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### HEADS OF AGENCIES – CMDh

**07 May**

[CORRECTION - Questions and Answers on Variations](#)

### HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

### EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
11/05/2026	<b>Document:</b> <a href="#">Agenda of the COMP Meeting 11-12 May 2026</a>	New
08/05/2026	<b>Document:</b> <a href="#">PDCO minutes of the 24-27 March 2026 meeting</a>	New
08/05/2026	<b>Page:</b> <a href="#">PRIME: priority medicines</a>	Updated
08/05/2026	<b>PSUSA:</b> <a href="#">PSUSA/00001232/202507 - periodic safety update report single assessment</a> epinephrine (except for nasal use)	New
08/05/2026	<b>Document:</b> <a href="#">Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 20-23 April 2026</a>	New
08/05/2026	<b>Document:</b> <a href="#">List of medicines currently in PRIME scheme</a>	Updated
08/05/2026	<b>Medicine:</b> <a href="#">Olanzapine Glenmark Europe</a> olanzapine	Updated
08/05/2026	<b>Medicine:</b> <a href="#">Olanzapine Glenmark</a> olanzapine	Updated

Date	Content	Status
08/05/2026	<b>Medicine: Elebrato Ellipta</b> fluticasone furoate; umeclidinium; vilanterol	Updated
08/05/2026	<b>Medicine: Trelegly Ellipta</b> fluticasone furoate; umeclidinium; vilanterol	Updated
08/05/2026	<b>Medicine: Opdivo</b> nivolumab	Updated
08/05/2026	<b>EU-M4all: Dengue Tetravalent Vaccine (Live, Attenuated) Takeda - opinion on medicine for use outside EU</b> dengue tetravalent vaccine (live, attenuated)	Updated
08/05/2026	<b>Medicine: Remsima</b> infliximab	Updated
08/05/2026	<b>Medicine: Arava</b> leflunomide	Updated
08/05/2026	<b>PSUSA: PSUSA/00002434/202508 - periodic safety update report single assessment</b> piretanide / ramipril, piretanide	New
08/05/2026	<b>Medicine: Pandemic influenza vaccine H5N1 AstraZeneca (previously Pandemic influenza vaccine H5N1 Medimmune)</b> pandemic influenza vaccine (H5N1) (live attenuated, nasal)	Updated
08/05/2026	<b>PSUSA: PSUSA/00000448/202508 - periodic safety update report single assessment</b> buclizine / codeine / paracetamol, caffeine / codeine / paracetamol	New
08/05/2026	<b>Medicine: Genvoya</b> elvitegravir; cobicistat; emtricitabine; tenofovir alafenamide	Updated
08/05/2026	<b>Medicine: Ixiaro</b> Japanese encephalitis vaccine (inactivated, adsorbed)	Updated
08/05/2026	<b>Medicine: Gardasil 9</b> human papillomavirus 9-valent vaccine (recombinant, adsorbed)	Updated
08/05/2026	<b>Medicine: Loargys</b> pegzilarginase	Updated
08/05/2026	<b>Medicine: Teriflunomide Viartis (previously Teriflunomide Mylan)</b> teriflunomide	Updated
08/05/2026	<b>Medicine: Esbriet</b> pirfenidone	Updated
08/05/2026	<b>Medicine: Tenofovir disoproxil Viartis (previously Tenofovir disoproxil Mylan)</b> tenofovir disoproxil	Updated
08/05/2026	<b>Medicine: Bimzelx</b> bimekizumab	Updated

Date	Content	Status
08/05/2026	<b>Medicine:</b> <a href="#">Teduglutide Viatriis</a> teduglutide	Updated
08/05/2026	<b>Medicine:</b> <a href="#">Bylvay</a> odevixibat	Updated
08/05/2026	<b>Medicine:</b> <a href="#">Strimvelis</a> autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence	Updated
08/05/2026	<b>Medicine:</b> <a href="#">Latuda</a> lurasidone	Updated
08/05/2026	<b>Medicine:</b> <a href="#">Talmanco (previously Tadalafil Generics)</a> tadalafil	Updated
08/05/2026	<b>Medicine:</b> <a href="#">Rivaroxaban Viatriis (previously Rivaroxaban Mylan)</a> rivaroxaban	Updated
08/05/2026	<b>Medicine:</b> <a href="#">Ritonavir Viatriis (previously Ritonavir Mylan)</a> ritonavir	Updated
08/05/2026	<b>Medicine:</b> <a href="#">Itovebi</a> inavolisib	Updated
08/05/2026	<b>News:</b> <a href="#">Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 4-7 May 2026</a>	New
08/05/2026	<b>Medicine:</b> <a href="#">Pregabalin Viatriis (previously Pregabalin Mylan)</a> pregabalin	Updated
08/05/2026	<b>Event:</b> <a href="#">Good manufacturing practice: Multistakeholder workshop on expert contributions to artificial intelligence guidance development (Annex 22)</a>	New
08/05/2026	<b>Medicine:</b> <a href="#">Pomalidomide Viatriis</a> pomalidomide	Updated
08/05/2026	<b>Medicine:</b> <a href="#">Emtricitabine / Rilpivirine / Tenofovir Alafenamide Viatriis</a> emtricitabine; rilpivirine; tenofovir alafenamide	Updated
08/05/2026	<b>Medicine:</b> <a href="#">Mayzent</a> siponimod	Updated
08/05/2026	<b>PIP:</b> <a href="#">EMA-001976-PIP02-18 - paediatric investigation plan 3-[5-[(1R,2S)-2-(2,2-difluoropropanoylamino)-1-(2,3-dihydro-1,4-benzodioxin-6-yl)propoxy]indazol-1-yl]-N-[(3R)-tetrahydrofuran-3-yl]benzamide (AZD7594)</a>	Updated
08/05/2026	<b>PIP:</b> <a href="#">EMA-001017-PIP01-10-M01 - paediatric investigation plan chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis</a>	Updated
08/05/2026	<b>PIP:</b> <a href="#">EMA-002183-PIP03-23 - paediatric investigation plan imlifidase</a>	Updated
08/05/2026	<b>PIP:</b> <a href="#">EMA-001013-PIP01-10-M01 - paediatric investigation plan chemically modified extract of trees pollen from birch and alder</a>	Updated

Date	Content	Status
08/05/2026	<b>PIP:</b> <a href="#">EMEA-001011-PIP01-10-M01 - paediatric investigation plan chemically modified house dust mites allergen extract of Dermatophagoides pteronyssinus and Dermatophagoides farina</a>	Updated
08/05/2026	<b>PIP:</b> <a href="#">EMEA-001374-PIP01-12 - paediatric investigation plan exon 53 specific phosphorothioate oligonucleotide</a>	Updated
08/05/2026	<b>PIP:</b> <a href="#">EMEA-001369-PIP01-12 - paediatric investigation plan exon 45 specific phosphorothioate oligonucleotide</a>	Updated
08/05/2026	<b>Medicine:</b> <a href="#">Nintedanib Viatriis</a> nintedanib	Updated
08/05/2026	<b>PIP:</b> <a href="#">EMEA-002051-PIP02-16 - paediatric investigation plan allopregnanolone</a>	Updated
08/05/2026	<b>Medicine:</b> <a href="#">Kanjinti</a> trastuzumab	Updated
08/05/2026	<b>Medicine:</b> <a href="#">Teizeild</a> teplizumab	Updated
08/05/2026	<b>Page:</b> <a href="#">Revamp of marketing authorisation assessment templates</a>	New
08/05/2026	<b>Medicine:</b> <a href="#">Dupixent</a> dupilumab	Updated
08/05/2026	<b>PSUSA:</b> <a href="#">PSUSA/00002357/202508 - periodic safety update report single assessment</a> pethidine	New
07/05/2026	<b>Medicine:</b> <a href="#">Mysildecard</a> sildenafil	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Febuxostat Viatriis (previously Febuxostat Mylan)</a> febuxostat	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Entecavir Viatriis (previously Entecavir Mylan)</a> entecavir	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Eltrombopag Viatriis</a> eltrombopag	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Duloxetine Viatriis (previously Duloxetine Mylan)</a> duloxetine	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Darunavir Viatriis (previously Darunavir Mylan)</a> darunavir	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Ibandronic Acid Sandoz</a> ibandronic acid	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Dapagliflozin Viatriis</a> dapagliflozin	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Cinacalcet Viatriis (previously Cinacalcet Mylan)</a> cinacalcet	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Rapilysin</a> reteplase	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Afiveg</a> afibercept	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Ambrisentan Viatriis (previously Ambrisentan Mylan)</a> ambrisentan	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Loqtorzi</a> toripalimab	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Humira</a> adalimumab	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Atazanavir Viatriis (previously Atazanavir Mylan)</a> atazanavir	Updated

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07/05/2026	<b>Medicine:</b> <a href="#">Ilumetri</a> tildrakizumab	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Comtan</a> entacapone	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Arixtra</a> fondaparinux sodium	Updated
07/05/2026	<b>News:</b> <a href="#">EU recommendations for 2026/2027 seasonal flu vaccine composition</a>	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Fintepla</a> fenfluramine	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Uzpruvo</a> ustekinumab	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Dimethyl fumarate Mylan</a> dimethyl fumarate	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Beovu</a> brolocizumab	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Truvelog Mix 30</a> insulin aspart	Updated
07/05/2026	<b>PIP:</b> <a href="#">EMA-003192-PIP03-23 - paediatric investigation plan ensitrelvir</a>	New
07/05/2026	<b>PIP:</b> <a href="#">EMA/PE/0000230710 - paediatric investigation plan rocatinlimab</a>	Updated
07/05/2026	<b>Medicine:</b> <a href="#">CellCept</a> mycophenolate mofetil	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Uplizna</a> inebilizumab	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Olumiant</a> baricitinib	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Kerendia</a> finerenone	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Dovprela (previously Pretomanid FGK)</a> pretomanid	Updated
07/05/2026	<b>Medicine:</b> <a href="#">Oncaspar</a> pegaspargase	Updated
07/05/2026	<b>Document:</b> <a href="#">List of industry subject matter experts and list of planned calls for industry subject matter experts</a>	Updated
07/05/2026	<b>Document:</b> <a href="#">Record of data processing activity for Modelling and Simulation Pilot - Use of clinical study data for scientific advice</a>	New
07/05/2026	<b>Document:</b> <a href="#">European Medicines Agency's data protection notice for Modelling and Simulation Pilot - Use of clinical study data for scientific advice</a>	New
07/05/2026	<b>Event:</b> <a href="#">Clinical Trials Information System (CTIS): Information day</a>	New
07/05/2026	<b>Medicine:</b> <a href="#">Usgena</a> ustekinumab	Updated
06/05/2026	<b>Page:</b> <a href="#">Clinical trials in human medicines</a>	Updated
06/05/2026	<b>Document:</b> <a href="#">Minutes of PRAC meeting on 9-12 March 2026</a>	New

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06/05/2026	<b>Shortage:</b> <a href="#">NexoBrid</a> concentrate of proteolytic enzymes enriched in bromelain	New
06/05/2026	<b>Medicine:</b> <a href="#">Tolucombi</a> telmisartan; hydrochlorothiazide	Updated
06/05/2026	<b>PIP:</b> <a href="#">EMA/PE/0000181993 - paediatric investigation plan</a> mosunetuzumab	Updated
06/05/2026	<b>PIP:</b> <a href="#">EMA/PE/0000290054 - paediatric investigation plan</a> human polyclonal immunoglobulin G against thymocyte	New
06/05/2026	<b>PIP:</b> <a href="#">EMA/PE/0000236886 - paediatric investigation plan</a> baricitinib	New
06/05/2026	<b>Medicine:</b> <a href="#">Integrilin</a> eptifibatide	Updated
06/05/2026	<b>PIP:</b> <a href="#">EMEA-002414-PIP01-18 - paediatric investigation plan</a> Humanized anti-CD19, Fc engineered, monoclonal antibody (XmAb5871)	Updated
06/05/2026	<b>PIP:</b> <a href="#">EMEA-002299-PIP01-17 - paediatric investigation plan</a> Enfortumab vedotin	Updated
06/05/2026	<b>Medicine:</b> <a href="#">Imcivree</a> setmelanotide	Updated
06/05/2026	<b>Medicine:</b> <a href="#">Korjony</a> catumaxomab	Updated
06/05/2026	<b>Medicine:</b> <a href="#">Truqap</a> capivasertib	Updated
06/05/2026	<b>Medicine:</b> <a href="#">Ifirmasta (previously Irbesartan Krka)</a> irbesartan	Updated
06/05/2026	<b>Medicine:</b> <a href="#">Irbesartan Teva</a> irbesartan	Updated
06/05/2026	<b>Medicine:</b> <a href="#">Ogsiveo</a> nirogacestat	Updated
05/05/2026	<b>Medicine:</b> <a href="#">Rhapsido</a> remibrutinib	Updated
05/05/2026	<b>Document:</b> <a href="#">Agenda - EnprEMA &amp; ACT EU workshop on paediatric clinical trials</a>	Updated
05/05/2026	<b>Document:</b> <a href="#">Agenda of the PRAC meeting 4-7 May 2026</a>	Updated
05/05/2026	<b>Document:</b> <a href="#">European Medicines Agency's data protection notice for the management of traineeships at EMA</a>	New
05/05/2026	<b>Document:</b> <a href="#">Minutes of the CAT meeting 18-20 March 2026</a>	New
05/05/2026	<b>Document:</b> <a href="#">Minutes of the COMP meeting 17-18 March 2026</a>	New
05/05/2026	<b>Page:</b> <a href="#">Quality of medicines: questions and answers - Part 2</a>	Updated
05/05/2026	<b>Document:</b> <a href="#">Questions and answers on implementation of Ph.Eur. Medicinal Product Monographs (MPM)</a>	Updated
05/05/2026	<b>Medicine:</b> <a href="#">Bimervax</a> COVID-19 Vaccine (recombinant, adjuvanted)	Updated
05/05/2026	<b>Medicine:</b> <a href="#">Onerji</a> levodopa; carbidopa	Updated
05/05/2026	<b>Medicine:</b> <a href="#">Palsonify</a> paltusotine	Updated

<b>Date</b>	<b>Content</b>	<b>Status</b>
05/05/2026	<b>Medicine:</b> <a href="#">Ilaris</a> canakinumab	Updated
05/05/2026	<b>Document:</b> <a href="#">QRD veterinary combined label-leaflet template v.9.1</a>	Updated
05/05/2026	<b>Medicine:</b> <a href="#">Mvabea</a> Ebola vaccine (MVA-BN-Filo [recombinant])	Updated
05/05/2026	<b>Medicine:</b> <a href="#">Zabdeno</a> ebola vaccine (Ad26.ZEBOV-GP [recombinant])	Updated
05/05/2026	<b>Medicine:</b> <a href="#">Qutenza</a> capsaicin	Updated
05/05/2026	<b>Medicine:</b> <a href="#">Comirnaty</a> COVID-19 mRNA vaccine	Updated
04/05/2026	<b>Document:</b> <a href="#">Template - Request for compliance check on an agreed paediatric investigation plan (PIP)</a>	Updated
04/05/2026	<b>Document:</b> <a href="#">FAQs: Supervise a Clinical Trial : Inspection records - CTIS Training Programme - Module 16</a>	Updated
04/05/2026	<b>Event:</b> <a href="#">European Shortages Monitoring Platform (ESMP) training on readable IDs and general updates for industry</a>	Updated
04/05/2026	<b>Document:</b> <a href="#">Meeting summary - Medicine Shortages SPOC Working Party meeting 16-17 March 2026</a>	New
04/05/2026	<b>Document:</b> <a href="#">Minutes of the Management Board meeting: 12 March 2026</a>	New
04/05/2026	<b>Document:</b> <a href="#">List of eligible industry stakeholder organisations</a>	Updated
04/05/2026	<b>Document:</b> <a href="#">Minutes - Executive Steering Group on Shortages of Medical Devices (MDSSG) (23 March 2026)</a>	New
04/05/2026	<b>Shortage:</b> <a href="#">Quetiapine</a>	Updated
04/05/2026	<b>Event:</b> <a href="#">Pharmacovigilance Risk Assessment Committee (PRAC): 4 - 7 May 2026</a>	Updated
04/05/2026	<b>Document:</b> <a href="#">Agenda of the COMP Meeting 14-16 April 2026</a>	Updated
04/05/2026	<b>Event:</b> <a href="#">Product Management Service (PMS) information day 2026</a>	Updated
04/05/2026	<b>Medicine:</b> <a href="#">Leqembi</a> lecanemab	Updated
04/05/2026	<b>Medicine:</b> <a href="#">Rapamune</a> sirolimus	Updated
04/05/2026	<b>Medicine:</b> <a href="#">Yeytuo</a> lenacapavir	Updated

## NOTICE TO APPLICANTS

No updates since October 30<sup>th</sup>, 2025.

## BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
08.05.2026	<b>Pharmacovigilance Risk Assessment Committee (PRAC)</b> Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 04.05. - 07.05.2026 behandelt wurden.
08.05.2026	<b>Rote-Hand-Brief zu Famenita 200 mg Weichkapseln: Fehlerhafte Kennzeichnung in der Blindenschrift</b> Wirkstoff: Progesteron Die Firma Exeltis Germany GmbH informiert über eine fehlerhafte Kennzeichnung in der äußeren Umhüllung.
06.05.2026	<b>Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 25.02.2026 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Albendazol</b> Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Albendazol infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

## BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since April 17<sup>th</sup>, 2026.

## PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since April 22<sup>nd</sup>, 2026.

## PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedeuropa updates will be presented quarterly.

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