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HEADS OF AGENCIES – CMDh

No updates since September 25th, 2025.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
06/10/2025	Medicine: Rixathon rituximab	Updated
06/10/2025	Page: Maximum residue limits (MRL)	Updated
06/10/2025	Document: Scientific advice on MRL classification of chemical-unlike biological substances considered as not requiring an MRL evaluation according to Regulation (EU) 2018/782	New
06/10/2025	Page: Business hours and holidays	Updated
06/10/2025	Medicine: Capvaxive pneumococcal polysaccharide conjugate vaccine (21-valent)	Updated
03/10/2025	Page: PRAC: Working parties and other groups of interest	New
03/10/2025	Page: PRAC Interest Group on Measuring the Impact of Pharmacovigilance Activities (PRAC IG Impact)	New
03/10/2025	Page: Granularity and Periodicity Advisory Group	New
03/10/2025	Document: Timetable: Companion diagnostic follow-up consultation	Updated
03/10/2025	Document: Timetable: Companion diagnostic follow-up consultation - ATMP	Updated
03/10/2025	Document: Timetable: Companion diagnostic initial consultation	Updated

Date	Content	Status
03/10/2025	Page: EU enlargement	Updated
03/10/2025	PSUSA: PSUSA/00001694/202503 - periodic safety update report single assessment hydroxyethyl starch / sodium chloride	New
03/10/2025	PSUSA: PSUSA/00001744/202503 - periodic safety update report single assessment influenza vaccine (surface antigen, inactivated)	New
03/10/2025	Document: SMS guidance for external users	Updated
03/10/2025	Document: Timetable: Companion diagnostic initial consultation - ATMP	Updated
03/10/2025	PSUSA: PSUSA/00010551/202501 - periodic safety update report single assessment mesterolone	New
03/10/2025	Document: Meeting summary - PCWP meeting, HCPWP meeting, joint PCWP/HCPWP meeting - 23-24 September 2025	New
03/10/2025	Document: QRD Appendix V - Adverse-drug-reaction reporting details	Updated
03/10/2025	Page: PRAC Risk Minimisation Alliance (PRISMA) Group	New
03/10/2025	PSUSA: PSUSA/00003133/202501 - periodic safety update report single assessment xipamide, triamterene / xipamide	New
03/10/2025	PSUSA: PSUSA/00001909/202501 - periodic safety update report single assessment lorazepam	New
03/10/2025	News: EMA Management Board: highlights of October 2025 meeting	New
03/10/2025	Post-authorisation: Sileo - withdrawal of application for variation to marketing authorisation dexmedetomidine	New
03/10/2025	PSUSA: PSUSA/00010289/202502 - periodic safety update report single assessment lisdexamfetamine	New
03/10/2025	PSUSA: PSUSA/00002982/202501 - periodic safety update report single assessment tofisopam	New
03/10/2025	PSUSA: PSUSA/00000901/202501 - periodic safety update report single assessment cyclophosphamide	New

Date	Content	Status
03/10/2025	Page: Data in regulation: Big data and other sources	Updated
03/10/2025	Document: European Medicines Agencies Network Data Strategy - Increasing the value of data for the benefit of public and animal health	New
03/10/2025	Medicine: Ogsiveo nirogacestat	Updated
03/10/2025	News: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 29 September - 2 October 2025	New
03/10/2025	Herbal: Calendulae flos - herbal medicinal product Calendula Flower	Updated
02/10/2025	PSUSA: PSUSA/00001760/202501 - periodic safety update report single assessment interferon gamma	New
02/10/2025	PSUSA: PSUSA/00001028/202411 - periodic safety update report single assessment diamorphine	New
02/10/2025	Event: Refresher training webinar on post-authorisation procedure management in IRIS for marketing authorisation holders	Updated
02/10/2025	Medicine: Tremfya guselkumab	Updated
02/10/2025	Medicine: Elahere mirvetuximab soravtansine	Updated
02/10/2025	Medicine: Tyenne tocilizumab	Updated
02/10/2025	Page: VICH GL62 on target animal safety of veterinary monoclonal antibody products (VMAPs) St4	New
02/10/2025	Medicine: Zynlonta loncastuximab tesirine	Updated
02/10/2025	Medicine: Vivlipeg pegfilgrastim	New
02/10/2025	Medicine: Takhzyro lanadelumab	Updated
02/10/2025	Document: Agenda - Management Board meeting: 2 October 2025	Updated
02/10/2025	Medicine: Talvey	Updated

Date	Content	Status
	talquetamab	
02/10/2025	Page: Annual fees payable to the European Medicines Agency	Updated
02/10/2025	Page: Fees payable to the European Medicines Agency	Updated
02/10/2025	Page: Fees payable to the European Medicines Agency: Guidance for all applicants	Updated
02/10/2025	Page: Fees for human medicines	Updated
02/10/2025	Page: Fees for veterinary medicines	Updated
02/10/2025	Page: Other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices	Updated
02/10/2025	Medicine: Oxlumo lumasiran	Updated
02/10/2025	Medicine: Brukinsa zanubrutinib	Updated
02/10/2025	Page: Website outages and upgrades	Updated
02/10/2025	Document: HMPC: overview of assessment work - priority list	Updated
02/10/2025	Document: Minutes - Enpr-EMA Coordinating Group & networks meeting - June 2025	New
02/10/2025	News: Advice on end-of-year submission dates for type I variations in 2025	Updated
02/10/2025	Medicine: Leqembi lecanemab	Updated
02/10/2025	Medicine: Xtandi enzalutamide	Updated
02/10/2025	Document: Products Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 1: Registration requirements	Updated
01/10/2025	Page: Accessibility	Updated
01/10/2025	Document: Organisation chart: Advisory functions	Updated
01/10/2025	Medicine: Adcetris brentuximab vedotin	Updated
01/10/2025	Medicine: Nidlegly bifikafusp alfa; onfekafusp alfa	Updated
01/10/2025	Page: Paediatric clinical trials	Updated

Date	Content	Status
01/10/2025	Page: Submitting results of paediatric studies	Updated
01/10/2025	Medicine: Farydak panobinostat	Updated
01/10/2025	Document: Information on the Member States requirement for the nomination of a pharmacovigilance (PhV) contact person at national level	Updated
01/10/2025	Page: In-use stability testing of veterinary medicinal products - Scientific guideline	Updated
01/10/2025	Document: Guideline on in-use stability testing of veterinary medicinal products	New
30/09/2025	Document: Veterinary pre-submission meeting request form - in accordance with Regulation (EU) No 2019/6	Updated
30/09/2025	Medicine: Bosulif bosutinib	Updated
30/09/2025	Page: Quality of medicines questions and answers: Part 1	Updated
30/09/2025	Event: EMA multi-stakeholder workshop on the clinical evaluation of therapeutic radiopharmaceuticals in oncology	Updated
30/09/2025	Medicine: Evrenzo roxadustat	Updated
30/09/2025	Document: Minutes of the CAT meeting 12-14 August 2025 - written procedure	New
30/09/2025	Medicine: Micardis telmisartan	Updated
30/09/2025	Medicine: Deferasirox Accord deferasirox	Updated
30/09/2025	Document: Minutes of the CAT meeting 16-18 July 2025	New
30/09/2025	Document: List of centrally authorised products with safety-related changes to the product information	Updated
30/09/2025	Medicine: Lynparza olaparib	Updated
30/09/2025	Document: Members of the Coordinating group of European network of paediatric research at the European Medicines Agency (Enpr-EMA)	Updated
30/09/2025	Medicine: Sitagliptin / Metformin hydrochloride Mylan sitagliptin hydrochloride monohydrate; metformin hydrochloride	Updated
30/09/2025	Medicine: Orkambi	Updated

Date	Content	Status
	lumacaftor; ivacaftor	
30/09/2025	Medicine: Maapliv amino acids	Updated
30/09/2025	Medicine: Siklos hydroxycarbamide	Updated
30/09/2025	PSUSA: PSUSA/00010432/202410 - periodic safety update report single assessment timolol (systemic use)	New
30/09/2025	Medicine: Riltrava Aerosphere formoterol fumarate dihydrate; glycopyrronium; budesonide	Updated
30/09/2025	Medicine: Jevtana cabazitaxel	Updated
30/09/2025	Medicine: Hirobriz Breezhaler indacaterol	Updated
30/09/2025	Medicine: Sorafenib Accord sorafenib	Updated
30/09/2025	Medicine: Wegovy semaglutide	Updated
30/09/2025	Medicine: Rybelsus semaglutide	Updated
30/09/2025	Medicine: Orgovyx relugolix	Updated
30/09/2025	Medicine: Oslif Breezhaler indacaterol	Updated
30/09/2025	Medicine: Ozempic semaglutide	Updated
30/09/2025	Medicine: Onbrez Breezhaler indacaterol	Updated
30/09/2025	Page: Clinical evaluation of medicinal products intended for treatment of hepatitis B - Scientific guideline	Updated
30/09/2025	Document: Draft guideline on the clinical evaluation of medicinal products intended for the treatment of chronic hepatitis B (CHB) - Revision 1	New

Date	Content	Status
30/09/2025	Page: Clinical investigation of medicinal products for the treatment of psoriatic arthritis - Scientific guideline	Updated
30/09/2025	Document: Draft guideline on clinical investigation of medicinal products for the treatment of psoriatic arthritis - Revision 1	New
30/09/2025	Event: Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting September 2025	Updated
30/09/2025	Post-authorisation: Remsima - opinion on variation to marketing authorisation infliximab	New
30/09/2025	Document: Concept paper on new guidance on the clinical investigation of medicinal products for the treatment of idiopathic pulmonary fibrosis (IPF)	New
30/09/2025	Page: Clinical investigation of medicinal products for the treatment of idiopathic pulmonary fibrosis (IPF) - Scientific guideline	New
30/09/2025	Medicine: Usrenty ustekinumab	Updated
29/09/2025	Medicine: Hexyon diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed)	Updated
29/09/2025	Medicine: Evrysdi risdiplam	Updated
29/09/2025	Medicine: Retacrit epoetin zeta	Updated
29/09/2025	Event: Clinical Trials Information System (CTIS): Walk-in clinic September 2025	Updated
29/09/2025	Medicine: Hexacima diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus influenzae type b conjugate vaccine (adsorbed)	Updated
29/09/2025	Shortage: Human normal immunoglobulins human normal immunoglobulins	Updated
29/09/2025	Medicine: Deferasirox Mylan deferasirox	Updated
29/09/2025	Medicine: Zefyalti	Updated

Date	Content	Status
	filgrastim	
29/09/2025	Medicine: Truxima rituximab	Updated
29/09/2025	Page: Patients' and Consumers' Working Party	Updated
29/09/2025	Document: Agenda of the PRAC meeting 29 September - 2 October 2025	New
29/09/2025	Medicine: Yesafili aflibercept	Updated
29/09/2025	Document: Minutes of the HMPC meeting 7-9 July 2025	New
29/09/2025	Medicine: Zurzuvae zuranolone	Updated
29/09/2025	Page: Artificial intelligence	Updated
29/09/2025	Medicine: Empliciti elotuzumab	Updated
29/09/2025	Medicine: Spikevax (previously COVID-19 Vaccine Moderna) COVID-19 mRNA vaccine	Updated
29/09/2025	Medicine: ellaOne ulipristal acetate	Updated
29/09/2025	Document: HMA-EMA joint Network Data Steering Group meeting - 17 July 2025	New
29/09/2025	Medicine: Bortezomib Accord bortezomib	Updated
29/09/2025	Document: List of signals discussed at PRAC since September 2012	Updated
29/09/2025	Page: PRAC recommendations on safety signals	Updated
29/09/2025	Document: PRAC recommendations on signals adopted at the 1-4 September 2025 PRAC meeting	New
29/09/2025	Document: New product information wording: extracts from PRAC recommendations on signals adopted at the 1-4 September 2025 PRAC	New
29/09/2025	Medicine: Blitzima rituximab	Updated
29/09/2025	Page: Eligible patients and consumers organisations	Updated
29/09/2025	Event: ACT EU multi-stakeholder platform annual meeting	New

Date	Content	Status
29/09/2025	News: A path to better include patients' perspectives in the regulation of medicines	New
29/09/2025	Medicine: Eliquis apixaban	Updated
29/09/2025	Medicine: Yuflyma adalimumab	Updated
29/09/2025	Medicine: Xalkori crizotinib	Updated

NOTICE TO APPLICANTS

No updates since September 03rd, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
06.10.2025	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since September 24th, 2025.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since September 26th, 2025.

PHARMEUROPA TEXTS FOR COMMENT

	Group	Issue	Deadline
2.4.24. Identification and control of residual solvents Reference number: PA/PH/Exp. MG/T (25) 2 ANP Text number: 20424 Direct link	MG	37.4	2025-12-31
2.8.23. Microscopic examination of herbal drugs Reference number: PA/PH/Exp. 13A/T (24) 82 ANP Text number: 20823	13A	37.4	2025-12-31

Direct link			
<p>2.8.28. Determination of thujone Reference number: PA/PH/Exp. 13A/T (25) 57 ANP Text number: 20828 Direct link</p>	13A	37.4	2025-12-31
<p>3.2.9. Rubber closures for containers for aqueous parenteral preparations, for powders and for freeze-dried powders Reference number: PA/PH/Exp. 16/T (24) 18 ANP Text number: 30209 Direct link</p>	16	37.4	2025-12-31
<p>Aloes dry extract, standardised Reference number: PA/PH/Exp. 13B/T (24) 69 ANP Text number: 0259 Direct link</p>	13B	37.4	2025-12-31
<p>Aloes, Cape Reference number: PA/PH/Exp. 13B/T (24) 68 ANP Text number: 0258 Direct link</p>	13B	37.4	2025-12-31
<p>Ascorbyl palmitate Reference number: PA/PH/Exp. VIT/T (21) 24 ANP Text number: 0807 Direct link</p>	VIT	37.4	2025-12-31
<p>Azelaic acid Reference number: PA/PH/Exp. 11/T (24) 19 ANP Text number: 3244 Direct link</p>	11	37.4	2025-12-31
<p>Cannabis flower Reference number: PA/PH/Exp. 13B/T (25) 40 ANP Text number: 3028 Direct link</p>	13B	37.4	2025-12-31
<p>Cetylpyridinium chloride monohydrate Reference number: PA/PH/Exp. 10B/T (25) 45 ANP Text number: 0379 Direct link</p>	10B	37.4	2025-12-31

<p>Chloroquine phosphate Reference number: PA/PH/Exp. SIT/T (25) 41 ANP Text number: 0544 Direct link</p>	11	37.4	2025-12-31
<p>Chloroquine sulfate monohydrate Reference number: PA/PH/Exp. SIT/T (25) 40 ANP Text number: 0545 Direct link</p>	11	37.4	2025-12-31
<p>Cineole Reference number: PA/PH/Exp. 11/T (24) 100 ANP Text number: 1973 Direct link</p>	11	37.4	2025-12-31
<p>Clarithromycin Reference number: PA/PH/Exp. 7/T (25) 23 ANP Text number: 1651 Direct link</p>	7	37.4	2025-12-31
<p>Clindamycin phosphate Reference number: PA/PH/Exp. 7/T (25) 25 ANP Text number: 0996 Direct link</p>	7	37.4	2025-12-31
<p>Cochinchinese asparagus root Reference number: PA/PH/Exp. TCM/T (25) 74 ANP Text number: 3221 Direct link</p>	TCM	37.4	2025-12-31
<p>Croscarmellose sodium Reference number: PA/PH/Exp. CEL/T (21) 28 ANP R1 Text number: 0985 Direct link</p>	CEL	37.4	2025-12-31
<p>Econazole Reference number: PA/PH/Exp. SIT/T (25) 43 ANP Text number: 2049 Direct link</p>	10B	37.4	2025-12-31
<p>Ibandronate sodium monohydrate Reference number: PA/PH/Exp. 11/T (25) 53 ANP Text number: 2771 Direct link</p>	11	37.4	2025-12-31

<p>Iomeprol Reference number: PA/PH/Exp. 10B/T (25) 46 ANP Text number: 2925 Direct link</p>	10B	37.4	2025-12-31
<p>Levocetirizine dihydrochloride Reference number: PA/PH/Exp. 10C/T (25) 31 ANP Text number: 3115 Direct link</p>	10C	37.4	2025-12-31
<p>Liquid preparations for oral use Reference number: PA/PH/Exp. 12/T (25) 22 ANP Text number: 0672 Direct link</p>	12	37.4	2025-12-31
<p>Maltitol, liquid Reference number: PA/PH/Exp. CRB/T (25) 6 ANP Text number: 1236 Direct link</p>	CRB	37.4	2025-12-31
<p>Mitoxantrone hydrochloride Reference number: PA/PH/Exp. 11/T (24) 99 ANP R1 Text number: 1243 Direct link</p>	11	37.4	2025-12-31
<p>Mupirocin Reference number: PA/PH/Exp. 7/T (13) 15 ANP Text number: 1450 Direct link</p>	7	37.4	2025-12-31
<p>Mupirocin calcium dihydrate Reference number: PA/PH/Exp. 7/T (13) 16 ANP Text number: 1451 Direct link</p>	7	37.4	2025-12-31
<p>Naproxen Reference number: PA/PH/Exp. SIT/T (25) 34 ANP Text number: 0731 Direct link</p>	10A	37.4	2025-12-31
<p>Naproxen sodium Reference number: PA/PH/Exp. SIT/T (25) 35 ANP Text number: 1702 Direct link</p>	10A	37.4	2025-12-31

<p>Nikethamide Reference number: PA/PH/Exp. 10A/T (18) 187 ANP Text number: 0233 Direct link</p>	10A	37.4	2025-12-31
<p>Noscapine Reference number: PA/PH/Exp. 11/T (25) 4 ANP Text number: 0516 Direct link</p>	11	37.4	2025-12-31
<p>Olaparib Reference number: PA/PH/Exp. P4/T (24) 1 ANP Text number: 3238 Direct link</p>	P4	37.4	2025-12-31
<p>Olaparib tablets Reference number: PA/PH/Exp. P4/T (24) 4 ANP Text number: 3239 Direct link</p>	P4	37.4	2025-12-31
<p>Parenteral preparations Reference number: PA/PH/Exp. 12/T (25) 23 ANP Text number: 0520 Direct link</p>	12	37.4	2025-12-31
<p>Procainamide hydrochloride Reference number: PA/PH/Exp. SIT/T (25) 42 ANP Text number: 0567 Direct link</p>	11	37.4	2025-12-31
<p>Sorbitol, liquid (crystallising) Reference number: PA/PH/Exp. CRB/T (24) 34 ANP Text number: 0436 Direct link</p>	CRB	37.4	2025-12-31
<p>Sorbitol, liquid (non-crystallising) Reference number: PA/PH/Exp. CRB/T (25) 8 ANP Text number: 0437 Direct link</p>	CRB	37.4	2025-12-31
<p>Sorbitol, liquid, partially dehydrated Reference number: PA/PH/Exp. CRB/T (25) 7 ANP Text number: 2048 Direct link</p>	CRB	37.4	2025-12-31

Tioguanine Reference number: PA/PH/Exp. 11/T (25) 67 ANP Text number: 3260 Direct link	11	37.4	2025-12-31
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