

TABLE OF CONTENTS

HEADS OF AGENCIES – CMDH.....	1
HEADS OF AGENCIES – PAEDIATRIC REGULATION	1
EUROPEAN MEDICINES AGENCY (EMA)	1
NOTICE TO APPLICANTS.....	6
BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)	6
BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)	7
PEI - VIGILANZ (SPECIFIC FOR GERMANY)	7
PHARMEUROPA TEXTS FOR COMMENT.....	7

HEADS OF AGENCIES – CMDh

No updates since October 23rd, 2025.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
31/10/2025	Medicine: Lazcluzel azertinib	Updated
31/10/2025	Medicine: Quadramet samarium [¹⁵³ Sm] lexidronam pentasodium	Updated
31/10/2025	Medicine: Levetiracetam Hospiral evetiracetam	Updated
31/10/2025	Document: Agenda - Public webinar on shortages: putting patients first	Updated
31/10/2025	Event: Workshop on the use of external controls for evidence generation in regulatory decision-making	Updated
31/10/2025	Shortage: Insulin (human insulin) (various short-, rapid-, intermediate-, mixed- and long-acting forms)	New
31/10/2025	Document: Medicine shortage communication (MSC): Insulin (human insulin) (various short-, rapid-, intermediate-, mixed- and long-acting forms)	New
31/10/2025	Shortage: Salbutamol inhalation products salbutamol	Updated
31/10/2025	PSUSA: PSUSA/00002157/202412 - periodic safety update report single assessment niflumic acid	New
31/10/2025	PSUSA: PSUSA/00003083/202503 - periodic safety update report single assessment	New

Date	Content	Status
	urokinase	
31/10/2025	PSUSA: PSUSA/00001306/202503 - periodic safety update report single assessment ethinylestradiol	New
31/10/2025	News: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 27 - 30 October 2025	New
31/10/2025	PSUSA: PSUSA/00010005/202502 - periodic safety update report single assessment Mannitol (all indications apart from cystic fibrosis)	New
31/10/2025	Page: COVID-19 vaccines: key facts	Updated
31/10/2025	PSUSA: PSUSA/00002922/202503 - periodic safety update report single assessment thiamazole	New
31/10/2025	PSUSA: PSUSA/00003005/202503 - periodic safety update report single assessment trandolapril / verapamil	New
31/10/2025	PSUSA: PSUSA/00001173/202503 - periodic safety update report single assessment doxycycline	New
31/10/2025	PSUSA: PSUSA/00002064/202410 - periodic safety update report single assessment milrinone	New
31/10/2025	Medicine: Zurzuvae zuranolone	Updated
31/10/2025	Medicine: Januvia sitagliptin	Updated
31/10/2025	Document: List of centrally authorised products with safety-related changes to the product information	Updated
31/10/2025	Page: PRIME: priority medicines	Updated
31/10/2025	Document: List of medicines currently in PRIME scheme	Updated
31/10/2025	Document: Recommendations on eligibility to PRIME scheme adopted at the CHMP meeting of 13-16 October 2025	New
30/10/2025	PSUSA: PSUSA/00001535/202501 - periodic safety update report single assessment glipizide	New
30/10/2025	PSUSA: PSUSA/00000957/202411 - periodic safety update report single assessment dermatan sulfate	New
30/10/2025	Medicine: Syfovre pegcetacoplan	Updated

Date	Content	Status
30/10/2025	Medicine: Puregon follitropin beta	Updated
30/10/2025	Medicine: Elonva corifollitropin alfa	Updated
30/10/2025	Medicine: Teysono tegafur; gimeracil; oteracil	Updated
30/10/2025	Medicine: Keytruda pembrolizumab	Updated
30/10/2025	Medicine: Ristabensitagliptin	Updated
30/10/2025	Document: Antimicrobial Sales and Use (ASU) Platform: Release notes	Updated
30/10/2025	Medicine: Orkambilumacaftor ; ivacaftor	Updated
30/10/2025	Medicine: M-M-RVaxPromeasles , mumps and rubella vaccine (live)	Updated
30/10/2025	Shortage: Cyanokithydroxocobalamin	Updated
30/10/2025	Event: European Medicines Agency (EMA) and European Association of Urology (EAU) bilateral meeting	Updated
30/10/2025	Medicine: Vocabriacabotegravir	Updated
30/10/2025	Medicine: Pyzchivaustekinumab	Updated
30/10/2025	Medicine: Perjeta pertuzumab	Updated
30/10/2025	Medicine: Palonosetron Accord palonosetron	Updated
30/10/2025	Medicine: Enerzair Breezhaler indacaterol; glycopyrronium bromide; mometasone	Updated
30/10/2025	Medicine: Zimbus Breezhaler indacaterol; glycopyrronium; mometasone furoate	Updated
29/10/2025	Page: Clinical Trials Information System	Updated
29/10/2025	Medicine: Brukinsazanubrutinib	Updated
29/10/2025	Medicine: Fabhalta iptacopan	Updated
29/10/2025	Medicine: Lytgobifutibatini b	Updated
29/10/2025	Medicine: Lynparza olaparib	Updated
29/10/2025	Event: Unlocking PMS API potential: Edit functionality training for MAHs	Updated
29/10/2025	Event: EMA roundtable with stakeholders on the 20th anniversary of the SME Regulation	Updated
29/10/2025	Medicine: Rybrevant amivantamab	Updated
29/10/2025	Event: Questions and answers clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API) - October 2025	Updated

Date	Content	Status
29/10/2025	Document: List of medicinal products under additional monitoring	Updated
29/10/2025	Document: List of medicinal products under additional monitoring	Updated
29/10/2025	Page: List of medicines under additional monitoring	Updated
29/10/2025	Document: EU Regulatory System Incident Management Plan for Medicines for Human Use	Updated
29/10/2025	Document: Business process description for pharmacovigilance	Updated
29/10/2025	DHPC: Lenalidomide Mylan - direct healthcare professional communication (DHPC) lenalidomide	New
29/10/2025	Page: What we publish on medicines and when	Updated
28/10/2025	PIP: EMEA-001260-PIP01-11-M03 - paediatric investigation plan outer membrane vesicles (OMV) from n. meningitidis strain NZ 98/254; recombinant neisseria meningitis group B Protein 936-741; meningococcal group W-135 oligosaccharides conjugated to corynebacterium diphtheriae CRM197 protein; meningococcal group A oligosaccharides conjugated to corynebacterium diphtheriae CRM197 protein; meningococcal group C oligosaccharides conjugated to corynebacterium diphtheriae CRM197 protein; recombinant neisseria meningitis group B Protein 287-953; recombinant Neisseria meningitis group B Protein 961c; meningococcal group Y oligosaccharides conjugated to corynebacterium diphtheriae CRM197 protein (MenABCWY)	Updated
28/10/2025	PIP: EMEA-002996-PIP01-21 - paediatric investigation plan ExPEC9V	Updated
28/10/2025	PIP: EMEA-002575-PIP02-20 - paediatric investigation plan pralsetinib	Updated
28/10/2025	Page: Plasma master file certificates	Updated
28/10/2025	Medicine: Cabometryx cabozantinib	Updated
28/10/2025	Medicine: Phesgo pertuzumab; trastuzumab	Updated
28/10/2025	Medicine: Votrient pazopanib	Updated
28/10/2025	Page: Advanced therapy classification	Updated
28/10/2025	Medicine: Roctavian valoctocogene roxaparvovec	Updated
28/10/2025	Document: Article 57 product data	Updated
28/10/2025	Event: ACT EU multi-stakeholder platform annual meeting	Updated
28/10/2025	Document: Agenda - ACT EU multi-stakeholder platform annual meeting - October 2025	Updated

Date	Content	Status
28/10/2025	Page: Pre-authorisation guidance	Updated
28/10/2025	Medicine: Usymro ustekinumab	Updated
28/10/2025	Document: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure	Updated
28/10/2025	Document: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure: document with tracked changes	Updated
28/10/2025	Document: Template for sharing EMA documents by Industry to support reliance	New
28/10/2025	Medicine: Abilify Maintena aripiprazole	Updated
28/10/2025	Medicine: Multaq dronedarone	Updated
28/10/2025	Medicine: Kisunla donanemab	Updated
28/10/2025	Referral: Sodium oxybate-containing syrup and oral solution for alcohol dependence - referral sodium oxybate	Updated
28/10/2025	Page: Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)	Updated
28/10/2025	Medicine: Keppra levetiracetam	Updated
28/10/2025	Page: Accessibility	Updated
28/10/2025	Page: Website outages and upgrades	Updated
27/10/2025	Document: Agenda of the PRAC meeting 27 - 30 October 2025	New
27/10/2025	PIP: EMEA-002712-PIP01-19-M01 - paediatric investigation plan cotadutide	Updated
27/10/2025	PIP: EMEA-002287-PIP01-17-M03 - paediatric investigation plan cotadutide	Updated
27/10/2025	Medicine: Fanskya Mozafancogene autotemcel	Updated
27/10/2025	Medicine: Cejemly sugemalimab	Updated
27/10/2025	Medicine: Lemtrada alemtuzumab	Updated
27/10/2025	Medicine: Dupixent dupilumab	Updated
27/10/2025	Medicine: Darzalex	Updated

Date	Content	Status
	daratumumab	
27/10/2025	Medicine: Imbruvica ibrutinib	Updated
27/10/2025	PSUSA: PSUSA/00010631/202412 - periodic safety update report single assessment testosterone (all formulations apart from topical use)	New
27/10/2025	Medicine: Adtralza tralokinumab	Updated
27/10/2025	Medicine: Elzonris tagraxofusp	Updated
27/10/2025	Medicine: Bildyos denosumab	Updated
27/10/2025	Medicine: Bilprevda denosumab	Updated
27/10/2025	Page: Emergency Task Force (ETF) recommendations	Updated
27/10/2025	Page: Substance, product, organisation and referential (SPOR) master data	Updated
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

NOTICE TO APPLICANTS

News announcement, 30 October 2025

[New and updated documents - EudraLex Volume 10: Clinical trials guidelines](#)

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
31.10.2025	<p>Pharmacovigilance Risk Assessment Committee (PRAC)</p> <p>Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 27.10.-30.10.2025 behandelt wurden.</p>

Date	Title
28.10.2025	<p data-bbox="386 264 1372 367">Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 24.07.2025 betreffend die Zulassungen für Humanarzneimittel mit der Wirkstoffkombination Bisoprolol/Hydrochlorothiazid</p> <p data-bbox="386 407 1385 539">Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffkombination Bisoprolol/Hydrochlorothiazid infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.</p>

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 Pharmeuropa updates will be presented quarterly.

Trotz regelmäßiger Aktualisierung und sorgfältiger Überwachung der Veröffentlichungen können wir keine Haftung oder Garantie für die Aktualität, Richtigkeit und Vollständigkeit der hier bereitgestellten Informationen übernehmen. Dieser Newsletter enthält Links zu anderen Websites. Trotz sorgfältiger inhaltlicher Kontrolle übernehmen wir keine Haftung für die Inhalte externer Links. Für den Inhalt der verlinkten Seiten sind ausschließlich deren Betreiber verantwortlich.

Despite regular updating and careful monitoring of the publications, we cannot take any responsibility or guarantee for the topicality, correctness and completeness of the information provided here. This Newsletter contains links to other websites. Despite careful control of the content we would like to point out that we are not liable for the contents of external web links. The editors of the respective websites are fully responsible for their contents.