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HEADS OF AGENCIES – CMDh

04 March 2026

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

[NEW - Art. 45 PAR Benzocaine / Tyrothricin](#)

[NEW - 2025 Statistics for New Applications \(MRP/DCP\), Variations, Referrals and Paediatric Worksharing procedures](#)

[UPDATE - Q&A on Biologicals](#)

[NEW - CMDh Multi-Annual Workplan to 2025 - Summary Report](#)

[NEW - Report from the meeting held on 24-25 February 2026](#)

[NEW - Overview of biological active substances of non-recombinant origin](#)

[NEW - 27-28 January CMDh Minutes](#)

03 March 2026

[CORRECTION - 09-11 December CMDh minutes](#)

[CORRECTION - Report from the meeting held on 9-11 December 2025](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
06/03/2026	PIP: EMA/PE/0000222532 - paediatric investigation plan tofacitinib	Updated

Date	Content	Status
06/03/2026	PIP: EMA/PE/0000221604 - paediatric investigation plan ravulizumab	Updated
06/03/2026	PIP: EMA/PE/0000221583 - paediatric investigation plan famtozinameran; riltozinameran; tozinameran	Updated
06/03/2026	PIP: EMA/PE/0000225594 - paediatric investigation plan imlifidase	Updated
06/03/2026	PIP: EMA/PE/0000221462 - paediatric investigation plan [225Ac]Ac-PSMA-617	New
06/03/2026	PIP: EMA/PE/0000221213 - paediatric investigation plan blinatumomab	Updated
06/03/2026	PIP: EMA/PE/0000221296 - paediatric investigation plan ravulizumab	Updated
06/03/2026	PIP: EMA/PE/0000184081 - paediatric investigation plan etrasimod	Updated
06/03/2026	PIP: EMA/PE/0000183827 - paediatric investigation plan tabelecleucel	Updated
06/03/2026	PIP: EMA/PE/0000182607 - paediatric investigation plan Maribavir	Updated
06/03/2026	PIP: EMA/PE/0000182245 - paediatric investigation plan 5,8-dichloro-2-[(4-methoxy-6-methyl-2-oxo-1,2-dihydropyridin-3-yl)methyl]-7-[(R)-methoxy(oxetan-3-yl)methyl]-3,4-dihydroisoquinolin-1(2H)-one	New
06/03/2026	PIP: EMA/PE/0000182075 - paediatric investigation plan venetoclax	Updated
06/03/2026	PIP: EMA/PE/0000181243 - paediatric investigation plan glutamatergic neurotransmission enhancer BI 1569912	New
06/03/2026	PIP: EMA/PE/0000181174 - paediatric investigation plan Dasiglucagon	Updated
06/03/2026	PIP: EMA/PE/0000181050 - paediatric investigation plan lonigutamab	New
06/03/2026	Medicine: Sprycel dasatinib (anhydrous)	Updated
06/03/2026	Document: Minutes of the HMPC meeting 19-21 January 2026	New
06/03/2026	Document: Opinion of the CVMP on the establishment of maximum residue limits: Fluralaner (EMEA/V/MRL/004380/EXTN/0002)	New
06/03/2026	Document: Opinion of the CVMP on the establishment of maximum residue limits: Lidocaine (EMEA/V/MRL/003649/MODF/0004)	New
06/03/2026	Page: ICH E2D post-approval safety data management - scientific guideline	Updated
06/03/2026	Document: EU implementation strategy of ICH E2D(R1) Guideline - Post-approval safety data: Definitions and standards for management and reporting of individual case safety reports	New

Date	Content	Status
06/03/2026	Document: Highlight report - Combination Products Operational Group (COMBO) - In Vitro Diagnostics stream - February 2026	New
06/03/2026	Document: Darwin EU: Making health data count	Updated
06/03/2026	PSUSA: PSUSA/00000594/202506 - periodic safety update report single assessment cefixime	New
06/03/2026	Medicine: MicardisPlus telmisartan; hydrochlorothiazide	Updated
06/03/2026	Medicine: Tyruko natalizumab	Updated
06/03/2026	Event: 16th Industry Standing Group (ISG) meeting	Updated
06/03/2026	PSUSA: PSUSA/00002846/202504 - periodic safety update report single assessment tamoxifen	New
06/03/2026	Medicine: Opdivo nivolumab	Updated
06/03/2026	Page: Orphan designation: Overview	Updated
05/03/2026	Medicine: Inhixa enoxaparin sodium	Updated
05/03/2026	Medicine: Waskyra etuvetidigene autotemcel	Updated
05/03/2026	PIP: EMA/PE/0000225681 - paediatric investigation plan recombinant human ectonucleotide pyrophosphatase/phosphodiesterase 1 fused to the Fc fragment of IgG1	Updated
05/03/2026	PIP: EMA/PE/0000225592 - paediatric investigation plan ulixacaltamide (hydrochloride)	New
05/03/2026	PIP: EMA/PE/0000225245 - paediatric investigation plan nedosiran	Updated
05/03/2026	PIP: EMA/PE/0000223498 - paediatric investigation plan Infigratinib	Updated
05/03/2026	PIP: EMA/PE/0000223490 - paediatric investigation plan Eptinezumab	Updated
05/03/2026	PIP: EMA/PE/0000223351 - paediatric investigation plan Cipaglucoasidase alfa	Updated
05/03/2026	PIP: EMA/PE/0000223288 - paediatric investigation plan evenamide	Updated

Date	Content	Status
05/03/2026	PIP: EMA/PE/0000222938 - paediatric investigation plan Neisseria meningitidis group A polysaccharide conjugated to tetanus toxoid carrier protein (MenABCWY); Neisseria meningitidis group C polysaccharide conjugated to tetanus toxoid carrier protein; Neisseria meningitidis group W-135 polysaccharide conjugated to tetanus toxoid carrier protein; Neisseria meningitidis group Y polysaccharide conjugated to tetanus toxoid carrier protein; recombinant Neisseria meningitidis serogroup B protein 1; recombinant Neisseria meningitidis serogroup B protein 2; recombinant Neisseria meningitidis serogroup B protein 3; Neisseria meningitidis serogroup B Protein-based active substance (MenPenta vaccine)	Updated
05/03/2026	PIP: EMA-003219-PIP01-22 - paediatric investigation plan inclacumab	Updated
05/03/2026	PSUSA: PSUSA/00001855/202505 - periodic safety update report single assessment levomethadone	New
05/03/2026	Post-authorisation: Scenesse - withdrawal of application for variation to marketing authorisation afamelanotide	Updated
05/03/2026	Medicine: Toujeo (previously Optisulin) insulin glargine	Updated
05/03/2026	Medicine: Apidra insulin glulisine	Updated
05/03/2026	Medicine: VacPertagen pertussis vaccine (recombinant, acellular, component, adsorbed)	Updated
05/03/2026	Medicine: Lantus insulin glargine	Updated
05/03/2026	Medicine: Insuman insulin human	Updated
05/03/2026	Medicine: Imatinib Teva imatinib	Updated
05/03/2026	Page: Variations not requiring assessment (veterinary medicines)	Updated
05/03/2026	Page: Transferring a veterinary marketing authorisation	Updated
05/03/2026	Page: Pre-authorisation guidance under the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6)	Updated
05/03/2026	Page: Clinical trials in human medicines	Updated
05/03/2026	Page: Product-information requirements for veterinary medicines	Updated
05/03/2026	News: New guidance on the conduct of clinical trials during public health emergencies in the EU	New
05/03/2026	Medicine: Simponi golimumab	Updated

Date	Content	Status
05/03/2026	Document: Agenda - Ad hoc Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - 5 March 2026	New
05/03/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - 5 March 2026	New
04/03/2026	Medicine: Eylea afibercept	Updated
04/03/2026	Page: Plasma master file certificates	Updated
04/03/2026	Medicine: mNexspike COVID-19 mRNA vaccine	Updated
04/03/2026	Medicine: Kefdensis denosumab	Updated
04/03/2026	Medicine: Otezla apremilast	Updated
04/03/2026	Medicine: Vitrakvi larotrectinib	Updated
04/03/2026	Medicine: Leqvio inclisiran	Updated
04/03/2026	Document: List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs)	Updated
04/03/2026	PIP: EMA/PE/0000230484 - paediatric investigation plan alprazolam	Updated
04/03/2026	PIP: EMA/PE/0000227908 - paediatric investigation plan nerandomilast	Updated
04/03/2026	PIP: EMA/PE/0000227558 - paediatric investigation plan danicopan	Updated
04/03/2026	PIP: EMA/PE/0000227526 - paediatric investigation plan ceftobiprole medocaril (sodium)	Updated
04/03/2026	PIP: EMA/PE/0000227462 - paediatric investigation plan deucricitbant monohydrate	Updated
04/03/2026	PIP: EMA/PE/0000227425 - paediatric investigation plan efgartigimod alfa	Updated
04/03/2026	Medicine: Hemgenix etranacogene dezaparvovec	Updated
04/03/2026	PIP: EMA/PE/0000227394 - paediatric investigation plan tezacaftor; ivacaftor	Updated
04/03/2026	PIP: EMA/PE/0000226957 - paediatric investigation plan efgartigimod alfa	Updated
04/03/2026	Document: Draft guidance on the conduct of clinical trials during public health emergencies	New
04/03/2026	Document: Records of data processing activity for the handling the contribution towards commuting costs	Updated

Date	Content	Status
04/03/2026	Medicine: Xevudy sotrovimab	Updated
04/03/2026	Page: Data Analysis and Real World Interrogation Network (DARWIN EU)	Updated
04/03/2026	Document: DARWIN EU Advisory Board: Membership	Updated
04/03/2026	Document: DARWIN EU data partners onboarded in phases I, II, III and IV	Updated
04/03/2026	Document: Darwin EU study: Co-prescribing medicines in pulmonary arterial hypertension	New
04/03/2026	Document: Darwin EU study: How medicines are used to treat adults and children with lupus	New
04/03/2026	Document: Darwin EU study: Clozapine and the incidence of severe neutropenia over time	New
04/03/2026	Document: Darwin EU study: Treatment patterns and user characteristics for novel migraine medicines	New
04/03/2026	Document: Darwin EU study: Overall survival in patients with non-small cell lung cancer treated with selected immunotherapies	New
04/03/2026	Document: Darwin EU: Is there a risk of suicidality after taking the antibiotic doxycycline	New
04/03/2026	Document: Darwin EU study: Is there a link between blood clots and common painkillers in women who use hormonal birth control	New
04/03/2026	Document: Darwin EU: How often respiratory syncytial virus (RSV) affects different age groups in Europe	New
04/03/2026	Document: Darwin EU study: Use of higher-risk antibiotics from the WHO Watch list, including azithromycin	New
04/03/2026	Document: Darwin EU study: Background incidence rates of selected vaccine adverse events of special in Europe	New
04/03/2026	Document: Minutes of the CAT meeting 21-23 January 2026	New
03/03/2026	Document: Annual report on the use of the special contribution for orphan medicinal products - 2025	New
03/03/2026	Document: Questions and answers on the use of out-of-specification batches of authorised cell and tissue-based advanced therapy medicinal products	Updated

Date	Content	Status
03/03/2026	Document: Consolidated 3-year work plan for the clinical domain	New
03/03/2026	Document: Scientific advice and protocol assistance adopted during the CHMP meeting 23-26 February 2026	New
03/03/2026	Page: Medicines for human use under evaluation	Updated
03/03/2026	PIP: EMA/PE/0000228283 - paediatric investigation plan balstilimab	New
03/03/2026	Medicine: Afqfir aflibercept	Updated
03/03/2026	Shortage: Ifosfamide ifosfamide	Updated
03/03/2026	Shortage: Cyclophosphamide cyclophosphamide	Updated
03/03/2026	Event: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	Updated
03/03/2026	PIP: EMA/PE/0000226753 - paediatric investigation plan mRNA encoding Influenza A, H1N1 strain, hemagglutinin glycoprotein; mRNA encoding Influenza A, H3N2 strain, hemagglutinin glycoprotein; mRNA encoding Influenza B/Victoria, hemagglutinin glycoprotein	New
03/03/2026	Medicine: Entyvio vedolizumab	Updated
16/02/2023	News: Human medicines: highlights of 2022	New
03/03/2026	Document: Human medicines highlights 2022	Updated
03/03/2026	Medicine: Zeposia ozanimod	Updated
03/03/2026	Medicine: Vyloy zolbetuximab	Updated
03/03/2026	Medicine: Myqorzo aficamten	Updated
03/03/2026	Medicine: Aqneursa L-acetylleucine	Updated
03/03/2026	Page: Artificial intelligence	Updated
03/03/2026	Document: Scientific Explorer - Frequently Asked Questions	Updated
03/03/2026	Document: Veterinary pre-submission meeting request form - in accordance with Regulation (EU) No 2019/6	Updated
02/03/2026	Page: Fees for veterinary medicines	Updated
02/03/2026	Herbal: Combination: Hyperici herba - herbal medicinal product St. John's Wort	Updated

Date	Content	Status
02/03/2026	Medicine: Lotilaner / Milbemycin Elanco lotilaner; milbemycin oxime	Updated
02/03/2026	Medicine: Nivestim filgrastim	Updated
02/03/2026	Medicine: Retacrit epoetin zeta	Updated
02/03/2026	Medicine: Lamzede velmanase alfa	Updated
02/03/2026	Medicine: Fingolimod Accord fingolimod	Updated
02/03/2026	Medicine: Rasilez aliskiren	Updated
02/03/2026	Event: 3Rs Working Party (3RsWP) stakeholder meeting - Public session on the 2026-2028 work plan	New
02/03/2026	Medicine: Pylclari piflufolastat (18F)	Updated
02/03/2026	Medicine: Herceptin trastuzumab	Updated
02/03/2026	Page: One Health approach	Updated
02/03/2026	Event: Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPPD) service - February 2026	Updated
02/03/2026	Event: European Medicines Agency (EMA) and European Alliance of Associations for Rheumatology (EULAR) bilateral meeting	New
02/03/2026	Page: Medical devices	Updated
02/03/2026	Document: Report - Highlights of the 15th Industry Standing Group (ISG) meeting	Updated
02/03/2026	Page: Non-clinical development and evaluation of microbiome-based medicinal products - Scientific guideline	New
02/03/2026	Document: Draft concept paper on the development of a reflection paper on the non-clinical development and evaluation of microbiome-based medicinal products	New
02/03/2026	Medicine: Neoclarityn desloratadine	Updated
02/03/2026	Medicine: Nemluvio nemolizumab	Updated
02/03/2026	Medicine: Azomyr desloratadine	Updated
02/03/2026	Medicine: Aerius desloratadine	Updated

Date	Content	Status
02/03/2026	Event: Electronic application form (eAF) Q&A clinic	Updated
02/03/2026	Medicine: Nexium Control esomeprazole	Updated
02/03/2026	Medicine: Xbonzy denosumab	Updated
02/03/2026	Page: Quality of medicines: questions and answers - Part 1	Updated
02/03/2026	Event: Healthcare Professionals' Working Party (HCPWP) plenary meeting February 2026	Updated
02/03/2026	Event: Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting	Updated

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
05.03.2026	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
03.03.2026	92. Sitzung (20. Januar 2026 per Videokonferenz) – Ergebnisprotokoll Sachverständigen-Ausschuss für Verschreibungspflicht nach § 53 Absatz 2 AMG

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
05.03.2026	HIIS-VZ nach § 374a SGB V Mit dem in Kraft treten von § 374a Fünftes Buch Sozialgesetzbuch (SGB V) stehen Hersteller von Hilfsmitteln und Implantaten (im Folgenden "HiMi") ab dem 01.07.2027 in der Verantwortung, interoperable Schnittstellen anzubieten, sodass erhobene Gesundheitsdaten in standardisierter Form an das Backend einer in das Verzeichnis nach § 139e SGB V Absatz 1 aufgenommene digitale Gesundheitsanwendung (DiGA) übermittelt und dort weiterverarbeitet werden können.
04.03.2026	Die Handreichung für das Verzeichnis der Hilfsmittel- und Implantat-Schnittstellen nach § 374a SGB V Version 1.0 vom 27.02.2026

Date	Title
04.03.2026	Stellungnahme der geburtshilflichen Fachgesellschaften zum Einsatz der Celox-Tamponade bei postpartaler Hämorrhagie (PPH) Dem Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) wurden im Rahmen des Medizinprodukte-Vigilanzsystems Verdachtsmeldungen über schwerwiegende unerwünschte Ereignisse im zeitlichen Zusammenhang mit dem Einsatz der Celox® PPH-Tamponade übermittelt.
04.03.2026	Hinweis zur Anwendung der Celox PPH Tamponade Die Tamponaden werden als Uterustamponade zur Behandlung bei postpartaler Blutung (PPH) eingesetzt, wenn andere Maßnahmen keine ausreichende blutungsstillende Wirkung erzielen. Vor dem Hintergrund der aktuellen Empfehlung der Weltgesundheitsorganisation (WHO) zur Behandlung der postpartalen Blutung hat sich der Hersteller entschieden, die Celox PPH Tamponade nicht weiter auf dem Markt bereitzustellen.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since February 13th, 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedeuropa updates will be presented quarterly.

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