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HEADS OF AGENCIES – CMDh

29 September

- [UPDATE - 'Blue-box' requirements](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
02/10/2026	PSUSA: PSUSA/00002550/202601 - periodic safety update report single assessment propafenone	New
02/10/2026	Medicine: Orgovyx relugolix	Updated
02/10/2026	Medicine: Ziextenzo pegfilgrastim	Updated
02/10/2026	Event: Regulatory sandboxes: Joint European Commission (EC) / European Medicines Agency (EMA) multi-stakeholder workshop	Updated
02/10/2026	Medicine: Arsenic trioxide Accord arsenic trioxide	Updated
02/10/2026	PIP: EMA/PE/0000302950 - paediatric investigation plan humanised IgG4 bispecific antibody against programmed cell death protein 1 and vascular endothelial growth factor A, long form	New
02/10/2026	PIP: EMA/PE/0000291645 - paediatric investigation plan mRNA encoding Human cytomegalovirus UL128; mRNA encoding Human cytomegalovirus UL130; mRNA encoding Human cytomegalovirus UL131A; mRNA encoding Human cytomegalovirus glycoprotein H; mRNA encoding Human cytomegalovirus glycoprotein B; mRNA encoding Human cytomegalovirus glycoprotein L	Updated
02/10/2026	Medicine: Rasilez aliskiren	Updated
02/10/2026	PIP: EMA/PE/0000261512 - paediatric investigation plan Dexamethasone sodium phosphate encapsulated in human autologous erythrocytes	Updated

02/10/2026	Medicine: Ordspono odronextamab	Updated
02/10/2026	Medicine: Sialanar glycopyrronium bromide	Updated
02/10/2026	Medicine: Andembry garadacimab	Updated
02/10/2026	Medicine: Fymkina ustekinumab	Updated
02/10/2026	Medicine: Sprycel dasatinib (anhydrous)	Updated
02/10/2026	Page: Procedural timetables	Updated
02/10/2026	Event: Committee for Herbal Medicinal Products (HMPC): 6-8 July 2026	Updated
02/10/2026	Document: Minutes of the HMPC meeting 6-8 July 2026	New
02/10/2026	Document: List of centrally authorised products with safety-related changes to the product information	Updated
02/10/2026	News: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 28 September - 1 October	New
02/10/2026	Medicine: Itvisma onasemnogene abeparvovec	Updated
02/10/2026	Medicine: Bysumlog insulin lispro	Updated
02/10/2026	EU-M4all: Ivermectin/Albendazole - opinion on medicine for use outside EU ivermectin; albendazole	Updated
02/10/2026	Event: Good manufacturing practice: Multistakeholder workshop on expert contributions to artificial intelligence guidance development (Annex 22)	Updated
02/10/2026	Medicine: Riltrava Aerosphere formoterol fumarate dihydrate; glycopyrronium; budesonide	Updated
02/10/2026	Medicine: Leqvio inclisiran	Updated
02/10/2026	Medicine: Ebvallo tabelecleucel	Updated
02/10/2026	Page: External whistleblowing policy	Updated
02/10/2026	Medicine: Byetta exenatide	Updated
02/10/2026	Document: Policy 0072: Policy on the handling of information from external persons on breaches related to the authorisation, supervision and maintenance of human and veterinary medicinal products or other EMA activities	Updated
02/10/2026	Medicine: Bydureon exenatide	Updated
02/10/2026	Medicine: Adzynma rADAMTS13	Updated
01/10/2026	Medicine: Constella linaclotide	Updated
01/10/2026	Medicine: Sibnaya potassium citrate; potassium hydrogen carbonate	Updated
01/10/2026	Event: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	Updated
01/10/2026	Document: Meeting summary - Medicine shortages SPOC working party meeting 15 July 2026	New
01/10/2026	Medicine: Degevma denosumab	Updated

01/10/2026	Event: European Medicines Agency workshop on bacteriophage therapy	New
01/10/2026	Event: Seventeenth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines	New
01/10/2026	News: Advice on ‘end-of-year’ submission dates for type I variations in 2026	New
01/10/2026	News: EMA Management Board: highlights of September 2026 meeting	New
01/10/2026	Document: Proceedings for the nomination and appointment of the next EMA Executive Director	New
01/10/2026	Medicine: Epruvy (previously Ranibizumab Midas) ranibizumab	Updated
01/10/2026	Medicine: Byooviz ranibizumab	Updated
01/10/2026	Page: International Coalition of Medicines Regulatory Authorities (ICMRA)	Updated
01/10/2026	News: Global regulators call for advancing alternatives to animal testing across the medicine lifecycle	New
01/10/2026	Page: EudraVigilance: electronic reporting	Updated
01/10/2026	News: Executive Director speech at EMA women’s health multi-stakeholder workshop	New
01/10/2026	Medicine: Pomalidomide Teva pomalidomide	Updated
01/10/2026	Medicine: Lucentis ranibizumab	Updated
30/09/2026	Document: Minutes of PRAC meeting on 6-9 July 2026	New
30/09/2026	Medicine: Denbrayce denosumab	Updated
30/09/2026	Medicine: Comirnaty COVID-19 mRNA vaccine	Updated
30/09/2026	Medicine: Spikevax (previously COVID-19 Vaccine Moderna) COVID-19 mRNA vaccine	Updated
30/09/2026	News: Women are missing from medicines development: EMA’s roadmap for change	New
30/09/2026	Page: List of medicines under additional monitoring	Updated
30/09/2026	Document: List of medicinal products under additional monitoring	Updated
30/09/2026	Document: List of medicinal products under additional monitoring	Updated
30/09/2026	Medicine: Datroway datopotamab deruxtecan	Updated
30/09/2026	Medicine: Ximluci ranibizumab	Updated
30/09/2026	Document: European Shortages Monitoring Platform (ESMP): Implementation guide for national competent authorities	Updated
30/09/2026	Document: European Shortages Monitoring Platform (ESMP) User guide for national competent authorities	Updated
30/09/2026	Medicine: Xalkori crizotinib	Updated
29/09/2026	Page: Certification procedures for advanced therapies under development by micro-, small- and medium-sized enterprises (SMEs)	Updated
29/09/2026	Document: Agenda - Management Board meeting: 30 September 2026	New
29/09/2026	Medicine: Tafamidis Accord tafamidis	Updated
29/09/2026	Page: Medicine shortages and availability issues	Updated
29/09/2026	Page: Outcomes of imposed non-interventional post-authorisation safety studies	Updated
29/09/2026	Page: Website outages and upgrades	Updated

29/09/2026	Medicine: Gilenya fingolimod	Updated
29/09/2026	Medicine: Xbryk denosumab	Updated
29/09/2026	Document: List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment	Updated
28/09/2026	Medicine: Pemetrexed Baxter pemetrexed	Updated
28/09/2026	Document: Agenda of the PRAC meeting 28 September - 1 October 2026	New
28/09/2026	Page: Reform of the EU pharmaceutical legislation	Updated
28/09/2026	Page: PRAC recommendations on safety signals	Updated
28/09/2026	Document: List of signals discussed at PRAC since September 2012	Updated

NOTICE TO APPLICANTS

No updates since July 10th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
02.10.2026	Pharmacovigilance Risk Assessment Committee (PRAC) Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 28.09.-01.10.2026 behandelt wurden.
02.10.2026	Aktuelle Hinweise zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
01.10.2026	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 22.07.2026 betreffend die Zulassungen für Humanarzneimittel mit der Wirkstoffkombination Phenylephrin/Tropicamid Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffkombination Phenylephrin/Tropicamid 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 September 25th, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since September 17th, 2026.

PHARMEUROPA TEXTS FOR COMMENT

	Group	Issue	Deadline
2.5.32. Water: micro determination Reference number: PA/PH/Exp. MG/T (26) 7 ANP Text number: 20532	MG	38.4	2026-12-31

[Direct link](#)

2.6.16. Tests for extraneous agents in viral vaccines for human use

15 38.4 2026-12-31

Reference number: PA/PH/Exp. 15/T (25) 3 ANP

Text number: 20616

[Direct link](#)

2.8.18. Determination of aflatoxin B1 in herbal drugs

13B 38.4 2026-12-31

Reference number: PA/PH/Exp. 13B/T (26) 39 ANP

Text number: 20818

[Direct link](#)

2.9.58. Adhesive properties of patches and medicated plasters

12 38.4 2026-12-31

Reference number: PA/PH/Exp. 12/T (26) 12 ANP

Text number: 20958

[Direct link](#)

2.9.9. Measurement of consistency by penetrometry

12 38.4 2026-12-31

Reference number: PA/PH/Exp. 12/T (24) 6 ANP

Text number: 20909

[Direct link](#)

3.1.19. (Ethylene-methacrylic acid) - zinc copolymer

16 38.4 2026-12-31

Reference number: PA/PH/Exp. 16/T (26) 18 ANP

Text number: 30119

[Direct link](#)

5.2.3. Cell substrates for the production of vaccines for human use

15 38.4 2026-12-31

Reference number: PA/PH/Exp. 15/T (25) 4 ANP

Text number: 50203

[Direct link](#)

Anthrax spore vaccine (live) for veterinary use

15V 38.4 2026-12-31

Reference number: PA/PH/Exp. 15V/T (25) 10 ANP

Text number: 0441

[Direct link](#)

Ceritinib

Reference number: PA/PH/Exp. P4/T (22) 23 ANP

P4 38.4 2026-12-31

Text number: 3181

[Direct link](#)

Cloprostenol sodium for veterinary use

10B 38.4 2026-12-31

Reference number: PA/PH/Exp. 10B/T (26) 41 ANP

Text number: 1715

[Direct link](#)

Dabrafenib mesilate

Reference number: PA/PH/Exp. P4/T (21) 16 ANP

P4 38.4 2026-12-31

Text number: 3184

[Direct link](#)

Estradiol hemihydrate

Reference number: PA/PH/Exp. 10B/T (26) 75 ANP

10B 38.4 2026-12-31

Text number: 0821

[Direct link](#)

Immunosera for human use, animal

Reference number: PA/PH/Exp. 15/T (26) 12 ANP 15 38.4 2026-12-31

Text number: 0084

[Direct link](#)

Iron sucrose complex

Reference number: PA/PH/Exp. NBC/T (14) 11 ANP R1 NANO 38.4 2026-12-31

Text number: 2753

[Direct link](#)

Manganese glycerophosphate hydrate

Reference number: PA/PH/Exp. 9/T (26) 21 ANP 9 38.4 2026-12-31

Text number: 2163

[Direct link](#)

Microcrystalline wax

Reference number: PA/PH/Exp. 13H/T (26) 26 ANP 13H 38.4 2026-12-31

Text number: 2399

[Direct link](#)

Mitoxantrone hydrochloride

Reference number: PA/PH/Exp. 11/T (24) 99 ANP R3 11 38.4 2026-12-31

Text number: 1243

[Direct link](#)

Paraffin, hard

Reference number: PA/PH/Exp. 13H/T (26) 27 ANP 13H 38.4 2026-12-31

Text number: 1034

[Direct link](#)

Patches

Reference number: PA/PH/Exp. 12/T (24) 37 ANP 12 38.4 2026-12-31

Text number: 1011

[Direct link](#)

Pharmaceutical preparations

Reference number: PA/PH/Exp. 12/T (26) 28 ANP PHP 38.4 2026-12-31

Text number: 2619

[Direct link](#)

Plasters, medicated

Reference number: PA/PH/Exp. 12/T (26) 34 ANP 12 38.4 2026-12-31

Text number: 3032

[Direct link](#)

Premixes for medicated feeding stuffs for veterinary use

Reference number: PA/PH/Exp. 12/T (25) 16 ANP 12 38.4 2026-12-31

Text number: 1037

[Direct link](#)

Propyl gallate

Reference number: PA/PH/Exp. 10A/T (26) 49 ANP 10A 38.4 2026-12-31

Text number: 1039

[Direct link](#)

Sodium glycerophosphatehydrate

Reference number: PA/PH/Exp. 9/T (26) 20 ANP

9 38.4 2026-12-31

Text number: 1995

[Direct link](#)

Sulfamerazine

Reference number: PA/PH/Exp. SIT/T (26) 21 ANP

7 38.4 2026-12-31

Text number: 0358

[Direct link](#)

Suppression of Chloroquine sulfate

Reference number: PA/PH/Exp. 11/T (26) 54 ANP

11 38.4 2026-12-31

Text number: 0545

[Direct link](#)

Suppression of Digitalis leaf

Reference number: PA/PH/Exp. 13B/T (26) 42 ANP

13B 38.4 2026-12-31

Text number: 0117

[Direct link](#)

Suppression of Hyoscyamine sulfate

Reference number: PA/PH/Exp. 11/T (26) 53 ANP

11 38.4 2026-12-31

Text number: 0501

[Direct link](#)

Suppression of Stramonium leaf

Reference number: PA/PH/Exp. 13B/T (26) 40 ANP

13B 38.4 2026-12-31

Text number: 0246

[Direct link](#)

Suppression of Stramonium, prepared

Reference number: PA/PH/Exp. 13B/T (26) 41 ANP

13B 38.4 2026-12-31

Text number: 0247

[Direct link](#)

Triptorelin

Reference number: PA/PH/Exp. 6/T (19) 22 ANP

6 38.4 2026-12-31

Text number: 3055

[Direct link](#)

Vaccines for human use

Reference number: PA/PH/Exp. 15/T (25) 6 ANP

15 38.4 2026-12-31

Text number: 0153

[Direct link](#)

Winter ulcer vaccine (inactivated, oil-adjuvanted, injectable) for salmonids

Reference number: PA/PH/Exp. 15V/T (26) 14 ANP

15V 38.4 2026-12-31

Text number: 2151

[Direct link](#)

Wool fat

Reference number: PA/PH/Exp. 13H/T (25) 98 ANP

13H 38.4 2026-12-31

Text number: 0134

[Direct link](#)

Wool fat, hydrous

Reference number: PA/PH/Exp. 13H/T (26) 66 ANP

13H

38.4

2026-12-31

Text number: 0135

[Direct link](#)

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