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### HEADS OF AGENCIES – CMDh

**27 January**

[UPDATE - Contact Points](#)

### HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

### EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
30/01/2026	<b>Document:</b> <a href="#">Validation checklist for Type II (non) clinical variations</a>	Updated
30/01/2026	<b>Page:</b> <a href="#">Obtaining and maintaining a scientific opinion on a medicine for use outside the European Union</a>	Updated
30/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00010396/202504 - periodic safety update report single assessment</a> valsartan, hydrochlorothiazide / valsartan	New
30/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00000583/202503 - periodic safety update report single assessment</a> cefaclor	New
30/01/2026	<b>Medicine:</b> <a href="#">Simponi</a> golimumab	Updated
30/01/2026	<b>Referral:</b> <a href="#">Tecovirimat SIGA - referral</a> tecovirimat	Updated
30/01/2026	<b>Medicine:</b> <a href="#">Osvyrti</a> denosumab	Updated
30/01/2026	<b>Medicine:</b> <a href="#">Evrysdi</a> risdiplam	Updated
30/01/2026	<b>Medicine:</b> <a href="#">Trisenox</a> arsenic trioxide	Updated
30/01/2026	<b>Medicine:</b> <a href="#">Lenvima</a> lenvatinib	Updated
30/01/2026	<b>Page:</b> <a href="#">Quality of medicines questions and answers: Part 2</a>	Updated

Date	Content	Status
30/01/2026	<b>Page:</b> <a href="#">Use of Bayesian methods in clinical development - Scientific guideline</a>	New
30/01/2026	<b>Document:</b> <a href="#">Concept paper for the development of a reflection paper on the use of Bayesian methods in clinical development</a>	New
30/01/2026	<b>Medicine:</b> <a href="#">Kisplyx</a> lenvatinib	Updated
30/01/2026	<b>Document:</b> <a href="#">Concept paper on the revision of the guideline on clinical evaluation of diagnostic agents and its appendix 1 on imaging agents</a>	New
30/01/2026	<b>Medicine:</b> <a href="#">Pemetrexed Accord</a> pemetrexed	Updated
30/01/2026	<b>Medicine:</b> <a href="#">Vizamyl</a> flutemetamol (18F)	Updated
30/01/2026	<b>Referral:</b> <a href="#">Tavneos - referral</a> avacopan	Updated
30/01/2026	<b>Document:</b> <a href="#">Network Data Steering Group (NDSG) 2025 annual report</a>	New
30/01/2026	<b>Document:</b> <a href="#">Agenda - PCWP and HCPWP joint meeting February 2026</a>	New
30/01/2026	<b>Medicine:</b> <a href="#">Spikevax (previously COVID-19 Vaccine Moderna)</a> COVID-19 mRNA vaccine	Updated
30/01/2026	<b>Medicine:</b> <a href="#">Kineret</a> anakinra	Updated
30/01/2026	<b>Document:</b> <a href="#">HMPC: overview of assessment work - priority list</a>	Updated
30/01/2026	<b>Document:</b> <a href="#">Committee on Herbal Medicinal Products (HMPC): Work Plan 2026</a>	New
30/01/2026	<b>Event:</b> <a href="#">Meeting on the impact of chemical and environmental policies on the healthcare sector and availability of medicines</a>	Updated
30/01/2026	<b>News:</b> <a href="#">First treatment for rare thymidine kinase 2 deficiency</a>	New
30/01/2026	<b>Medicine:</b> <a href="#">Fylrevy</a> estetrol	New
30/01/2026	<b>Medicine:</b> <a href="#">Rezurock</a> Belumosudil	Updated
30/01/2026	<b>Medicine:</b> <a href="#">Kygevvi</a> doxycitine; doxribtimine	New
30/01/2026	<b>Medicine:</b> <a href="#">Ilumira</a> lutetium (177Lu) chloride	New
30/01/2026	<b>Medicine:</b> <a href="#">Kayshild</a> semaglutide	New
30/01/2026	<b>Medicine:</b> <a href="#">Supemtek</a> trivalent influenza vaccine (recombinant, prepared in cell culture)	New
30/01/2026	<b>Medicine:</b> <a href="#">Mounjaro</a> tirzepatide	Updated
30/01/2026	<b>Medicine:</b> <a href="#">Scenesse</a> afamelanotide	Updated
30/01/2026	<b>News:</b> <a href="#">Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 26-29 January 2026</a>	New
30/01/2026	<b>News:</b> <a href="#">EMA starts review of Tavneos, a medicine for rare autoimmune diseases GPA and MPA</a>	New

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30/01/2026	<b>Post-authorisation:</b> <a href="#">Iclusig - opinion on variation to marketing authorisation</a> ponatinib	New
30/01/2026	<b>Post-authorisation:</b> <a href="#">Eurneffy - opinion on variation to marketing authorisation</a> epinephrine	New
30/01/2026	<b>Post-authorisation:</b> <a href="#">Zynyz - opinion on variation to marketing authorisation</a> retifanlimab	New
30/01/2026	<b>Post-authorisation:</b> <a href="#">Imfinzi - opinion on variation to marketing authorisation</a> durvalumab	New
30/01/2026	<b>Post-authorisation:</b> <a href="#">Noxafil - opinion on variation to marketing authorisation</a> posaconazole	New
30/01/2026	<b>Post-authorisation:</b> <a href="#">Kerendia - opinion on variation to marketing authorisation</a> finerenone	New
30/01/2026	<b>Post-authorisation:</b> <a href="#">Efmody - opinion on variation to marketing authorisation</a> hydrocortisone	New
30/01/2026	<b>Post-authorisation:</b> <a href="#">Opdivo - opinion on variation to marketing authorisation</a> nivolumab	New
30/01/2026	<b>Post-authorisation:</b> <a href="#">Akeega - opinion on variation to marketing authorisation</a> niraparib; abiraterone acetate	New
30/01/2026	<b>Medicine:</b> <a href="#">Trulicity</a> dulaglutide	Updated
30/01/2026	<b>Document:</b> <a href="#">List of centrally authorised products with safety-related changes to the product information</a>	Updated
30/01/2026	<b>Medicine:</b> <a href="#">Qdenga</a> dengue tetravalent vaccine (live, attenuated)	Updated
30/01/2026	<b>Document:</b> <a href="#">Final programming document 2026-28</a>	New
30/01/2026	<b>Document:</b> <a href="#">List of industry subject matter experts and list of planned calls for industry subject matter experts</a>	Updated
29/01/2026	<b>PIP:</b> <a href="#">EMEA-002109-PIP01-16 - paediatric investigation plan</a> 1,4-dihydro-1-[(2R)-2-(2-methoxyphenyl)-2-[(tetrahydro-2H-pyran-4-yl)oxy]ethyl]- $\alpha,\alpha,5$ -trimethyl-6-(2-oxazolyl)-2,4-dioxo-thieno[2,3-d]pyrimidine-3(2H)-acetic acid (GS-0976)	Updated
29/01/2026	<b>PIP:</b> <a href="#">EMEA-002828-PIP01-20 - paediatric investigation plan</a> firsocostat; cilofexor	Updated
29/01/2026	<b>PIP:</b> <a href="#">EMEA-003393-PIP01-23 - paediatric investigation plan</a> tanimilast	Updated
29/01/2026	<b>PIP:</b> <a href="#">EMEA-002572-PIP01-19 - paediatric investigation plan</a> soticlestat	Updated
29/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00000911/202503 - periodic safety update report single assessment</a> cytarabine	New

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29/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00001797/202506 - periodic safety update report single assessment isradipine</a>	New
29/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00002998/202506 - periodic safety update report single assessment torasemide</a>	New
29/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00001888/202504 - periodic safety update report single assessment linezolid</a>	New
29/01/2026	<b>Herbal:</b> <a href="#">Curcumae longae rhizoma - herbal medicinal product Turmeric</a>	Updated
29/01/2026	<b>Medicine:</b> <a href="#">Spinraza nusinersen</a>	Updated
29/01/2026	<b>Medicine:</b> <a href="#">Zubsolv buprenorphine; naloxone</a>	Updated
29/01/2026	<b>Medicine:</b> <a href="#">Remsima infliximab</a>	Updated
29/01/2026	<b>Medicine:</b> <a href="#">Firazyr icatibant</a>	Updated
29/01/2026	<b>Page:</b> <a href="#">Eligible patients and consumers organisations</a>	Updated
29/01/2026	<b>Medicine:</b> <a href="#">INOmax nitric oxide</a>	Updated
29/01/2026	<b>Medicine:</b> <a href="#">Insulin lispro Sanofi insulin lispro</a>	Updated
29/01/2026	<b>Medicine:</b> <a href="#">Zykadia ceritinib</a>	Updated
29/01/2026	<b>Medicine:</b> <a href="#">Arixtra fondaparinux sodium</a>	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Varenzin molidustat</a>	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Hepilisav B hepatitis B surface antigen</a>	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Biktarvy bictegravir; emtricitabine; tenofovir alafenamide</a>	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Erbitux cetuximab</a>	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Leflunomide Zentiva (previously Leflunomide Winthrop) leflunomide</a>	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Saphnelo anifrolumab</a>	Updated
28/01/2026	<b>Document:</b> <a href="#">Emerging safety issues (ESI) contact points at the national competent authority (NCA) level</a>	Updated
28/01/2026	<b>Document:</b> <a href="#">HMA-EMA Network Data Steering Group: membership list</a>	Updated
28/01/2026	<b>Document:</b> <a href="#">HMA-EMA joint Network Data Steering Group meeting - 8 December 2025</a>	New
28/01/2026	<b>Event:</b> <a href="#">Healthcare Professionals' Working Party (HCPWP) plenary meeting February 2026</a>	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Pomalidomide Teva pomalidomide</a>	Updated

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28/01/2026	<b>Medicine:</b> <a href="#">Hukyndra</a> adalimumab	Updated
28/01/2026	<b>Document:</b> <a href="#">Minutes of the HMPC meeting 17-19 November 2025</a>	New
28/01/2026	<b>Medicine:</b> <a href="#">Koselugo</a> selumetinib	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Alymsys</a> bevacizumab	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Abevmy</a> bevacizumab	Updated
28/01/2026	<b>Document:</b> <a href="#">Questions and answers on Implementing Regulation (EU) 2025/1466: Amendment of Regulation (EU) No 520/2012 and Conclusion of the Signal Detection in EudraVigilance Pilot by marketing authorisation holders</a>	Updated
28/01/2026	<b>Page:</b> <a href="#">Questions and answers on how to use a CEP in the context of a Marketing Authorisation Application or a Marketing Authorisation Variation</a>	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Zirabev</a> bevacizumab	Updated
28/01/2026	<b>Page:</b> <a href="#">ICH Q3E Extractables and leachables - scientific guideline</a>	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Vegzelma</a> bevacizumab	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Oyavas</a> bevacizumab	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Aybintio</a> bevacizumab	Updated
28/01/2026	<b>Document:</b> <a href="#">Report - Highlights of the 15th Industry Standing Group (ISG) meeting</a>	New
28/01/2026	<b>Page:</b> <a href="#">Questions and answers regarding co-processed excipients used in solid oral dosage forms</a>	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Zavesca</a> miglustat	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Movymia</a> teriparatide	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Herzuma</a> trastuzumab	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Dexdor</a> dexmedetomidine	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Genvoya</a> elvitegravir; cobicistat; emtricitabine; tenofovir alafenamide	Updated
28/01/2026	<b>Page:</b> <a href="#">Quality of medicines questions and answers: Part 1</a>	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Vpriv</a> velaglucerase alfa	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Jaypirca</a> pirtobrutinib	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Tadalafil Lilly</a> tadalafil	Updated
28/01/2026	<b>Page:</b> <a href="#">List of medicines under additional monitoring</a>	Updated

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28/01/2026	<b>Document:</b> <a href="#">List of medicinal products under additional monitoring</a>	Updated
28/01/2026	<b>Document:</b> <a href="#">List of medicinal products under additional monitoring</a>	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Cialis</a> tadalafil	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Omvoh</a> mirikizumab	Updated
28/01/2026	<b>Medicine:</b> <a href="#">Forsteo</a> teriparatide	Updated
27/01/2026	<b>Page:</b> <a href="#">Handling competing interests</a>	Updated
27/01/2026	<b>PIP:</b> <a href="#">EMA-001745-PIP01-14 - paediatric investigation plan 4-Amino-2-butoxy-8-[3-(pyrrolidin-1-ylmethyl)benzyl]-7,8-dihydropteridin-6(5H)-one (GS-9620)</a>	Updated
27/01/2026	<b>PIP:</b> <a href="#">EMA-002572-PIP02-19-M05 - paediatric investigation plan soticlestat</a>	Updated
27/01/2026	<b>Medicine:</b> <a href="#">Emgality</a> galcanezumab	Updated
27/01/2026	<b>Medicine:</b> <a href="#">Verzenios</a> abemaciclib	Updated
27/01/2026	<b>Medicine:</b> <a href="#">Opruma</a> raloxifene	Updated
27/01/2026	<b>Medicine:</b> <a href="#">Adcirca (previously Tadalafil Lilly)</a> tadalafil	Updated
27/01/2026	<b>Medicine:</b> <a href="#">Beovu</a> brolucizumab	Updated
27/01/2026	<b>Document:</b> <a href="#">Medicinal products for human use: monthly figures - December 2025</a>	New
27/01/2026	<b>Medicine:</b> <a href="#">Minjuvi</a> tafasitamab	Updated
27/01/2026	<b>Event:</b> <a href="#">Paediatric Committee (PDCO): 27-30 January 2026</a>	Updated
27/01/2026	<b>Document:</b> <a href="#">Agenda - PDCO agenda of the 27-30 January 2026 meeting</a>	New
27/01/2026	<b>Page:</b> <a href="#">Scientific Advisory Group on Vaccines and Therapies for Infectious Diseases (SAG-V&amp;ID)</a>	Updated
27/01/2026	<b>Medicine:</b> <a href="#">Imcivree</a> setmelanotide	Updated
27/01/2026	<b>Medicine:</b> <a href="#">Rybelsus</a> semaglutide	Updated
27/01/2026	<b>Medicine:</b> <a href="#">Ozempic</a> semaglutide	Updated
27/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00011084/202503 - periodic safety update report single assessment dienogest ethinylestradiol (prolonged-release tablet)</a>	New
27/01/2026	<b>Page:</b> <a href="#">Avian influenza (bird flu)</a>	Updated
27/01/2026	<b>Medicine:</b> <a href="#">Cetrotide</a> cetorelix	Updated
27/01/2026	<b>Medicine:</b> <a href="#">Constella</a> linaclotide	Updated

<b>Date</b>	<b>Content</b>	<b>Status</b>
27/01/2026	<b>Medicine:</b> <a href="#">Cimzia</a> certolizumab pegol	Updated
27/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00001469/202505 - periodic safety update report single assessment</a> formoterol	New
27/01/2026	<b>Medicine:</b> <a href="#">Avastin</a> bevacizumab	Updated
27/01/2026	<b>Event:</b> <a href="#">Quarterly System Demo - Q4 2026</a>	New
27/01/2026	<b>Event:</b> <a href="#">Quarterly System Demo - Q1 2026</a>	New
27/01/2026	<b>Event:</b> <a href="#">Quarterly System Demo - Q2 2026</a>	New
27/01/2026	<b>Event:</b> <a href="#">Quarterly System Demo - Q3 2026</a>	New
27/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00010488/202505 - periodic safety update report single assessment</a> isotretinoin (oral formulations)	New
27/01/2026	<b>Page:</b> <a href="#">Clinical investigation of medicinal products in the treatment of peripheral-arterial occlusive disease - Scientific guideline</a>	Updated
27/01/2026	<b>Medicine:</b> <a href="#">Leqvio</a> inclisiran	Updated
27/01/2026	<b>Page:</b> <a href="#">Pharmaceutical quality of inhalation and nasal products - Scientific guideline</a>	Updated
27/01/2026	<b>Medicine:</b> <a href="#">Avzivi</a> bevacizumab	Updated
27/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00002303/202505 - periodic safety update report single assessment</a> hyoscine butylbromide paracetamol	New
27/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00002037/202506 - periodic safety update report single assessment</a> metolazone	New
27/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00001859/202506 - periodic safety update report single assessment</a> sulpiride levosulpiride	New
27/01/2026	<b>Document:</b> <a href="#">Minutes of the CAT meeting 5-7 November 2025</a>	New
27/01/2026	<b>Medicine:</b> <a href="#">Mvasi</a> bevacizumab	Updated
27/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00002131/202503 - periodic safety update report single assessment</a> nefopam	New
27/01/2026	<b>Event:</b> <a href="#">SPOR and XEVMPD status update webinar - Q1 2026</a>	Updated
27/01/2026	<b>Event:</b> <a href="#">Q&amp;A clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API) - January 2026</a>	Updated
27/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00001500/202504 - periodic safety update report single assessment</a> gadobenic acid	New
27/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00003154/202505 - periodic safety update report single assessment</a> zotepine	New

Date	Content	Status
27/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00001509/202504</a> - periodic safety update report single assessment gadoxetic acid disodium	New
27/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00001504/202504</a> - periodic safety update report single assessment gadopentetic acid	New
27/01/2026	<b>Medicine:</b> <a href="#">Briviact</a> (in Italy: Nubriveo) brivaracetam	Updated
27/01/2026	<b>Medicine:</b> <a href="#">Wainzua</a> eplontersen	Updated
27/01/2026	<b>Event:</b> <a href="#">Q&amp;A clinic on Substance, Organisation, Referentials Management Services - January 2026</a>	Updated
26/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00001503/202504</a> - periodic safety update report single assessment gadodiamide	New
26/01/2026	<b>Medicine:</b> <a href="#">Levetiracetam Actavis</a> levetiracetam	Updated
26/01/2026	<b>Page:</b> <a href="#">Environmental management</a>	Updated
26/01/2026	<b>PSUSA:</b> <a href="#">PSUSA/00001502/202504</a> - periodic safety update report single assessment gadobutrol	New
26/01/2026	<b>Medicine:</b> <a href="#">Levetiracetam Teva</a> levetiracetam	Updated
26/01/2026	<b>Medicine:</b> <a href="#">Levetiracetam Actavis Group</a> levetiracetam	Updated
26/01/2026	<b>Medicine:</b> <a href="#">Levetiracetam ratiopharm</a> levetiracetam	Updated
26/01/2026	<b>Document:</b> <a href="#">Environmental Statement 2024</a>	New
26/01/2026	<b>Medicine:</b> <a href="#">Recarbrio</a> imipenem; cilastatin; relebactam	Updated
26/01/2026	<b>Medicine:</b> <a href="#">Avtozma</a> tocilizumab	Updated
26/01/2026	<b>Document:</b> <a href="#">European Medicines Agency's data protection notice for Eudra Vigilance Human (EV)</a>	Updated
26/01/2026	<b>Medicine:</b> <a href="#">Nucala</a> mepolizumab	Updated
26/01/2026	<b>Medicine:</b> <a href="#">Aspaveli</a> pegcetacoplan	Updated
26/01/2026	<b>Medicine:</b> <a href="#">Exelon</a> rivastigmine	Updated
26/01/2026	<b>Event:</b> <a href="#">Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - February 2026</a>	Updated
26/01/2026	<b>Event:</b> <a href="#">Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - January 2026</a>	Updated
26/01/2026	<b>Medicine:</b> <a href="#">Enurev Breezhaler</a> glycopyrronium bromide	Updated
26/01/2026	<b>Medicine:</b> <a href="#">Tovanor Breezhaler</a> glycopyrronium bromide	Updated



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26/01/2026	<b>Medicine:</b> <a href="#">Seebri Breezhaler</a> glycopyrronium bromide	Updated
26/01/2026	<b>Document:</b> <a href="#">Annex to agenda of the CHMP meeting 26-29 January 2026</a>	New
26/01/2026	<b>Document:</b> <a href="#">Agenda of the CHMP meeting 26-29 January 2026</a>	New
26/01/2026	<b>Medicine:</b> <a href="#">Zynyz</a> retifanlimab	Updated
26/01/2026	<b>Medicine:</b> <a href="#">Triumeq</a> abacavir; dolutegravir; lamivudine	Updated
26/01/2026	<b>Medicine:</b> <a href="#">Kisqali</a> ribociclib	Updated
26/01/2026	<b>Medicine:</b> <a href="#">Zegalogue</a> dasiglucagon	Updated
26/01/2026	<b>Medicine:</b> <a href="#">Tevimbra</a> tislelizumab	Updated
26/01/2026	<b>Page:</b> <a href="#">Medical device expert panels</a>	Updated
26/01/2026	<b>Medicine:</b> <a href="#">Dapagliflozin Viatriis</a> dapagliflozin	Updated
26/01/2026	<b>Event:</b> <a href="#">Q&amp;A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPPD) service - January 2026</a>	Updated
26/01/2026	<b>Document:</b> <a href="#">EVVet3 EVWeb Production - Release notes</a>	Updated
26/01/2026	<b>Document:</b> <a href="#">Agenda - Webinar on the use of platform technologies in the non-clinical and clinical domains</a>	Updated
26/01/2026	<b>Medicine:</b> <a href="#">Zypadhera</a> olanzapine	Updated
26/01/2026	<b>Document:</b> <a href="#">European Medicines Agency's data protection notice for the EudraVigilance Signal and Safety Analytics (EV SSA) platform</a>	New
26/01/2026	<b>Page:</b> <a href="#">Questions and answers on the use of Product Lifecycle Management (PLCM) document - Scientific guideline</a>	New

## NOTICE TO APPLICANTS

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

## BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
30.01.2026	<p><b><a href="#">Tavneos (Avacopan): Überprüfung der Wirksamkeit aufgrund von Fragen zur Datenintegrität der Hauptstudie</a></b></p> <p>Wirkstoff: Avacopan</p> <p>Der Ausschuss für Humanarzneimittel (CHMP) der EMA hat eine Überprüfung von Tavneos (Avacopan) eingeleitet, nachdem neue Informationen bekannt geworden sind, die Fragen hinsichtlich der Datenintegrität der Advocate-Studie aufwerfen.</p>

<b>Date</b>	<b>Title</b>
29.01.2026	<b>Erklärung zur Vorlage von Schulungsmaterial (Educational Material) für Parallelvertreiber und Parallelimporteure - Anhang zur Bekanntmachung vom 16.05.2013 über die Modalitäten der elektronischen Erst- und Folgeeinreichung sowie über die Bearbeitung von Schulungs- und Informationsmaterialien</b>
28.01.2026	<b>Ausschreibung eines Pharmakovigilanzforschungsprojektes zur Untersuchung des Risikos für eine primäre Abhängigkeitsentwicklung bei therapeutischer Anwendung von mittelpotenten Opioiden und Gabapentinoiden</b> vom 28.01.2026
28.01.2026	<b>Rote-Hand-Brief zu Digimerck 0,07 mg Tabletten: Geringfügige Überschreitung der Spezifikationsgrenze bei der Summe der Abbauprodukte am Ende der Haltbarkeit</b> Wirkstoff: Digitoxin Die Firma Merck Healthcare Germany GmbH informiert über einen Qualitätsmangel des Arzneimittels Digimerck 0,07 mg Tabletten.
27.01.2026	<b>Informationen zu Einreichung und Genehmigung von Schulungsmaterial</b> Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.

#### **BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)**

<b>Date</b>	<b>Title</b>
27.01.2026	<b>Selbstauskunft zur Umsetzung der Anforderungen zum Schreiben in die elektronische Patientenakte/Authentisierung mittels der GesundheitsID gemäß § 4 Absatz 6, § 5 Absatz 10 sowie § 6a der Digitale Gesundheitsanwendungen-Verordnung (DiGAV)</b> Selbstauskunft zur Umsetzung der Anforderungen zum Schreiben in die elektronische Patientenakte/Authentisierung mittels der GesundheitsID gemäß § 4 Absatz 6, § 5 Absatz 10 sowie § 6a der Digitale Gesundheitsanwendungen-Verordnung (DiGAV), Stand 23.01.2026
27.01.2026	<b>Wissenswertes zu DiGA</b> Weitere Informationen für das Schreiben der DiGA in die ePA/Implementierung der GesundheitsID wurden ergänzt.

#### **PEI - VIGILANZ (SPECIFIC FOR GERMANY)**

<b>Date</b>	<b>Title</b>
27.01.2026	<b>Informationsschreiben von Regeneron GmbH: Ordspono (Odronextamab)</b>

#### **PHARMEUROPA TEXTS FOR COMMENT**

Information on Pharmedeuropa updates will be presented quarterly.

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