

TABLE OF CONTENTS

HEADS OF AGENCIES – CMDH	1
HEADS OF AGENCIES – PAEDIATRIC REGULATION	1
EUROPEAN MEDICINES AGENCY (EMA)	1
NOTICE TO APPLICANTS	9
BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)	9
BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)	9
PEI - VIGILANZ (SPECIFIC FOR GERMANY)	9
PHARMEUROPA TEXTS FOR COMMENT	10

HEADS OF AGENCIES – CMDh

25 June

[NEW - Agenda of the CMDh meeting with Interested Parties](#)

22 June

[NEW - 23-25 June CMDh agenda](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
26/06/2026	Post-authorisation: DuoResp Spiromax - withdrawal of application for variation to marketing authorisation budesonide; formoterol	New
26/06/2026	Post-authorisation: BiResp Spiromax - withdrawal of application for variation to marketing authorisation budesonide; formoterol	New
26/06/2026	Page: Guideline on data requirements for authorisation of immunological veterinary medicinal products in exceptional circumstances - Scientific guideline	Updated
26/06/2026	Event: Updates to industry contact management for authorisation products (IRIS)	Updated
26/06/2026	Document: HMA-EMA Network Data Steering Group: membership list	Updated

Date	Content	Status
26/06/2026	Document: Step-by-step guide : Support with workload management in the authority workspace - CTIS Training Programme - Module 04	Updated
26/06/2026	Document: FAQs: Support with workload management by workspace - CTIS Training Programme - Module 04	Updated
26/06/2026	Document: Clinical Trial Information System (CTIS) - Sponsor handbook	Updated
26/06/2026	Medicine: Denosumab Ascend denosumab	New
26/06/2026	Medicine: Nylaspeg pegfilgrastim	New
26/06/2026	Medicine: Yartemlea Narsoplimab	New
26/06/2026	Medicine: Tacquell Autologous melanoma-derived tumor infiltrating lymphocytes, ex vivo-expanded	New
26/06/2026	Medicine: Xervyteg Allogeneic faecal microbiota, pooled	New
26/06/2026	Medicine: Aujemflu Influenza vaccine (surface antigen, inactivated, adjuvanted, prepared in cell culture)	New
26/06/2026	Medicine: Mounjaro tirzepatide	Updated
26/06/2026	Medicine: Onswik Insulin efsitora alfa	New
26/06/2026	Medicine: Hopledo levodopa; carbidopa	New
26/06/2026	Referral: Tavneos - referral avacopan	Updated
26/06/2026	Referral: Rifadin oral suspension and syrup and associated names - referral rifampicin	New
26/06/2026	News: EMA recommends revoking marketing authorisation for Tavneos	New
26/06/2026	News: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 22-25 June 2026	New

Date	Content	Status
26/06/2026	Post-authorisation: Jaypirca - opinion on variation to marketing authorisation pirtobrutinib	New
26/06/2026	Post-authorisation: Rinvoq - opinion on variation to marketing authorisation upadacitinib	New
26/06/2026	Post-authorisation: Rinvoq - opinion on variation to marketing authorisation upadacitinib	New
26/06/2026	Post-authorisation: Orladeyo - opinion on variation to marketing authorisation berotralstat	New
26/06/2026	Post-authorisation: Vyndaqel - opinion on variation to marketing authorisation tafamidis	New
26/06/2026	Post-authorisation: Datroway - opinion on variation to marketing authorisation datopotamab deruxtecan	New
26/06/2026	Post-authorisation: Leqvio - opinion on variation to marketing authorisation inclisiran	New
26/06/2026	Post-authorisation: MenQuadfi - opinion on variation to marketing authorisation meningococcal group A, C, W-135 and Y conjugate vaccine	New
26/06/2026	Post-authorisation: Opzelura - opinion on variation to marketing authorisation ruxolitinib	New
26/06/2026	Post-authorisation: Imvanex - opinion on variation to marketing authorisation smallpox and monkeypox vaccine (Live Modified Vaccinia Virus Ankara)	New
26/06/2026	Post-authorisation: Tecvayli - opinion on variation to marketing authorisation teclistamab	New
26/06/2026	Post-authorisation: Rezolsta - opinion on variation to marketing authorisation darunavir; cobicistat	New
26/06/2026	Page: Reform of the EU pharmaceutical legislation	Updated
25/06/2026	Event: Workshop on advancing proof-of-concept data in paediatric oncology drug development	New

Date	Content	Status
25/06/2026	Document: European Medicines Agency's data protection notice for sharing contact details of network representatives in Agile teams via the restricted Network Portfolio website	New
25/06/2026	Medicine: Feraccru ferric maltol	Updated
25/06/2026	Medicine: Lojuxta lomitapide	Updated
25/06/2026	Medicine: Constella linaclotide	Updated
25/06/2026	Post-authorisation: Stelara - opinion on variation to marketing authorisation ustekinumab	New
25/06/2026	Medicine: Trajenta linagliptin	Updated
25/06/2026	Medicine: Skyrizi risankizumab	Updated
25/06/2026	Event: European Medicines Regulatory Network (EMRN) workshop on geographic atrophy endpoints	Updated
25/06/2026	Medicine: Inaqovi cedazuridine; decitabine	Updated
25/06/2026	MRL: Recombinant equine Chorionic Gonadotropin (reCG) - maximum residue limit recombinant equine Chorionic Gonadotropin (reCG)	New
25/06/2026	PIP: EMA-002451-PIP02-21 - paediatric investigation plan ritlecitinib	Updated
25/06/2026	Medicine: Nintedanib Accord nintedanib	Updated
25/06/2026	Document: List of medicinal products under additional monitoring	Updated
25/06/2026	Page: List of medicines under additional monitoring	Updated
25/06/2026	Document: List of medicinal products under additional monitoring	Updated
25/06/2026	Event: HMA/EMA multistakeholder AI and Data forum: Build trustworthy AI on strong data foundations	New

Date	Content	Status
25/06/2026	PSUSA: PSUSA/00002633/202511 - periodic safety update report single assessment a-tocopherol / ergocalciferol / phytomenadion / retinol palmitate	New
25/06/2026	Medicine: Padcev enfortumab vedotin	Updated
25/06/2026	Medicine: Tezspire tezepelumab	Updated
25/06/2026	PSUSA: PSUSA/00009050/202511 - periodic safety update report single assessment aluminium chloride hexahydrate	New
25/06/2026	Medicine: Cenrifki tolebrutinib	Updated
24/06/2026	Medicine: Yervoy ipilimumab	Updated
24/06/2026	Document: Overview of Network Data Steering Group (NDSG) change management activities 2025-2026	Updated
24/06/2026	Document: Outcome of written procedures finalised during the period from 04 March 2026 to 03 June 2026	New
24/06/2026	Event: Breakthrough medical devices: information session	Updated
24/06/2026	Medicine: Dazluma troriluzole	Updated
24/06/2026	Medicine: Tecvayli teclistamab	Updated
24/06/2026	Medicine: Privigen human normal immunoglobulin (IVIg)	Updated
24/06/2026	Page: ICH E22 General considerations for patient preference studies - Scientific guideline	Updated
24/06/2026	Document: Appendix 1: Acceptable intakes established for N-nitrosamines	Updated
24/06/2026	Document: Fee regulation working arrangements	Updated
24/06/2026	Page: Cookies	Updated
23/06/2026	Event: Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) multistakeholder workshop on real-world data collection	Updated

Date	Content	Status
	in Duchenne muscular dystrophy	
23/06/2026	Medicine: Hemangiol propranolol	Updated
23/06/2026	Medicine: Evfraxy denosumab	Updated
23/06/2026	Medicine: Opdivo nivolumab	Updated
23/06/2026	Medicine: Balversa erdafitinib	Updated
23/06/2026	Medicine: Lynkuet elinzanetant	Updated
23/06/2026	PIP: EMA-000925-PIP02-10 - paediatric investigation plan mixture of Phleum pratense and Secale cereale allergen extracts	Updated
23/06/2026	Medicine: Qalsody tofersen	Updated
23/06/2026	PIP: EMA-000924-PIP01-10 - paediatric investigation plan Phleum pratense allergen extract	Updated
23/06/2026	Medicine: Tagrisso osimertinib	Updated
23/06/2026	PIP: EMA-000923-PIP02-10 - paediatric investigation plan mixture of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis (Grasses-Mix) and Secale cereale (75/25) allergen extracts	Updated
23/06/2026	PIP: EMA-000922-PIP02-10 - paediatric investigation plan mixture of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis (Grasses-Mix) and Secale cereale (50/50) allergen extracts	Updated
23/06/2026	Medicine: Ikervis ciclosporin	Updated
23/06/2026	PIP: EMA-000921-PIP01-10 - paediatric investigation plan mixture of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis allergen extracts	Updated
23/06/2026	PIP: EMA-000918-PIP01-10 - paediatric investigation plan Birch allergen extract; Hazel allergen extract; Alder allergen extract	Updated
23/06/2026	Event: Paediatric Committee (PDCO): 23-26 June 2026	Updated
23/06/2026	Document: Agenda - PDCO agenda of the 23-26 June 2026 meeting	Updated

Date	Content	Status
23/06/2026	PIP: EMEA-000919-PIP01-10 - paediatric investigation plan Betula alba allergen extract	Updated
23/06/2026	Medicine: Pomalidomide Accord pomalidomide	Updated
23/06/2026	Medicine: Epidyolex cannabidiol	Updated
23/06/2026	PIP: EMEA-000926-PIP01-10 - paediatric investigation plan mixture of Dermatophagoides pteronyssinus and Dermatophagoides farinae allergen extracts	Updated
23/06/2026	Medicine: Ahzantive aflibercept	Updated
23/06/2026	PIP: EMEA-000920-PIP01-10 - paediatric investigation plan Dermatophagoides pteronyssinus allergen extract	Updated
23/06/2026	Medicine: Baiana aflibercept	Updated
23/06/2026	Medicine: Enzalutamide Viatriis enzalutamide	Updated
23/06/2026	Medicine: Keytruda pembrolizumab	Updated
23/06/2026	Medicine: Palbociclib Viatriis palbociclib	Updated
23/06/2026	Medicine: Agamree vamorolone	Updated
23/06/2026	Medicine: Imdylltra tarlatamab	Updated
23/06/2026	Medicine: Adstiladrin nadofaragene firadenovec	Updated
23/06/2026	Event: Good manufacturing practice: Multistakeholder workshop on expert contributions to artificial intelligence guidance development (Annex 22)	Updated
23/06/2026	Document: Annex 22 expert workshop draft agenda: Day 1 - session with interested parties	New
23/06/2026	Event: Clinical Trials Information System (CTIS): Information day	Updated
23/06/2026	PIP: EMA/PE/0000231892 - paediatric investigation plan apremilast	Updated

Date	Content	Status
23/06/2026	PIP: EMA/PE/0000233122 - paediatric investigation plan Fluocinolone acetonide	Updated
23/06/2026	PIP: EMA/PE/0000228373 - paediatric investigation plan Gepotidacin	New
23/06/2026	PIP: EMA/PE/0000241855 - paediatric investigation plan brensocatib	Updated
23/06/2026	PIP: EMA/PE/0000228531 - paediatric investigation plan elasomeran; imelsomeran; davesomeran; andusomeran SARS-CoV-2 JN.1 mRNA	Updated
23/06/2026	PIP: EMA/PE/0000225778 - paediatric investigation plan sipavibart	Updated
22/06/2026	Medicine: Hexacima diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed)	Updated
22/06/2026	Medicine: Hexyon diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed)	Updated
22/06/2026	Medicine: Kuvan sapropterin	Updated
22/06/2026	Medicine: Bimervax COVID-19 Vaccine (recombinant, adjuvanted)	Updated
22/06/2026	Event: Fifth European Medicines Agency and Nuclear Medicines Europe bilateral meeting	New
22/06/2026	Document: Minutes - HMA-EMA joint Network Data Steering Group meeting - 21 May 2026	New
22/06/2026	Event: ETF-stakeholders meeting on biodistribution of mRNA vaccines	New
22/06/2026	Page: PRAC recommendations on safety signals	Updated
22/06/2026	Page: CVMP recommendations on limited market classification and eligibility for authorisation under Article 23	Updated
22/06/2026	Document: List of signals discussed at PRAC since September 2012	Updated
22/06/2026	Medicine: Tecentriq atezolizumab	Updated

Date	Content	Status
22/06/2026	Medicine: Rinvoq upadacitinib	Updated
22/06/2026	Event: Shortage prevention plan (SPP) workshop	Updated
22/06/2026	DHPC: Evrysdi - direct healthcare professional communication (DHPC) risdiplam	New
22/06/2026	Page: Website outages and upgrades	Updated

NOTICE TO APPLICANTS

Date	Title
24.06.2026	Eudralex Volume 4: Reference and Retention Samples (revised, applicable as of 24 September 2026)

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
26.06.2026	Rifadin-Suspension und Rifadin-Sirup: Überprüfung in Bezug auf den Inhaltsstoff Diethanolamin Wirkstoff: Rifampicin Die Europäische Arzneimittel-Agentur (EMA) beginnt mit der Überprüfung von flüssigen Darreichungsformen des Antibiotikums Rifampicin (Rifadin-Suspension und Rifadin-Sirup).

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
23.06.2026	Möglicher Zusammenhang zwischen Brustimplantaten und der Entstehung eines anaplastischen großzelligen Lymphoms (ALCL) Aktuelle Informationen zu texturierten Brustimplantaten
23.06.2026	Brustimplantate aus Silikon: Allgemeine Hinweise und Risiken Aus zahlreichen Quellen ist dem BfArM bekannt geworden, dass sich viele Brustimplantateträgerinnen bei der Entscheidung zu diesem Eingriff der damit verbundenen möglichen Risiken und möglichen Folgen nicht ausreichend bewusst waren. Das BfArM möchte daher einen Beitrag dazu leisten, dass Frauen die mit der Implantation verbundenen Konsequenzen und möglichen Risiken besser kennenlernen.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since May 12th, 2026.

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.