

## 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) .....	8
PEI - VIGILANZ (SPECIFIC FOR GERMANY) .....	8
PHARMEUROPA TEXTS FOR COMMENT.....	8

### HEADS OF AGENCIES – CMDh

#### 24 February

[NEW - 24-25 February CMDh agenda](#)

### HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

### EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
27/02/2026	<b>PSUSA:</b> <a href="#">PSUSA/00002709/202504 - periodic safety update report single assessment simvastatin</a>	New
27/02/2026	<b>Medicine:</b> <a href="#">Ztalmy</a> ganaxolone	Updated
27/02/2026	<b>Medicine:</b> <a href="#">Epidyolex</a> cannabidiol	Updated
27/02/2026	<b>Medicine:</b> <a href="#">Jeraygo</a> aprocitentan	Updated
27/02/2026	<b>Event:</b> <a href="#">Meeting of the HMA-EMA group focused on AI with industry stakeholders - February 2026</a>	New
27/02/2026	<b>Medicine:</b> <a href="#">Zyprexa</a> olanzapine	Updated
27/02/2026	<b>Event:</b> <a href="#">Quality Innovation Group (QIG): Listen and learn focus group meeting on sustainability</a>	New
27/02/2026	<b>Medicine:</b> <a href="#">Aumseqa</a> Aumolertinib	Updated
27/02/2026	<b>Event:</b> <a href="#">EMA multi-stakeholder workshop on supporting innovation in cardiovascular medicines and medical devices in the EU</a>	Updated

Date	Content	Status
27/02/2026	<b>Medicine:</b> <a href="#">Comirnaty</a> COVID-19 mRNA vaccine	Updated
27/02/2026	<b>Medicine:</b> <a href="#">Spikevax (previously COVID-19 Vaccine Moderna)</a> COVID-19 mRNA vaccine	Updated
27/02/2026	<b>Page:</b> <a href="#">EU Innovation Network (EU-IN)</a>	Updated
27/02/2026	<b>Medicine:</b> <a href="#">Nustendi</a> bempedoic acid; ezetimibe	Updated
27/02/2026	<b>Medicine:</b> <a href="#">Nilemdo</a> bempedoic acid	Updated
27/02/2026	<b>Medicine:</b> <a href="#">Alecensa</a> alectinib	Updated
27/02/2026	<b>Medicine:</b> <a href="#">Cometriq</a> cabozantinib	Updated
27/02/2026	<b>Medicine:</b> <a href="#">Cabometyx</a> cabozantinib	Updated
27/02/2026	<b>Document:</b> <a href="#">Agenda of the HMPC meeting 2-4 March 2026</a>	New
27/02/2026	<b>Page:</b> <a href="#">Orphan designation: Overview</a>	Updated
27/02/2026	<b>Document:</b> <a href="#">List of centrally authorised products with safety-related changes to the product information</a>	Updated
27/02/2026	<b>Medicine:</b> <a href="#">Onerji</a> levodopa; carbidopa	New
27/02/2026	<b>Medicine:</b> <a href="#">Ojemda</a> tovorafenib	New
27/02/2026	<b>Medicine:</b> <a href="#">Fubelv</a> etanercept	New
27/02/2026	<b>Medicine:</b> <a href="#">Tuyory</a> tocilizumab	New
27/02/2026	<b>Medicine:</b> <a href="#">Rhapsido</a> remibrutinib	New
27/02/2026	<b>Medicine:</b> <a href="#">Bysumlog</a> insulin lispro	New
27/02/2026	<b>Medicine:</b> <a href="#">Dazparda</a> insulin aspart	New
27/02/2026	<b>Medicine:</b> <a href="#">Palsonify</a> paltusotine	New
27/02/2026	<b>Medicine:</b> <a href="#">mCOMBRIAX</a> Influenza; COVID-19 mRNA vaccine	New
27/02/2026	<b>Medicine:</b> <a href="#">Poherdy</a> pertuzumab	New
27/02/2026	<b>Medicine:</b> <a href="#">Iloperidone Vanda Pharmaceuticals</a> iloperidone	New
27/02/2026	<b>Medicine:</b> <a href="#">Daybu</a> trofinetide	New

Date	Content	Status
27/02/2026	<b>Medicine:</b> <a href="#">Zumrad</a> sasanlimab	New
27/02/2026	<b>Medicine:</b> <a href="#">Zandoriah</a> teriparatide	New
27/02/2026	<b>Medicine:</b> <a href="#">Xolremdi</a> mavorixafor	New
27/02/2026	<b>News:</b> <a href="#">New single-dose oral treatment for human African trypanosomiasis (sleeping sickness)</a>	New
27/02/2026	<b>News:</b> <a href="#">Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 23-26 February 2026</a>	New
27/02/2026	<b>Post-authorisation:</b> <a href="#">Dupixent - opinion on variation to marketing authorisation</a> dupilumab	New
27/02/2026	<b>Post-authorisation:</b> <a href="#">Keytruda - opinion on variation to marketing authorisation</a> pembrolizumab	New
27/02/2026	<b>Post-authorisation:</b> <a href="#">Olumiant - opinion on variation to marketing authorisation</a> baricitinib	New
27/02/2026	<b>Post-authorisation:</b> <a href="#">Scemblix - opinion on variation to marketing authorisation</a> asciminib	New
27/02/2026	<b>Post-authorisation:</b> <a href="#">Stelara - opinion on variation to marketing authorisation</a> ustekinumab	New
27/02/2026	<b>Post-authorisation:</b> <a href="#">Jorveza - opinion on variation to marketing authorisation</a> budesonide	New
27/02/2026	<b>EU-M4all:</b> <a href="#">Acoziborole Winthrop - opinion on medicine for use outside EU</a> acoziborole	New
27/02/2026	<b>Document:</b> <a href="#">Info sheet - Orphan medicines in the EU</a>	Updated
27/02/2026	<b>News:</b> <a href="#">New medicine to treat paediatric low-grade glioma</a>	New
27/02/2026	<b>Referral:</b> <a href="#">Tecovirimat SIGA - referral</a> tecovirimat	Updated
27/02/2026	<b>Medicine:</b> <a href="#">Flucelvax Tetra</a> influenza vaccine (surface antigen, inactivated, prepared in cell cultures)	Updated
26/02/2026	<b>Medicine:</b> <a href="#">Taltz</a> ixekizumab	Updated
26/02/2026	<b>Medicine:</b> <a href="#">Evkeeza</a> evinacumab	Updated
26/02/2026	<b>Medicine:</b> <a href="#">Mounjaro</a> tirzepatide	Updated

Date	Content	Status
26/02/2026	<b>Document:</b> <a href="#">Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) annual activity report 2025</a>	New
26/02/2026	<b>Document:</b> <a href="#">Minutes of the Management Board meeting: 17-18 December 2025</a>	New
26/02/2026	<b>Medicine:</b> <a href="#">Yeytuo</a> lenacapavir	Updated
26/02/2026	<b>Document:</b> <a href="#">European Medicines Agency (EMA) stakeholder relations management framework</a>	Updated
26/02/2026	<b>Medicine:</b> <a href="#">Adenuric</a> febuxostat	Updated
26/02/2026	<b>Medicine:</b> <a href="#">Remsima</a> infliximab	Updated
26/02/2026	<b>Medicine:</b> <a href="#">Sunlenca</a> lenacapavir	Updated
26/02/2026	<b>Medicine:</b> <a href="#">Fluad Tetra</a> influenza vaccine (surface antigen, inactivated, adjuvanted)	Updated
26/02/2026	<b>Document:</b> <a href="#">Standard operating procedure for annual review of VeDDRA list to be used in EudraVigilance Veterinary</a>	Updated
26/02/2026	<b>Medicine:</b> <a href="#">Conexxence</a> denosumab	Updated
26/02/2026	<b>Medicine:</b> <a href="#">Kisunla</a> donanemab	Updated
26/02/2026	<b>Referral:</b> <a href="#">Melatomed and associated names - referral</a> melatonin	Updated
26/02/2026	<b>Document:</b> <a href="#">New product information wording – Extracts from PRAC recommendations on signals adopted at the 28-31 October 2024 PRAC</a>	Updated
26/02/2026	<b>Medicine:</b> <a href="#">Revolade</a> eltrombopag	Updated
26/02/2026	<b>Medicine:</b> <a href="#">Vydura</a> rimegepant	Updated
26/02/2026	<b>Medicine:</b> <a href="#">Yesafili</a> aflibercept	Updated
25/02/2026	<b>PIP:</b> <a href="#">EMA/PE/0000226657 - paediatric investigation plan</a> abelacimab	Updated
25/02/2026	<b>PIP:</b> <a href="#">EMA/PE/0000226303 - paediatric investigation plan</a> naldemedine tosilate	Updated
25/02/2026	<b>PIP:</b> <a href="#">EMEA-003395-PIP02-23 - paediatric investigation plan</a> iodine (131I) apamistamab	Updated
25/02/2026	<b>PIP:</b> <a href="#">EMEA-001238-PIP02-20 - paediatric investigation plan</a> vatiquinone	Updated
25/02/2026	<b>Medicine:</b> <a href="#">Epizootic haemorrhagic disease vaccine (recombinant protein)</a> <a href="#">Laboratorios Syva S.A.</a> Epizootic haemorrhagic disease vaccine (recombinant protein)	Updated

Date	Content	Status
25/02/2026	<b>Medicine:</b> <a href="#">Kavigale</a> sipavibart	Updated
25/02/2026	<b>Medicine:</b> <a href="#">Steqeyma</a> ustekinumab	Updated
25/02/2026	<b>Page:</b> <a href="#">Fees payable to the European Medicines Agency: Guidance for all applicants</a>	Updated
25/02/2026	<b>Medicine:</b> <a href="#">Sycrest</a> asenapine	Updated
25/02/2026	<b>Medicine:</b> <a href="#">Daxas</a> roflumilast	Updated
25/02/2026	<b>Medicine:</b> <a href="#">DaTSCAN</a> ioflupane (1231)	Updated
25/02/2026	<b>Medicine:</b> <a href="#">Eltrombopag Accord</a> eltrombopag	Updated
25/02/2026	<b>Medicine:</b> <a href="#">Tadalafil Mylan</a> tadalafil	Updated
25/02/2026	<b>Medicine:</b> <a href="#">Byooviz</a> ranibizumab	Updated
25/02/2026	<b>Medicine:</b> <a href="#">Hepcludex</a> bulevirtide	Updated
25/02/2026	<b>Medicine:</b> <a href="#">Tibsovo</a> ivosidenib	Updated
25/02/2026	<b>Medicine:</b> <a href="#">Qaialdo</a> spironolactone	Updated
25/02/2026	<b>Page:</b> <a href="#">List of medicines under additional monitoring</a>	Updated
25/02/2026	<b>Document:</b> <a href="#">List of medicinal products under additional monitoring</a>	Updated
25/02/2026	<b>Document:</b> <a href="#">List of medicinal products under additional monitoring</a>	Updated
25/02/2026	<b>Medicine:</b> <a href="#">Verzenios</a> abemaciclib	Updated
25/02/2026	<b>Medicine:</b> <a href="#">CellCept</a> mycophenolate mofetil	Updated
25/02/2026	<b>Medicine:</b> <a href="#">Sprycel</a> dasatinib (anhydrous)	Updated
25/02/2026	<b>Medicine:</b> <a href="#">Gotenfia</a> golimumab	Updated
25/02/2026	<b>Event:</b> <a href="#">Cancer Medicines Forum: December 2025</a>	New
25/02/2026	<b>Event:</b> <a href="#">Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - January 2026</a>	Updated
25/02/2026	<b>PIP:</b> <a href="#">EMA-003618-PIP01-24 - paediatric investigation plan 2-isopropyl-3H-naphtho[1,2-d]imidazole-4,5-dione</a>	New

Date	Content	Status
24/02/2026	<b>Document:</b> <a href="#">Electronic reporting to EudraVigilance - List of reference documents</a>	New
24/02/2026	<b>Page:</b> <a href="#">EudraVigilance: electronic reporting</a>	Updated
24/02/2026	<b>Medicine:</b> <a href="#">Vivlipeg</a> pegfilgrastim	Updated
24/02/2026	<b>Medicine:</b> <a href="#">Enzalutamide Viatrix</a> enzalutamide	Updated
24/02/2026	<b>Page:</b> <a href="#">EudraVigilance training and support</a>	Updated
24/02/2026	<b>Shortage:</b> <a href="#">Cyclophosphamide</a> cyclophosphamide	New
24/02/2026	<b>Document:</b> <a href="#">EudraVigilance support guide</a>	Updated
24/02/2026	<b>Document:</b> <a href="#">EudraVigilance - EVWEB user manual</a>	Updated
24/02/2026	<b>Medicine:</b> <a href="#">Exelon</a> rivastigmine	Updated
24/02/2026	<b>Shortage:</b> <a href="#">Ifosfamide</a> ifosfamide	Updated
24/02/2026	<b>Medicine:</b> <a href="#">Erleada</a> apalutamide	Updated
24/02/2026	<b>Page:</b> <a href="#">ICH E22 General considerations for patient preference studies - Scientific guideline</a>	Updated
24/02/2026	<b>Medicine:</b> <a href="#">Zoledronic Acid Accord</a> zoledronic acid	Updated
24/02/2026	<b>Page:</b> <a href="#">Website outages and upgrades</a>	Updated
24/02/2026	<b>Medicine:</b> <a href="#">Apixaban Accord</a> apixaban	Updated
24/02/2026	<b>Medicine:</b> <a href="#">Teriflunomide Accord</a> teriflunomide	Updated
24/02/2026	<b>Medicine:</b> <a href="#">Eribulin Baxter</a> eribulin	Updated
24/02/2026	<b>Medicine:</b> <a href="#">Acvybra</a> denosumab	Updated
24/02/2026	<b>Medicine:</b> <a href="#">Lenalidomide Accord</a> lenalidomide	Updated
24/02/2026	<b>Medicine:</b> <a href="#">Fymiskina</a> ustekinumab	Updated
24/02/2026	<b>Medicine:</b> <a href="#">Ranluspec</a> ranibizumab	Updated
24/02/2026	<b>Medicine:</b> <a href="#">Tivdak</a> tisotumab vedotin	Updated
24/02/2026	<b>Medicine:</b> <a href="#">Tepadina</a> thiotepa	Updated

Date	Content	Status
24/02/2026	<b>Document:</b> <a href="#">Agenda - Webinar on the use of platform approaches in the non-clinical and clinical domains</a>	Updated
24/02/2026	<b>Medicine:</b> <a href="#">Fintepla</a> fenfluramine	Updated
24/02/2026	<b>Page:</b> <a href="#">ICH Q14 Analytical procedure development - Scientific guideline</a>	Updated
24/02/2026	<b>Document:</b> <a href="#">European Medicines Agency's data protection notice for the operation of the Security Access Control System</a>	Updated
24/02/2026	<b>Document:</b> <a href="#">Record of data processing activity relating to Security Access Control System</a>	Updated
24/02/2026	<b>Event:</b> <a href="#">Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting</a>	Updated
24/02/2026	<b>Event:</b> <a href="#">Product Management Service (PMS) information day 2026</a>	Updated
24/02/2026	<b>Document:</b> <a href="#">Agenda - PDCO agenda of the 24-27 February 2026 meeting</a>	New
23/02/2026	<b>PIP:</b> <a href="#">EMA/PE/0000257243 - paediatric investigation plan pozelimab</a>	Updated
23/02/2026	<b>PIP:</b> <a href="#">EMA/PE/0000231113 - paediatric investigation plan nemvaleukin alfa</a>	Updated
23/02/2026	<b>Referral:</b> <a href="#">Ipidacrine-containing medicinal products - referral ipidacrine</a>	Updated
23/02/2026	<b>Medicine:</b> <a href="#">Inluriyo</a> imlunestrant	Updated
23/02/2026	<b>Medicine:</b> <a href="#">Efmody</a> hydrocortisone	Updated
23/02/2026	<b>Medicine:</b> <a href="#">Ogivri</a> trastuzumab	Updated
23/02/2026	<b>Shortage:</b> <a href="#">Natpar</a> parathyroid hormone	Updated
23/02/2026	<b>Event:</b> <a href="#">Electronic application form (eAF) Q&amp;A clinic</a>	New
23/02/2026	<b>Medicine:</b> <a href="#">Entyvio</a> vedolizumab	Updated
23/02/2026	<b>Medicine:</b> <a href="#">Emblaveo</a> aztreonam; avibactam	Updated
23/02/2026	<b>Medicine:</b> <a href="#">Beyfortus</a> nirsevimab	Updated
23/02/2026	<b>Document:</b> <a href="#">Agenda of the CHMP meeting 23-26 February 2026</a>	New
23/02/2026	<b>Document:</b> <a href="#">Annex to agenda of the CHMP meeting 23-26 February 2026</a>	New

## NOTICE TO APPLICANTS

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

### BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
24.02.2026	<p><b>Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 13.11.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Tranexamsäure</b></p> <p>Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Tranexamsäure 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 January 27<sup>th</sup>, 2026.

### PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since February 13<sup>th</sup>, 2026.

### PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedeuropa updates will be presented quarterly.

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