

TABLE OF CONTENTS

HEADS OF AGENCIES – CMDH	1
HEADS OF AGENCIES – PAEDIATRIC REGULATION	1
EUROPEAN MEDICINES AGENCY (EMA)	1
NOTICE TO APPLICANTS.....	8
BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY).....	8
BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY).....	9
PEI - VIGILANZ (SPECIFIC FOR GERMANY)	9
PHARMEUROPA TEXTS FOR COMMENT	9

HEADS OF AGENCIES – CMDh

17 October

[NEW - 16-18 September CMDh minutes](#)

13 October

[NEW - 14-15 October CMDh agenda](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
20/10/2025	PIP: EMA-002600-PIP03-21-M03 - paediatric investigation plan pegcetacoplan	Updated
20/10/2025	PIP: EMA-002535-PIP04-21-M02 - paediatric investigation plan Ibexafungerp citrate	Updated
17/10/2025	Medicine: Tryngolza olezarsen	Updated
17/10/2025	Medicine: Izamby denosumab	Updated
17/10/2025	Medicine: Mynzepli afibercept	Updated
17/10/2025	Medicine: Skyrizi risankizumab	Updated
17/10/2025	Medicine: Qoyvolma ustekinumab	Updated
17/10/2025	Medicine: Kavigale sipavibart	Updated
17/10/2025	Medicine: Otulfi ustekinumab	Updated
17/10/2025	Medicine: Sapropterin Dipharma sapropterin	Updated
17/10/2025	Medicine: Tecartus brexucabtagene autoleucel	Updated

Date	Content	Status
17/10/2025	Document: Clinical Trial Information System (CTIS) structured data form - Notifications, Annual Safety Report (ASR) and results	Updated
17/10/2025	PIP: EMA-002475-PIP03-22-M01 - paediatric investigation plan spesolimab	Updated
17/10/2025	PIP: EMA-002499-PIP03-24 - paediatric investigation plan tafasitamab	New
17/10/2025	PIP: EMA-002350-PIP02-20-M01 - paediatric investigation plan Deucravacitinib	Updated
17/10/2025	PIP: EMA-002341-PIP01-18-M03 - paediatric investigation plan Ganaxolone	Updated
17/10/2025	Medicine: Polivy polatuzumab vedotin	Updated
17/10/2025	Document: Start of Union reviews adopted during the CHMP meeting of 13-16 October 2025	New
17/10/2025	Medicine: Hydrocortisone Aguettant	New
17/10/2025	Post-authorisation: Paxlovid - opinion on variation to marketing authorisation nirmatrelvir; ritonavir	New
17/10/2025	Orphan: EU/3/19/2205 - orphan designation for treatment of graft-versus-host disease 2-(3-(4-(1H-Indazol-5-ylamino)quinazolin-2-yl)phenoxy)-N-isopropylacetamide-methane sulfonic acid salt	Updated
17/10/2025	News: First treatment for serious chronic lung disease	New
17/10/2025	Medicine: Austedo deutetrabenazine	Updated
17/10/2025	Medicine: Wayrilz rilzabrutinib	New
17/10/2025	Medicine: Rezurock Belumosudil	New
17/10/2025	Medicine: Brinsupri Brensocatib	New
17/10/2025	Referral: Oxbryta - referral voxelotor	Updated
17/10/2025	News: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 13-16 October 2025	New
17/10/2025	News: EMA confirms suspension of sickle cell disease medicine Oxbryta	New
17/10/2025	PIP: EMA-002319-PIP01-17-M03 - paediatric investigation plan rezafungin acetate	Updated
17/10/2025	Post-authorisation: Pyrkynd - opinion on variation to marketing authorisation mitapivat	New
17/10/2025	Post-authorisation: Gazyvaro - opinion on variation to marketing authorisation obinutuzumab	New
17/10/2025	Post-authorisation: Breyanzi - opinion on variation to marketing authorisation lisocabtagene maraleucel	New
17/10/2025	Post-authorisation: Libtayo - opinion on variation to marketing authorisation cemiplimab	New
17/10/2025	Post-authorisation: Cejemly - opinion on variation to marketing authorisation sugemalimab	New

Date	Content	Status
17/10/2025	Post-authorisation: Scemblix - opinion on variation to marketing authorisation asciminib	New
17/10/2025	Post-authorisation: Tremfya - opinion on variation to marketing authorisation guselkumab	New
17/10/2025	EU-M4all: Fexinidazole Winthrop - opinion on medicine for use outside EU fexinidazole	Updated
17/10/2025	PIP: EMA-002166-PIP01-17-M08 - paediatric investigation plan lasmiditan	Updated
17/10/2025	Medicine: Arava leflunomide	Updated
17/10/2025	Medicine: Scenesse afamelanotide	Updated
17/10/2025	PIP: EMA-002152-PIP01-17-M04 - paediatric investigation plan Daratumumab	Updated
17/10/2025	PIP: EMA-002133-PIP01-17-M04 - paediatric investigation plan cefiderocol	Updated
17/10/2025	PIP: EMA-002106-PIP01-16-M03 - paediatric investigation plan Leriglitazone	Updated
17/10/2025	Document: Minutes of the CVMP meeting 15-17 July 2025	New
17/10/2025	PIP: EMA-001988-PIP01-16-M02 - paediatric investigation plan Macimorelin	Updated
16/10/2025	PIP: EMA-003638-PIP01-24 - paediatric investigation plan rememulgene arelactibac	New
16/10/2025	PIP: EMA-003632-PIP01-24 - paediatric investigation plan Empagliflozin / Derivative of 3-phenyl-3H,4H,6H,7H-pyrano[3,4-d]imidazol-4-one (BI 690517)	New
16/10/2025	Event: Workshop on the use of external controls for evidence generation in regulatory decision-making	Updated
16/10/2025	PIP: EMA-003629-PIP01-24 - paediatric investigation plan Montelukast sodium; rupatadine fumarate	New
16/10/2025	PIP: EMA-003571-PIP01-23 - paediatric investigation plan rilonacept	New
16/10/2025	PIP: EMA-003524-PIP01-23 - paediatric investigation plan adeno-associated viral vector serotype 8 containing the 3' human otoferlin coding sequence / adeno-associated viral vector serotype 8 containing the 5' human otoferlin coding sequence	New
16/10/2025	PIP: EMA-003510-PIP01-23 - paediatric investigation plan recombinant humanized IgG1, kappa light chain, long-acting monoclonal antibody (STAR-0215)	New
16/10/2025	PIP: EMA-003460-PIP01-23 - paediatric investigation plan mannose-1-phosphate (GLM101)	New
16/10/2025	PIP: EMA-003425-PIP02-23 - paediatric investigation plan belumosudil	New
16/10/2025	PIP: EMA-003388-PIP01-23 - paediatric investigation plan hydroxycarbamide	New
16/10/2025	PIP: EMA-003258-PIP02-23 - paediatric investigation plan retatrutide	New
16/10/2025	Medicine: Plegridy peginterferon beta-1a	Updated

Date	Content	Status
16/10/2025	Medicine: Avonex interferon beta-1a	Updated
16/10/2025	Medicine: Cosentyx secukinumab	Updated
16/10/2025	Event: Q&A clinic on web-based application form functionalities for CAPs and non-CAPs	Updated
16/10/2025	Medicine: Vaborem meropenem; vaborbactam	Updated
16/10/2025	Medicine: Mvasi bevacizumab	Updated
16/10/2025	Document: Product Management Service (PMS) – Frequently Asked Questions (FAQs)	Updated
16/10/2025	Document: Product Management Service (PMS) User Acceptance Testing (UAT) Application Programming Interface (API) registration process for industry - Chapter 1	New
16/10/2025	Document: Products Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 1: Registration requirements for production environments	Updated
16/10/2025	Document: Minutes of the CVMP meeting 10-12 June 2025	New
16/10/2025	Document: Minutes of the CVMP meeting 9-10 September 2025	New
16/10/2025	Document: Process for the electronic submission of medicinal product information - Chapter 3	Updated
16/10/2025	Document: Management Board - Outcome of written procedures finalised during the period from 29 June to 22 September 2025	Updated
16/10/2025	Shortage: Fasturtec rasburicase	Updated
16/10/2025	Shortage: Ixiaro Japanese encephalitis vaccine (inactivated, adsorbed)	Updated
15/10/2025	Medicine: Duloxetine Viatriis (previously Duloxetine Mylan) duloxetine	Updated
15/10/2025	Medicine: Zycortal desoxycortone	Updated
15/10/2025	Event: Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) multistakeholder workshop on Patient Registries for Alzheimer's disease	Updated
15/10/2025	Event: ACT EU multi-stakeholder platform annual meeting	Updated
15/10/2025	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - October 2025	Updated
15/10/2025	Document: Request for veterinary medicinal product classification	Updated
15/10/2025	Medicine: Zulvac SBV inactivated Schmallenberg virus, strain BH80/11-4	Updated
15/10/2025	Medicine: Zenalpha medetomidine hydrochloride; vatinoxan hydrochloride	Updated
15/10/2025	Medicine: Virbagen Omega interferon (omega)	Updated
15/10/2025	Medicine: Veraflox pradofloxacin	Updated
15/10/2025	Page: Scientific publications	Updated
15/10/2025	Medicine: Vepured E. coli verotoxoid vaccine (inactivated recombinant)	Updated
15/10/2025	Medicine: Vectra Felis pyriproxyfen; dinotefuran	Updated

Date	Content	Status
15/10/2025	Medicine: Vectormune FP ILT + AE fowlpox, avian infectious laryngotracheitis vaccine (live, recombinant) and avian encephalomyelitis vaccine (live)	Updated
15/10/2025	Medicine: Ponvory ponesimod	Updated
15/10/2025	Medicine: Kineret anakinra	Updated
15/10/2025	Medicine: Simponi golimumab	Updated
15/10/2025	Medicine: Zutectra human hepatitis B immunoglobulin	Updated
15/10/2025	Document: Guide for rapporteurs and coordinators on the multinational assessment teams	Updated
15/10/2025	Medicine: Nplate romiplostim	Updated
15/10/2025	Medicine: Zulvac BTB bluetongue virus vaccine (inactivated) (multistrain: 1 strain out of a set of 3)	Updated
15/10/2025	Page: Frequently asked questions about parallel distribution	Updated
15/10/2025	Medicine: Ondexxa andexanet alfa	Updated
15/10/2025	Medicine: Mayzent siponimod	Updated
15/10/2025	Medicine: Ahzantive aflibercept	Updated
15/10/2025	Medicine: Firazyr icatibant	Updated
15/10/2025	Medicine: Baiana aflibercept	Updated
15/10/2025	Medicine: Qinlock ripretinib	Updated
15/10/2025	Medicine: Zulvac 1+8 Ovis inactivated bluetongue serotype 1+8 vaccine	Updated
15/10/2025	Medicine: Zulvac 1+8 Bovis inactivated bluetongue virus, serotypes 1 and 8	Updated
15/10/2025	Medicine: Zulvac 8 Ovis inactivated bluetongue virus, serotype 8	Updated
15/10/2025	Medicine: VarroMed oxalic acid dihydrate / formic acid	Updated
15/10/2025	PIP: EMA-001720-PIP01-14-M04 - paediatric investigation plan patiromer sorbitex calcium	Updated
15/10/2025	Medicine: UpCard torasemide	Updated
15/10/2025	Medicine: Ultifend ND IBD Newcastle disease; infectious bursal disease; Marek's disease vaccine (live recombinant)	Updated
15/10/2025	PIP: EMA-001733-PIP02-15-M03 - paediatric investigation plan gemtuzumab ozogamicin	Updated
15/10/2025	PIP: EMA-001786-PIP01-15-M04 - paediatric investigation plan Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live)	Updated

Date	Content	Status
15/10/2025	PIP: EMEA-001930-PIP01-16-M06 - paediatric investigation plan Neisseria meningitidis serogroup A polysaccharide conjugated to tetanus toxoid; N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid; N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid; N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid (MenACYW)	Updated
15/10/2025	Herbal: Maydis stigma - herbal medicinal product Corn silk	Updated
15/10/2025	PIP: EMEA-001531-PIP01-13-M06 - paediatric investigation plan tasimelteon	Updated
15/10/2025	PIP: EMEA-001426-PIP01-13-M03 - paediatric investigation plan recombinant varicella zoster virus glycoprotein E	Updated
15/10/2025	Document: Frequently asked questions about parallel distribution	Updated
14/10/2025	Medicine: Suvaxyn Circo porcine circovirus vaccine (inactivated, recombinant)	Updated
14/10/2025	Medicine: Suvaxyn Circo+MH RTU porcine circovirus and porcine enzootic pneumonia vaccine (inactivated)	Updated
14/10/2025	Medicine: Suiseng Diff/A clostridioides difficile; clostridium perfringens vaccine, inactivated	Updated
14/10/2025	Medicine: Stelfonta tigilanol tiglate	Updated
14/10/2025	Medicine: Sevohale (previously Sevocalm) sevoflurane	Updated
14/10/2025	Medicine: Sedadex dexmedetomidine	Updated
14/10/2025	PIP: EMEA-002338-PIP01-18 - paediatric investigation plan Ianalumab	Updated
14/10/2025	PSUSA: PSUSA/00002698/202501 - periodic safety update report single assessment Sevoflurane	New
14/10/2025	Medicine: Orserdu elacestrant	Updated
14/10/2025	Medicine: Rabitec rabies vaccine (live, oral) for foxes and raccoon dogs	Updated
14/10/2025	Medicine: Bortezomib Sun bortezomib	Updated
14/10/2025	PIP: EMEA-000315-PIP02-15-M04 - paediatric investigation plan Osilodrostat	Updated
14/10/2025	PIP: EMEA-000157-PIP01-07-M06 - paediatric investigation plan belatacept	Updated
14/10/2025	Medicine: Ubac Streptococcus uberis vaccine (inactivated)	Updated
14/10/2025	Medicine: Tulissin tulathromycin	Updated
14/10/2025	Medicine: Abrysvo respiratory syncytial virus vaccine (bivalent, recombinant)	Updated
14/10/2025	Medicine: Tulinovet tulathromycin	Updated
14/10/2025	Medicine: Tulaven tulathromycin	Updated

Date	Content	Status
14/10/2025	PIP: EMA/PE/0000227301 - 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, mRNA-1283	New
14/10/2025	Medicine: Menveo meningococcal group A, C, W-135 and Y conjugate vaccine	Updated
14/10/2025	Document: IRIS guide for applicants - How to create, submit and manage IRIS applications, for industry and individual applicants	Updated
14/10/2025	Medicine: Vaxelis diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus type b conjugate vaccine (adsorbed)	Updated
14/10/2025	Medicine: Rabigen SAG2 live vaccine against rabies	Updated
14/10/2025	Medicine: Rhiniseng inactivated vaccine to prevent progressive and non-progressive atrophic rhinitis in pigs	Updated
14/10/2025	Medicine: Rexxolide tulathromycin	Updated
14/10/2025	Medicine: Respiporc FLUpa H1N1 porcine influenza vaccine (inactivated)	Updated
14/10/2025	PIP: EMA-001556-PIP02-24 - paediatric investigation plan aldesleukin	New
14/10/2025	Medicine: Arikayce liposomal amikacin	Updated
14/10/2025	Medicine: Quadrisol vedaprofen	Updated
14/10/2025	Document: Guide on access to unpublished documents	Updated
14/10/2025	Medicine: Okedi risperidone	Updated
14/10/2025	Document: Pool of patient and consumer experts: list for 2024-2029	Updated
14/10/2025	Document: Pool of healthcare professional experts: list for 2024-2029	Updated
14/10/2025	Medicine: Respiporc Flu3 inactivated influenza-A virus	Updated
14/10/2025	Medicine: ReproCyc ParvoFLEX porcine parvovirus vaccine (inactivated)	Updated
14/10/2025	Medicine: Reconcile fluoxetine	Updated
14/10/2025	Document: Template for scientific document for paediatric investigation plan or product-specific waiver	Updated
14/10/2025	Medicine: Spikevax (previously COVID-19 Vaccine Moderna) COVID-19 mRNA vaccine	Updated
14/10/2025	Medicine: ProZinc insulin human	Updated
14/10/2025	Medicine: Evusheld tixagevimab; cilgavimab	Updated
14/10/2025	Medicine: Profender emodepside; praziquantel	Updated
14/10/2025	Medicine: Procox emodepside; toltrazuril	Updated
14/10/2025	Medicine: Prevomax maropitant	Updated

Date	Content	Status
14/10/2025	DHPC: Leqembi - direct healthcare professional communication (DHPC) Lecanemab	New
14/10/2025	Event: EMA/HMA annual data forum	Updated
14/10/2025	Event: Refresher training webinar on post-authorisation procedure management in IRIS for marketing authorisation holders	Updated
14/10/2025	Shortage: Quetiapine	Updated
14/10/2025	Document: Agenda - Medicine Shortages (SPOC) Working Party meeting on 14-15 October 2025	New
14/10/2025	Document: Agenda - PDCO agenda of the 14-17 October 2025 meeting	New
14/10/2025	Document: Timetable: Type II variation and worksharing application monthly assessment	Updated
14/10/2025	Document: Timetable: Type II variation and worksharing application alternative monthly assessment	Updated
14/10/2025	Document: Timetable: Post-authorisation measure (PAM) assessed by PRAC	Updated
14/10/2025	Document: Respiporc Flu3 : EPAR - Medicine overview	Updated
14/10/2025	Document: List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment	Updated
14/10/2025	Document: Respiporc Flu3 : EPAR - All Authorised presentations	Updated
14/10/2025	Document: Respiporc Flu3 : EPAR - Scientific Discussion	Updated
14/10/2025	Document: Suvaxyn Circo+MH RTU : EPAR - Public assessment report	Updated
13/10/2025	Medicine: Ilaris canakinumab	Updated
13/10/2025	Referral: Quarter-based selective dry cow therapy - referral	Updated
13/10/2025	Medicine: Oxlumo lumasiran	Updated
13/10/2025	Medicine: Mycamine micafungin	Updated
13/10/2025	Medicine: Eltrombopag Accord eltrombopag	Updated
13/10/2025	Medicine: Prac-tic pyriprole	Updated
13/10/2025	Medicine: Posatex orbifloxacin; mometasone furoate; posaconazole	Updated
13/10/2025	Document: Annex to agenda of the CHMP meeting 13-16 October 2025	New
13/10/2025	Document: Agenda of the CHMP meeting 13-16 October 2025	New
13/10/2025	Document: Call for comments on the Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) standard list	Updated

NOTICE TO APPLICANTS

No updates since September 03rd, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
17.10.2025	Informationen zu Rote-Hand-Briefen und Informationsbriefen Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht neue Hinweise zu anstehenden Rote-Hand-Briefen und Informationsbriefen.

Date	Title
17.10.2025	Gesetze und Verordnungen zur Änderung der Arzneimittelverschreibungsverordnung (AMVV) Hier finden Sie alle Verordnungen in absteigender zeitlicher Reihenfolge.
17.10.2025	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien
13.10.2025	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 24.07.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Diamorphin Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Diamorphin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
15.10.2025	Feststellung des rechtlichen Status und Klassifizierung Medizinprodukte werden Risikoklassen zugeordnet. Die Klassifizierung von Medizinprodukten mit Ausnahme der In-vitro-Diagnostika, erfolgt nach den Klassifizierungsregeln des Anhangs VIII MDR. Die Produkte werden dabei in die vier Klassen I, IIa, IIb und III unterteilt, wobei Klasse III die höchste Risikoklasse darstellt.
15.10.2025	Landesbehörden Klassifizierung und Feststellung des rechtlichen Status Die folgende Liste der zuständigen Behörden und Bundeswehr, die mit Entscheidungen zur Klassifizierung und Feststellung des rechtlichen Status von Medizinprodukten und In-vitro Diagnostika befasst sind, ist alphabetisch nach Bundesländern sortiert.
15.10.2025	Antrag auf Klassifizierung und/oder Feststellung des rechtlichen Status Antrag auf Klassifizierung und/oder Feststellung des rechtlichen Status

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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