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HEADS OF AGENCIES – CMDh

23 October

MOVED - National information on MAH transfers
 NEW - Q&A Post-Brexit
 NEW - D70 Overview AR Template (incl. instructions)
 NEW - Art. 46 PAR Riamet (artemether / lumefantrine)
 NEW - Art. 46 PAR Panzyga and associated names (human normal immunoglobulin (IVIg))
 NEW - Art. 46 PAR Xalatan / Latanoprost Viatriis (latanoprost)
 NEW - Art. 46 PAR Hiberix (haemophilus influenzae type b polysaccharide (PRP) conjugated to tetanus toxoid (TT))
 NEW - Recommendations on submission dates in 2026 for Applications of the MRP
 NEW - Recommendations on submission dates in 2026 for Applications of the DCP

22 October

NEW - Report from the meeting held on 14-15 October 2025
 UPDATE - Guidance on eSubmissions

21 October

UPDATE - List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
27/10/2025	Event: HMA/EMA multi-stakeholder workshop on reporting and qualification of mechanistic models for regulatory assessment	Updated
27/10/2025	Document: List of signals discussed at PRAC since September 2012	Updated
27/10/2025	Document: PRAC recommendations on signals adopted at the 29 September - 2 October 2025 PRAC meeting	New
24/10/2025	Event: Second European Medicines Agency (EMA) and COCIR bilateral meeting	Updated
24/10/2025	Medicine: Minjuvi tafasitamab	Updated

Date	Content	Status
24/10/2025	Medicine: Emend aprepitant	Updated
24/10/2025	Medicine: Besremi ropeginterferon alfa-2b	Updated
24/10/2025	Medicine: Rystiggo rozanolixizumab	Updated
24/10/2025	Medicine: Sylvant siltuximab	Updated
24/10/2025	Medicine: Venclyxto venetoclax	Updated
24/10/2025	Medicine: Ozurdex dexamethasone	Updated
24/10/2025	Medicine: Rhokiinsa netarsudil	Updated
24/10/2025	Medicine: Columvi glofitamab	Updated
24/10/2025	News: ICMRA Summit 2025: EMA concludes its two mandates as chair	New
24/10/2025	Page: International Coalition of Medicines Regulatory Authorities (ICMRA)	Updated
24/10/2025	Document: Minutes of the PRAC meeting 1-4 September 2025	New
24/10/2025	Medicine: Alkindi hydrocortisone	Updated
24/10/2025	Event: Committee for Advanced Therapies (CAT) workshop on gene editing	Updated
24/10/2025	Page: Ethical use of animals in medicine testing	Updated
24/10/2025	Medicine: Siiltibcy Mycobacterium tuberculosis derived antigens (rdESAT-6 / rCFP-10)	Updated
24/10/2025	Event: SPOR and XEVMPD status update webinar - Q1 2026	New
24/10/2025	Page: Quality aspects of phage therapy medicinal products	Updated
24/10/2025	Page: Opinions and letters of support on the qualification of novel methodologies for medicine development	Updated
24/10/2025	Document: Annex IV - Discussion meeting with applicant - molecule-independent device bridging approach (MIDBA)	New
24/10/2025	Document: Annex I - Briefing document - molecule-independent device bridging approach (MIDBA)	New
24/10/2025	Document: Annex III - Written responses to list of issues - molecule-independent device bridging approach (MIDBA)	New
24/10/2025	Document: Annex II - Initial Qualification Opinion List of Issues - molecule-independent device bridging approach (MIDBA)	New
24/10/2025	Document: Draft qualification opinion for molecule-independent device bridging approach (MIDBA)	New
24/10/2025	Document: Draft guideline on quality aspects of phage therapy medicinal products	New
23/10/2025	Event: 15th Industry Standing Group (ISG) meeting	New
23/10/2025	PSUSA: PSUSA/00010468/202501 - periodic safety update report single assessment dexketoprofen / tramadol	New
23/10/2025	PSUSA: PSUSA/00009084/202412 - periodic safety update report single assessment botulinum neurotoxin type a (150 kd) free from complexing proteins	New
23/10/2025	Herbal: Primulae radix - herbal medicinal product Primula root	Updated

Date	Content	Status
23/10/2025	PSUSA: PSUSA/00000745/202412 - periodic safety update report single assessment ciclosporin (systemic use)	New
23/10/2025	Herbal: Primulae flos - herbal medicinal product Primula flower	Updated
23/10/2025	Medicine: Descovy emtricitabine; tenofovir alafenamide	Updated
23/10/2025	Medicine: Ponvory ponesimod	Updated
23/10/2025	Document: Clinical Trial Information System (CTIS) structured data form - Notifications, Annual Safety Report (ASR) and results	Updated
23/10/2025	Event: Workshop on the use of external controls for evidence generation in regulatory decision-making	Updated
23/10/2025	Document: Minutes of the COMP meeting 9-11 September 2025	New
23/10/2025	Event: First EMA/HMA multi-stakeholder forum on EudraVigilance and signal detection	Updated
23/10/2025	Medicine: Amtagvi lifileucel	Updated
23/10/2025	Page: Non-human primates in safety testing of human medicinal products and opportunities for 3Rs implementation - Scientific guideline	New
23/10/2025	Document: Reflection paper on non-human primates in safety testing of human medicinal products and opportunities for 3Rs implementation	New
23/10/2025	Medicine: Rolcya denosumab	Updated
23/10/2025	Event: ACT EU multi-stakeholder platform annual meeting	Updated
23/10/2025	Medicine: Tofidence tocilizumab	Updated
23/10/2025	PSUSA: PSUSA/00002737/202501 - periodic safety update report single assessment disodium hydrogen phosphate / sodium dihydrogen phosphate, phosphate sodium	New
23/10/2025	Document: Overview of (invented) names reviewed in September 2025 by the Name Review Group (NRG) adopted at the CHMP meeting of 16 October 2025	New
23/10/2025	Orphan: EU/3/09/657 - orphan designation for treatment of mucopolysaccharidosis, type IVA (Morquio A syndrome) recombinant human N-acetylgalactosamine-6-sulfatase (elosulfase alfa)	Updated
23/10/2025	Medicine: Vimizim elosulfase alfa	Updated
23/10/2025	Medicine: Tuznue trastuzumab	Updated
23/10/2025	Page: Website outages and upgrades	Updated
23/10/2025	Medicine: Camzyos mavacamten	Updated
23/10/2025	PIP: EMA-000434-PIP01-08-M10 - paediatric investigation plan ambrisentan	Updated
23/10/2025	PIP: EMA/PE/0000221282 - paediatric investigation plan teplizumab	Updated
23/10/2025	PIP: EMA/PE/0000181891 - paediatric investigation plan sildenafil citrate; testosterone	New
23/10/2025	PIP: EMA/PE/0000225106 - paediatric investigation plan Ibrexafungerp	Updated

Date	Content	Status
22/10/2025	Medicine: Prolia denosumab	Updated
22/10/2025	PIP: EMA-003440-PIP01-23 - paediatric investigation plan cyclic GMP-AMP synthase inhibitor (BI 3000202)	New
22/10/2025	PIP: EMA-001716-PIP08-23 - paediatric investigation plan venglustat	New
22/10/2025	PIP: EMA-001858-PIP02-16-M04 - paediatric investigation plan daunorubicin; cytarabine	Updated
22/10/2025	PIP: EMA-002358-PIP02-18-M04 - paediatric investigation plan avapritinib	Updated
22/10/2025	PIP: EMA-002482-PIP01-24 - paediatric investigation plan zirconium (89Zr) girentuximab senvedoxam	New
22/10/2025	PIP: EMA-000524-PIP02-24 - paediatric investigation plan teplizumab	New
22/10/2025	PIP: EMA-003531-PIP01-23 - paediatric investigation plan (R)-3-(1-cyclopropyl-3-(2-fluoro-4-(trifluoromethoxy)benzyl)ureido)piperidine-1-carboxamide (JNT-517)	New
22/10/2025	PIP: EMA-003565-PIP01-23 - paediatric investigation plan idroxioleic acid	New
22/10/2025	Medicine: Spinraza nusinersen	Updated
22/10/2025	Medicine: Bekemv eculizumab	Updated
22/10/2025	Medicine: Tygacil tigecycline	Updated
22/10/2025	Medicine: Mycophenolate mofetil Teva mycophenolate mofetil	Updated
22/10/2025	Medicine: Myfenax mycophenolate mofetil	Updated
22/10/2025	Page: Medicines for human use under evaluation	Updated
22/10/2025	PIP: EMA-003642-PIP01-24 - paediatric investigation plan dexfandrostat phosphate	New
22/10/2025	Medicine: Sitagliptin SUN sitagliptin fumarate	Updated
22/10/2025	PIP: EMA-003643-PIP01-24 - paediatric investigation plan recombinant human progranulin fused to an Fc fragment engineered to contain a human transferrin receptor 1 binding domain (DNL593)	New
22/10/2025	Medicine: Livtencity maribavir	Updated
22/10/2025	Event: 20th industry stakeholder platform - operation of European Union (EU) pharmacovigilance	New
22/10/2025	Document: Highlights – EMA/ EASD bilateral meeting	New
22/10/2025	Medicine: Insulin Human Rechon insulin human	Updated
22/10/2025	PIP: EMA-003646-PIP01-24 - paediatric investigation plan plinabulin	New
22/10/2025	PIP: EMA-003648-PIP01-24 - paediatric investigation plan ALK inhibitor (NVL-655)	New
22/10/2025	PIP: EMA-003649-PIP01-24 - paediatric investigation plan zidesamtinib	New
22/10/2025	PIP: EMA-003656-PIP01-24 - paediatric investigation plan zipalertinib	New
22/10/2025	Medicine: Xydalba dalbavancin	Updated

Date	Content	Status
22/10/2025	Medicine: Talvey talquetamab	Updated
22/10/2025	Medicine: Amsparity adalimumab	Updated
22/10/2025	Medicine: Zonisamide Viatriis (previously Zonisamide Mylan) zonisamide	Updated
22/10/2025	Medicine: Libtayo cemiplimab	Updated
22/10/2025	Medicine: Ultomiris ravulizumab	Updated
22/10/2025	Medicine: Tezspire tezepelumab	Updated
22/10/2025	PIP: EMA-003002-PIP03-22 - paediatric investigation plan derivative of 6-[2-(pyridin-2-yl)phenoxy]methyl}-1,2,3,4-tetrahydroisoquinoline	Updated
22/10/2025	PSUSA: PSUSA/00000420/202411 - periodic safety update report single assessment bisoprolol / hydrochlorothiazide	New
22/10/2025	PIP: EMA-000439-PIP03-23 - paediatric investigation plan bitopertin	New
22/10/2025	Document: Minutes - Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) (24 September 2025)	New
22/10/2025	Document: Medicinal products for human use: monthly figures - September 2025	New
22/10/2025	Page: Development of new medicinal products for the treatment of ulcerative colitis - Scientific guideline	Updated
21/10/2025	PIP: EMA-003526-PIP01-23 - paediatric investigation plan recombinant varicella zoster virus glycoprotein E adjuvanted (CRV-101)	New
21/10/2025	PIP: EMA-003089-PIP02-23 - paediatric investigation plan dazukibart	New
21/10/2025	PIP: EMA-003495-PIP02-24 - paediatric investigation plan 3,3-Dimethyl-N-(6-methyl-5-([2-(1-methyl-1H-pyrazol-4-yl)pyridine-4-yl]oxy)pyridine-2-yl)-2-oxopyrrolidine-1-carboxamide hydrochloride hydrate	New
21/10/2025	PIP: EMA-001794-PIP02-16-M09 - paediatric investigation plan vamorolone	Updated
21/10/2025	PIP: EMA-001501-PIP07-20-M02 - paediatric investigation plan dupilumab	Updated
21/10/2025	PIP: EMA-001160-PIP01-11-M05 - paediatric investigation plan recombinant human A disintegrin and metalloprotease with thrombospondin type-1 motifs 13	Updated
21/10/2025	Referral: Azithromycin-containing medicinal products for systemic use - referral azithromycin	Updated
21/10/2025	Medicine: Voriconazole Accord voriconazole	Updated
21/10/2025	PIP: EMA-001142-PIP02-16-M02 - paediatric investigation plan ceftolozane; tazobactam	Updated
21/10/2025	Medicine: Bimervax COVID-19 Vaccine (recombinant, adjuvanted)	Updated
21/10/2025	News: EMA partners with content creators to promote safe and responsible use of GLP-1 medicines	New
21/10/2025	Page: Press and social media	Updated

Date	Content	Status
21/10/2025	PIP: EMEA-001124-PIP01-10-M06 - paediatric investigation plan Lomitapide	Updated
21/10/2025	PIP: EMEA-001075-PIP04-15-M07 - paediatric investigation plan romosozumab	Updated
21/10/2025	Medicine: Lemtrada alemtuzumab	Updated
21/10/2025	PIP: EMEA-000468-PIP02-12-M09 - paediatric investigation plan posaconazole	Updated
21/10/2025	PIP: EMEA-000311-PIP03-11-M07 - paediatric investigation plan ustekinumab	Updated
21/10/2025	PIP: EMEA-002536-PIP01-18-M04 - paediatric investigation plan Lebrikizumab	Updated
21/10/2025	PIP: EMEA-002905-PIP01-20-M01 - paediatric investigation plan brensocatic	Updated
21/10/2025	PIP: EMEA-003133-PIP01-21-M01 - paediatric investigation plan fidrisertib	Updated
21/10/2025	PIP: EMEA-003174-PIP01-21-M02 - paediatric investigation plan pridopidine hydrochloride	Updated
21/10/2025	PIP: EMEA-003426-PIP01-23-M02 - paediatric investigation plan mRNA encoding for the linked NTD and RBD domains of the spike glycoprotein of SARS-CoV-2 (mRNA-1283)	Updated
21/10/2025	Medicine: Rayvow lasmiditan	Updated
21/10/2025	Medicine: Datroway datopotamab deruxtecan	Updated
21/10/2025	Document: List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs)	Updated
21/10/2025	Medicine: Luxturna voretigene neparvovec	Updated
21/10/2025	Medicine: Aquumeldi enalapril maleate	Updated
21/10/2025	Medicine: Cosentyx secukinumab	Updated
21/10/2025	Medicine: Idacio adalimumab	Updated
21/10/2025	PIP: EMEA-000069-PIP01-07-M09 - paediatric investigation plan Mepolizumab	Updated
21/10/2025	Medicine: Piasky crovalimab	Updated
21/10/2025	Document: Scientific recommendations on classification of advanced therapy medicinal products	Updated
21/10/2025	Medicine: Praluent alirocumab	Updated
21/10/2025	Event: 14th Industry Standing Group (ISG) meeting	Updated
21/10/2025	Event: European Platform for Regulatory Science Research meeting September 2025	Updated
20/10/2025	Medicine: Gardasil human papillomavirus vaccine [types 6, 11, 16, 18] (recombinant, adsorbed)	Updated
20/10/2025	Medicine: Herwenda trastuzumab	Updated
20/10/2025	Document: Union Product Database (UPD) - questions and answers for industry users	Updated

Date	Content	Status
20/10/2025	Medicine: MiPet Easecto sarolaner	Updated
20/10/2025	Medicine: Tremfya guselkumab	Updated
20/10/2025	Medicine: Elevidys delandistrogene moxeparvovec	Updated
20/10/2025	Medicine: Vueway gadopiclenol	Updated
20/10/2025	Medicine: Imvanex smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara)	Updated
20/10/2025	DHPC: Crysvita - direct healthcare professional communication (DHPC) burosumab	New
20/10/2025	Medicine: Pluvicto lutetium (177Lu) vipivotide tetraxetan	Updated
20/10/2025	Medicine: Herceptin trastuzumab	Updated
20/10/2025	Medicine: Diacomit stiripentol	Updated
20/10/2025	Medicine: Keppra levetiracetam	Updated
20/10/2025	Medicine: Onureg azacitidine	Updated
20/10/2025	Medicine: Xeljanz tofacitinib	Updated
20/10/2025	Referral: Ipidacrine-containing medicinal products - referral ipidacrine	Updated
20/10/2025	Medicine: Briviact (in Italy: Nubrivo) brivaracetam	Updated
20/10/2025	Medicine: Yescarta axicabtagene ciloleucel	Updated
20/10/2025	Medicine: Insuman insulin human	Updated
20/10/2025	Herbal: Plantaginis lanceolatae folium - herbal medicinal product Ribwort Plantain	Updated
20/10/2025	PIP: EMA-002972-PIP02-23 - paediatric investigation plan seralutinib	New
20/10/2025	PIP: EMA-002705-PIP06-23 - paediatric investigation plan iptacopan	New
20/10/2025	PIP: EMA-003009-PIP01-21-M01 - paediatric investigation plan zamtocabtagene autoleucel	Updated
20/10/2025	Event: Unlocking PMS API potential: Edit functionality training for MAHs	Updated
20/10/2025	Shortage: Pazenir paclitaxel	Updated
20/10/2025	PIP: EMA-002899-PIP01-20-M03 - paediatric investigation plan sotrovimab	Updated
20/10/2025	PIP: EMA-002818-PIP01-20-M01 - paediatric investigation plan Human plasma derived C1-inhibitor (OCTA-C1-INH)	Updated
20/10/2025	Event: Fifteenth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines	New
20/10/2025	PIP: EMA-002812-PIP02-20-M03 - paediatric investigation plan rimegepant	Updated

Date	Content	Status
20/10/2025	PIP: EMEA-002713-PIP02-21-M02 - paediatric investigation plan etrasimod	Updated

NOTICE TO APPLICANTS

No updates since September 03rd, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
27/10/2025	Sitzung (8. Dezember 2025 per Videokonferenz) – Tagesordnung Sachverständigen-Ausschuss für Apothekenpflicht nach § 53 Absatz 1 AMG
23/10/2025	Oxbryta: EMA bestätigt das Ruhen der Genehmigung für das Inverkehrbringen des Arzneimittels Oxbryta gegen Sichelzellanämie Wirkstoff: Voxelotor EMA bestätigt das Ruhen der Genehmigung für das Inverkehrbringen des Arzneimittels Oxbryta gegen Sichelzellanämie
22/10/2025	Vorläufige Tagesordnung der 97. Routinesitzung am 11. November 2025 Die 97. Routinesitzung nach § 63 AMG wird am 11. November 2025 ab 10:00 Uhr als Videokonferenz stattfinden.
21/10/2025	Umsetzung des Durchführungsbeschlusses der Europäischen Kommission vom 13.10.2025 zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Levetiracetam Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Levetiracetam infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
21/10/2025	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 October 15th, 2025.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since October 9th, 2025.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedeuropa updates will be presented quarterly.

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