2026	**Document**: Agenda - European Medicines Agency workshop on bacteriophage therapy	Updated
29/10/2026	**Document**: Highlight report - Combination Products Operational Group (COMBO) - In Vitro Diagnostics stream - October 2026	New
29/10/2026	**News**: EMA closed on All Souls' Day, 2 November	New
29/10/2026	**Medicine**: Casgevy exagamglogene autotemcel	Updated
29/10/2026	**Medicine**: Sogroya somapacitan	Updated
29/10/2026	**Medicine**: Micardis telmisartan	Updated
29/10/2026	**Medicine**: Tafamidis Accord tafamidis	Updated
28/10/2026	**Event**: Quarterly System Demo - Q4 2026	Updated
28/10/2026	**Medicine**: Cirbloc porcine circovirus vaccine (inactivated)	Updated
28/10/2026	**Document**: Notice to sponsors on validation and qualification of computerised systems used in clinical trials	Updated
28/10/2026	**Medicine**: Dazparda insulin aspart	Updated

28/10/2026	**Medicine**: Takhzyro lanadelumab	Updated
28/10/2026	**Event**: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	New
28/10/2026	**Event**: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	New
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28/10/2026	**Event**: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	New
28/10/2026	**Medicine**: Yaxwer denosumab	Updated
28/10/2026	**Page**: Medicine Shortages SPOC Working Party meetings	Updated
28/10/2026	**Medicine**: Pradaxa dabigatran etexilate	Updated
28/10/2026	**Medicine**: Memantine Mylan memantine	Updated
28/10/2026	**Post-authorisation**: Ibrance - withdrawal of application for variation to marketing authorisation palbociclib	Updated
28/10/2026	**Medicine**: Lamivudine Teva Pharma B.V. lamivudine	Updated
28/10/2026	**Page**: Website outages and upgrades	Updated
28/10/2026	**Scientific guideline**: ICH guideline M13B on bioequivalence for immediate-release solid oral dosage forms - additional strengths biowaiver - Scientific guideline	Updated
28/10/2026	**Scientific guideline**: Investigation of bioequivalence - Scientific guideline	Updated
28/10/2026	**Medicine**: Sapropterin Dipharma sapropterin	Updated
28/10/2026	**Medicine**: Hopledo levodopa; carbidopa	Updated
28/10/2026	**Document**: Valproate : CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - EMA/PASS/0000287665	Updated
28/10/2026	**Page**: List of medicines under additional monitoring	Updated
28/10/2026	**Document**: List of medicinal products under additional monitoring	Updated
28/10/2026	**Document**: List of medicinal products under additional monitoring	Updated

28/10/2026	**Document**: Agenda - Sixth Veterinary Data Stakeholder Forum	Updated
27/10/2026	**Medicine**: Hemlibra emicizumab	Updated
27/10/2026	**Medicine**: Idacio adalimumab	Updated
27/10/2026	**Medicine**: Vocabria cabotegravir	Updated
27/10/2026	**Medicine**: Sitagliptin SUN sitagliptin fumarate	Updated
27/10/2026	**Medicine**: Brimica Genuair aclidinium; formoterol fumarate dihydrate	Updated
27/10/2026	**Medicine**: Bretaris Genuair aclidinium bromide	Updated
27/10/2026	**Medicine**: Glivec imatinib	Updated
27/10/2026	**Scientific guideline**: Tofacitinib product-specific bioequivalence guidance - Scientific guideline	New
27/10/2026	**PIP**: EMA/PE/0000245403 - paediatric investigation plan vadadustat	Updated
27/10/2026	**PIP**: EMA/PE/0000183673 - paediatric investigation plan naronapride (dihydrochloride trihydrate)	New
27/10/2026	**Page**: Expert panel support for orphan medical devices	Updated
27/10/2026	**Page**: Scientific advice for high-risk medical devices	Updated
27/10/2026	**PIP**: EMA/PE/0000235382 - paediatric investigation plan vosoritide	New
27/10/2026	**PIP**: EMA/PE/0000225490 - paediatric investigation plan emapalumab	Updated
27/10/2026	**Medicine**: Semglee insulin glargine	Updated
27/10/2026	**Medicine**: Pyzchiva ustekinumab	Updated
27/10/2026	**Medicine**: Lynavoy Linerixibat	Updated
27/10/2026	**PIP**: EMA/PE/0000253868 - paediatric investigation plan Benralizumab	Updated
27/10/2026	**PIP**: EMA/PE/0000253350 - paediatric investigation plan humanised 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
27/10/2026	**Page**: Submitting a maximum residue limit application	Updated
27/10/2026	**Medicine**: Pregabalin Viatris (previously Pregabalin Mylan) pregabalin	Updated
26/10/2026	**Medicine**: Vokanamet canagliflozin; metformin	Updated
26/10/2026	**PIP**: EMA/PE/0000247019 - paediatric investigation plan Enmetazobactam; cefepime	Updated
26/10/2026	**PIP**: EMA/PE/0000245851 - paediatric investigation plan tirzepatide	Updated
26/10/2026	**PIP**: EMA/PE/0000240317 - paediatric investigation plan odevixibat sesquihydrate	Updated

26/10/2026	**PIP**: EMA/PE/0000241178 - paediatric investigation plan Benralizumab	Updated
26/10/2026	**PIP**: EMA/PE/0000240204 - paediatric investigation plan (12m)-(1s,2s)-n-((63s,4s,z)-11-ethyl-12-(2-((s)-1-methoxyethyl)-5-(4-methylpiperazin-1-yl)pyridin-3-yl)-10,10-dimethyl-5,7-dioxo-61,62,63,64,65,66-hexahydro-11h-8-oxa-2(4,2)-thiazola-1(5,3)-indola-6(1,3)-pyridazinacycloundecaphane-4-yl)-2-methylcyclopropane-1-carboxamide	New
26/10/2026	**PIP**: EMA/PE/0000182592 - paediatric investigation plan human polyclonal immunoglobulin G against thymocyte (SAB-142)	New
26/10/2026	**PIP**: EMEA-003022-PIP01-21 - paediatric investigation plan recombinant fusion protein linking human frataxin to TAT cell-penetrant peptide (nomlabofusp)	New
26/10/2026	**Document**: Agenda of the PRAC meeting 26 - 29 October 2026	New
26/10/2026	**PIP**: EMEA-000284-PIP01-08-M04 - paediatric investigation plan grass pollen	Updated
26/10/2026	**PIP**: EMA/PE/0000291645 - paediatric investigation plan mRNA encoding Human cytomegalovirus UL128; mRNA encoding Human cytomegalovirus UL130; mRNA encoding Human cytomegalovirus UL131A; mRNA encoding Human cytomegalovirus glycoprotein H; mRNA encoding Human cytomegalovirus glycoprotein B; mRNA encoding Human cytomegalovirus glycoprotein L	Updated
26/10/2026	**Medicine**: Wegovy semaglutide	Updated
26/10/2026	**Document**: New product information wording - extracts from PRAC recommendations on signals adopted at the 28 September-1 October 2026 PRAC	New
26/10/2026	**Document**: PRAC recommendations on signals adopted at the 28 September-1 October 2026 PRAC meeting	New
26/10/2026	**Document**: List of signals discussed at PRAC since September 2012	Updated
26/10/2026	**Medicine**: Rezdiffra resmetirom	Updated
26/10/2026	**Document**: CHMP PROM minutes for the meeting on 15 June 2026	New
26/10/2026	**Medicine**: Bavencio avelumab	Updated
26/10/2026	**Document**: CHMP PROM minutes for the meeting on 16 March 2026	New
26/10/2026	**Document**: CHMP PROM minutes for the meeting on 11 May 2026	New
26/10/2026	**Medicine**: Pemetrexed medac pemetrexed	Updated
26/10/2026	**Scientific guideline**: Raltegravir product-specific bioequivalence guidance - Scientific guideline	New
26/10/2026	**Scientific guideline**: Niraparib product-specific bioequivalence guidance - Scientific guideline	New
26/10/2026	**Document**: Pilot phase for the revised pre-submission interactions: Annex to request for rapporteurship	Updated
26/10/2026	**Scientific guideline**: Semaglutide product-specific bioequivalence guidance - Scientific guideline	New

NOTICE TO APPLICANTS

No updates since July 10th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Content
02.11.2026	Aktuelle Hinweise zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
	Pharmacovigilance Risk Assessment Committee (PRAC) Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 26.10.-29.10.2026 behandelt wurden.
30.10.2026	Deanxit (Flupentixol/Melitracen): Überprüfung des Nutzen-Risiko-Verhältnisses Wirkstoff: Flupentixol/MelitracenDie Europäische Arzneimittel-Agentur (EMA) beginnt mit der Überprüfung des Arzneimittels Deanxit (Flupentixol/Melitracen), das zur Behandlung von Depressionen und Angstzuständen eingesetzt wird.
30.10.2026	Rote-Hand-Brief zu Caelyx: Fläschchenstopfen und -dichtung können sich beim Entfernen der Kappe lösen, was die Sterilität beeinträchtigen und zu unbeabsichtigter beruflicher Exposition führen kann Wirkstoff: Doxorubicin-pegylated liposomalDie Firma Baxter Holding B.V. informiert über Fälle von unvollständigen Aluverbördelungen bei dem Arzneimittel Caelyx 50 mg/25 ml (2 mg/ml) zur Injektion, Einzeldosis-Fläschchen.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since September 25th, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Content
30.10.2026	Rote-Hand-Brief: Respreeza (humaner Alpha-1-Proteinase-Inhibitor)
29.10.2026	Informationsbrief von Grifols Deutschland GmbH: Gamunex 10%
15.10.2026	Chikungunya-Impfstoff Vimkunya mit französischer und schwedischer/finnischer Beschriftung in Deutschland verfügbar

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.

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