

TABLE OF CONTENTS

HEADS OF AGENCIES – CMDH	1
HEADS OF AGENCIES – PAEDIATRIC REGULATION	1
EUROPEAN MEDICINES AGENCY (EMA)	1
NOTICE TO APPLICANTS	7
BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)	7
BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)	8
PEI - VIGILANZ (SPECIFIC FOR GERMANY)	8
PHARMEUROPA TEXTS FOR COMMENT	8

HEADS OF AGENCIES – CMDh

08 January

[CORRECTION - CMDh Recommendation for classification of unforeseen variations according to Article 5 of Commission Regulation \(EC\) 1234/2008](#)

07 January

[UPDATE - ASMF Worksharing Procedure User Guide](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
09/01/2026	Document: IRIS guide for applicants - How to create, submit and manage IRIS applications, for industry and individual applicants	Updated
09/01/2026	Medicine: Usymro ustekinumab	Updated
09/01/2026	Medicine: Bilprevda denosumab	Updated
09/01/2026	Medicine: Tolvaptan Accord tolvaptan	Updated
09/01/2026	Medicine: Onureg azacitidine	Updated
09/01/2026	Medicine: Praluent alirocumab	Updated

Date	Content	Status
09/01/2026	Event: Healthcare Professionals' Working Party (HCPWP) plenary meeting February 2026	New
09/01/2026	Medicine: Ayvakyt avapritinib	Updated
09/01/2026	Medicine: Nurzigma pridopidine	Updated
09/01/2026	Medicine: Tysabri natalizumab	Updated
09/01/2026	Medicine: Fintepla fenfluramine	Updated
09/01/2026	Medicine: Harvoni ledispavir; sofosbuvir	Updated
09/01/2026	Medicine: Sovaldi sofosbuvir	Updated
09/01/2026	Medicine: Rimmyrah ranibizumab	Updated
08/01/2026	Event: Fifteenth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines	Updated
08/01/2026	PSUSA: PSUSA/00000811/202503 - periodic safety update report single assessment clomipramine	New
08/01/2026	Page: Financial management and budgetary reporting	Updated
08/01/2026	Document: European Medicines Agency budget for 2026	New
08/01/2026	Medicine: Ecovaxxin MS Mycoplasma synoviae, strain K588A, Live	Updated
08/01/2026	Event: Sixth European Medicines Agency (EMA) and the Association of the European Self-Care Industry (AESGP) bilateral meeting	Updated
08/01/2026	Event: Seventh European Medicines Agency - EuropaBio bilateral meeting	Updated
08/01/2026	Medicine: Reagila cariprazine	Updated
08/01/2026	Medicine: Xalkori crizotinib	Updated

Date	Content	Status
08/01/2026	Medicine: Cancidas (previously Caspofungin MSD) caspofungin	Updated
08/01/2026	Medicine: Wayrilz rilzabrutinib	Updated
08/01/2026	PSUSA: PSUSA/00000836/202503 - periodic safety update report single assessment clozapine	Updated
08/01/2026	Event: Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting	New
07/01/2026	Medicine: Cabazitaxel Accord cabazitaxel	Updated
07/01/2026	Medicine: Olanzapine Viatris (previously Olanzapine Mylan) olanzapine	Updated
07/01/2026	Medicine: Rotarix rotavirus vaccine, live	Updated
07/01/2026	Medicine: Herzuma trastuzumab	Updated
07/01/2026	Document: Nominations to the Network Portfolio Advisory Group	Updated
07/01/2026	Medicine: Zercepac trastuzumab	Updated
07/01/2026	Medicine: Norvir ritonavir	Updated
07/01/2026	Page: Eligible healthcare professionals' organisations	Updated
07/01/2026	Medicine: Dupixent dupilumab	Updated
07/01/2026	Medicine: Lenalidomide Krka (previously Lenalidomide Krka d.d. Novo mesto) lenalidomide	Updated
07/01/2026	Medicine: Lunsumio mosunetuzumab	Updated
07/01/2026	Medicine: Vaxxinact H5 Avian influenza virus, subtype H5, haemagglutinin (recombinant)	Updated
07/01/2026	Event: EMA workshop: Non-clinical data for regulatory decision-making on the efficacy of medical countermeasures	Updated

Date	Content	Status
07/01/2026	Medicine: Gazyvaro obinutuzumab	Updated
07/01/2026	Document: Report - Industry stakeholders' feedback on engagement and communication activities	Updated
07/01/2026	Medicine: Apremilast Accord apremilast	Updated
07/01/2026	Medicine: Voraxaze glucarpidase	Updated
07/01/2026	Medicine: Kuvan sapropterin	Updated
07/01/2026	Page: Combination Products Operational Group: agendas and highlight reports	Updated
07/01/2026	Document: Highlight report - Combination Products Operational Group (COMBO) - Medical Devices stream	New
07/01/2026	Document: Highlight report - Combination Products Operational Group (COMBO) - In Vitro Diagnostics stream	New
07/01/2026	Event: EMA press briefing on human medicines in 2025	New
07/01/2026	Medicine: Trazimera trastuzumab	Updated
06/01/2026	Medicine: Talmanco (previously Tadalafil Generics) tadalafil	Updated
06/01/2026	Medicine: Kaprivia difelikefalin	Updated
06/01/2026	Medicine: Itovebi inavolisib	Updated
06/01/2026	Page: Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) meetings	Updated
06/01/2026	Medicine: Obodence denosumab	Updated
06/01/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - January 2026	New

Date	Content	Status
06/01/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - February 2026	New
06/01/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - March 2026	New
06/01/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - April 2026	New
06/01/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - May 2026	New
06/01/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - June 2026	New
06/01/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - July 2026	New
06/01/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - September 2026	New
06/01/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - October 2026	New
06/01/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - November 2026	New
06/01/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - December 2026	New
06/01/2026	Medicine: Tyverb lapatinib	Updated
06/01/2026	Medicine: Bildyos denosumab	Updated
06/01/2026	Medicine: Imlygic talimogene laherparepvec	Updated
06/01/2026	Medicine: Eltrombopag Viatris eltrombopag	Updated
06/01/2026	Medicine: Ofev nintedanib	Updated

Date	Content	Status
06/01/2026	Medicine: Spedra avanafil	Updated
06/01/2026	Event: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	Updated
06/01/2026	Medicine: Vabysmo faricimab	Updated
06/01/2026	Page: Healthcare Professionals' Working Party	Updated
06/01/2026	Medicine: Veklury remdesivir	Updated
06/01/2026	Medicine: Vaxneuvance pneumococcal polysaccharide conjugate vaccine (adsorbed)	Updated
06/01/2026	Medicine: Efmody hydrocortisone	Updated
06/01/2026	Event: EMA/HMA annual data forum	Updated
06/01/2026	Medicine: Voriconazole Hikma (previously Voriconazole Hospira) voriconazole	Updated
06/01/2026	Document: HMA-EMA Network Data Steering Group: membership list	Updated
06/01/2026	Page: PRAC recommendations on safety signals	Updated
06/01/2026	Document: List of signals discussed at PRAC since September 2012	Updated
06/01/2026	Document: PRAC recommendations on signals adopted at the 24-27 November 2025 PRAC meeting	New
05/01/2026	Medicine: Levetiracetam Sun levetiracetam	Updated
05/01/2026	Medicine: Jalra vildagliptin	Updated
05/01/2026	Medicine: Alymsys bevacizumab	Updated
05/01/2026	Medicine: Junod denosumab	Updated
05/01/2026	Medicine: Telzir fosamprenavir	Updated

Date	Content	Status
05/01/2026	Medicine: Granupas (previously Para-aminosalicylic acid Lucane) para-aminosalicylic acid	Updated
05/01/2026	Medicine: Kefdensis denosumab	Updated
05/01/2026	Medicine: Zvogra denosumab	Updated
05/01/2026	Medicine: Xiliarx vildagliptin	Updated
05/01/2026	Medicine: Abiraterone Krka abiraterone acetate	Updated
05/01/2026	Medicine: Cablivi caplacizumab	Updated
05/01/2026	Event: Second webinar on new approach methodologies (NAMs) in ecotoxicology: Gill cell line assay for acute fish toxicity prediction	New
05/01/2026	Page: Pharmaceutical industry	Updated
05/01/2026	Document: Organisation chart: Task Forces	Updated
05/01/2026	Page: Emergency Task Force (ETF)	Updated
05/01/2026	Document: Composition of the Emergency Task Force (ETF) for preparedness	New

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
07.01.2026	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 15.10.2025 betreffend die Zulassungen für Humanarzneimittel mit der Wirkstoffstoffkombination Amlodipin/Atorvastatin Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffkombination Amlodipin/Atorvastatin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

Date	Title
05.01.2026	Rote-Hand-Brief zu Tegretal Suspension (Carbamazepin): Einschränkung der Anwendung bei Neugeborenen, da die Konzentration des Hilfsstoffs Propylenglykol den empfohlenen Grenzwert überschreitet Wirkstoff: Carbamazepin Die Firma Novartis Pharma GmbH informiert darüber, dass Tegretal (Carbamazepin) bei Neugeborenen bis zu einem Alter von 4 Wochen nicht angewendet werden darf.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since December 16th, 2025.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since December 19th, 2025.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedeuropa 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.