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HEADS OF AGENCIES – CMDh

16 July

[UPDATE - List of documents published on CMDh website](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
18/07/2025	Medicine: Apremilast Accord	Updated
18/07/2025	Medicine: Talzena	Updated
18/07/2025	Medicine: Ztalmy	Updated
18/07/2025	Event: EMA roundtable with stakeholders on the 20th anniversary of the SME Regulation	Updated
18/07/2025	Medicine: Lazcluze	Updated
18/07/2025	Medicine: Afqlir	Updated
18/07/2025	Document: PMS data matrix - Cross-platforms	New
18/07/2025	Document: European Medicines Agency Write PMS API implementation Guide (zip)	Updated
18/07/2025	Medicine: Osenvelt	Updated
18/07/2025	Document: European Medicines Agency Write PMS API implementation Guide	Updated
18/07/2025	Document: Applications for new human medicines under evaluation: July 2025	New
18/07/2025	Medicine: Yesafili	Updated
18/07/2025	Medicine: Fampridine Accord	Updated
18/07/2025	Medicine: Duvyzat	Updated
18/07/2025	Medicine: Aldara	Updated
18/07/2025	Medicine: Lynparza	Updated
18/07/2025	Page: Regulatory science research needs	Updated
18/07/2025	Document: Regulatory Science - Research needs - 2025 update	New
18/07/2025	Referral: Quarter-based selective dry cow therapy - referral	New
18/07/2025	Medicine: Tolura	Updated

Date	Content	Status
18/07/2025	Medicine: Soliris	Updated
18/07/2025	Event: Workshop on the use of Bayesian statistics in clinical development	Updated
18/07/2025	Medicine: Cevac Reomune	New
18/07/2025	Medicine: Hemosyvet	New
18/07/2025	Post-authorisation: Syvazul BTV 3 - opinion on variation to marketing authorisation	New
18/07/2025	Post-authorisation: Nobivac L4 - opinion on variation to marketing authorisation	Updated
18/07/2025	Post-authorisation: Nobivac LoVo L4 - opinion on variation to marketing authorisation	Updated
18/07/2025	News: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 15-17 July 2025	New
18/07/2025	Medicine: Rybrevant	Updated
18/07/2025	Document: Dates of 2026 Scientific Advice Working Party (SAWP) meetings and submission deadlines for scientific advice, protocol assistance, qualification of novel methodologies and HTACG/EMA parallel Joint Scientific Consultation (JSC) requests	Updated
17/07/2025	Medicine: Nordimet	Updated
17/07/2025	Document: Timetable: Annual renewal application of conditional marketing authorisation	Updated
17/07/2025	Page: Plasma master file certificates	Updated
17/07/2025	Document: Timetable: Annual reassessment - ATMP	Updated
17/07/2025	Document: Timetable: Annual renewal application of conditional marketing authorisation - ATMP	Updated
17/07/2025	Document: Timetable: Marketing authorisation renewal application - ATMP	Updated
17/07/2025	PSUSA: PSUSA/00001804/202412 - periodic safety update report single assessment	New
17/07/2025	Medicine: Kaftrio	Updated
17/07/2025	Medicine: Nimvastid	Updated
17/07/2025	Orphan: EU/3/20/2314 - orphan designation for treatment of primary sclerosing cholangitis	Updated
17/07/2025	Orphan: EU/3/24/2994 - orphan designation for treatment of primary IgA nephropathy	Updated
17/07/2025	Orphan: EU/3/14/1246 - orphan designation for diagnosis of gastro-entero-pancreatic neuroendocrine tumours	Updated
17/07/2025	Orphan: EU/3/18/2026 - orphan designation for treatment of transthyretin-mediated amyloidosis (ATTR amyloidosis)	Updated
17/07/2025	Orphan: EU/3/21/2414 - orphan designation for treatment of mucopolysaccharidosis type I	Updated
17/07/2025	Orphan: EU/3/18/1989 - orphan designation for treatment of C3 glomerulopathy	Updated
17/07/2025	Orphan: EU/3/22/2728 - orphan designation for treatment of amyotrophic lateral sclerosis	Updated
17/07/2025	Orphan: EU/3/22/2605 - orphan designation for treatment of acute lymphoblastic leukaemia	Updated
17/07/2025	Orphan: EU/3/22/2640 - orphan designation for treatment of ATTR amyloidosis	Updated
17/07/2025	Orphan: EU/3/25/3066 - orphan designation for treatment of systemic sclerosis	New

Date	Content	Status
17/07/2025	Orphan: EU/3/17/1925 - orphan designation for treatment of multiple myeloma	Updated
17/07/2025	Orphan: EU/3/25/3074 - orphan designation for treatment of fragile X syndrome	New
17/07/2025	Orphan: EU/3/25/3080 - orphan designation for treatment of amyotrophic lateral sclerosis	New
17/07/2025	Orphan: EU/3/25/3067 - orphan designation for treatment of hepatocellular carcinoma	New
17/07/2025	Medicine: Nemludio	Updated
17/07/2025	Medicine: Gardasil 9	Updated
17/07/2025	Medicine: Padcev	Updated
17/07/2025	Medicine: Ivabradine Zentiva	Updated
17/07/2025	Medicine: Coagadex	Updated
17/07/2025	Medicine: Byooviz	Updated
17/07/2025	Medicine: Shingrix	Updated
17/07/2025	Medicine: Fymiskina	Updated
17/07/2025	PSUSA: PSUSA/00002139/202411 - periodic safety update report single assessment	New
17/07/2025	Page: Type-II variations: questions and answers	Updated
17/07/2025	Medicine: Mepact	Updated
17/07/2025	PSUSA: PSUSA/00002036/202411 - periodic safety update report single assessment	New
17/07/2025	PSUSA: PSUSA/00002011/202412 - periodic safety update report single assessment	New
17/07/2025	Medicine: Comirnaty	Updated
17/07/2025	Page: Paediatric investigation plans: questions and answers	Updated
17/07/2025	Document: Timetable: Annual reassessment	Updated
17/07/2025	Medicine: Skyrizi	Updated
17/07/2025	Document: Timetable: Marketing authorisation renewal application	Updated
17/07/2025	Event: 13th Industry Standing Group (ISG) meeting	Updated
17/07/2025	PSUSA: PSUSA/00010270/202411 - periodic safety update report single assessment	New
16/07/2025	Medicine: Sugammadex Mylan	Updated
16/07/2025	Medicine: Elrexio	Updated
16/07/2025	Medicine: Ozempic	Updated
16/07/2025	Medicine: Crysvita	Updated
16/07/2025	Medicine: Javlor	Updated
16/07/2025	Page: Scientific and technical recommendations: Veterinary Medicines Regulation	Updated
16/07/2025	Event: EU Medicines Assessment - Opportunities for expert involvement	Updated
16/07/2025	Medicine: Opuviz	Updated
16/07/2025	Document: Guide to information on human medicines evaluated by European Medicines Agency: what the Agency publishes and when	Updated
16/07/2025	Document: HMPC: overview of assessment work - priority list	Updated
16/07/2025	Document: Procedural advice for orphan medicinal product designation: Guidance for sponsors	Updated

Date	Content	Status
16/07/2025	Document: Guidance notes on the use of Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) terminology for reporting suspected adverse events in animals and humans - Rev.17	Updated
16/07/2025	Medicine: Ilumetri	Updated
16/07/2025	Event: Clinical Trials Information System (CTIS) Bitesize talk: Redesign of the CTIS training material for sponsor users	Updated
16/07/2025	Medicine: Otezla	Updated
15/07/2025	PSUSA: PSUSA/00002291/202412 - periodic safety update report single assessment	New
15/07/2025	PSUSA: PSUSA/00003179/202411 - periodic safety update report single assessment	New
15/07/2025	PSUSA: PSUSA/00002443/202412 - periodic safety update report single assessment	New
15/07/2025	PSUSA: PSUSA/00010734/202411 - periodic safety update report single assessment	New
15/07/2025	PSUSA: PSUSA/00000769/202412 - periodic safety update report single assessment	New
15/07/2025	PSUSA: PSUSA/00000219/202412 - periodic safety update report single assessment	New
15/07/2025	PSUSA: PSUSA/00002300/202411 - periodic safety update report single assessment	New
15/07/2025	Document: List of EU Medicines Regulatory Agency Organisation with single and multiple LOC IDs for Product Management Services (PMS) data enrichment - Chapter 2 Annex III	New
15/07/2025	Page: Pre-authorisation guidance	Updated
15/07/2025	Page: Changing the labelling and package leaflet (Article 61(3) notifications)	Updated
15/07/2025	Page: Transfer of marketing authorisation: questions and answers	Updated
15/07/2025	Page: Grouping of variations: questions and answers	Updated
15/07/2025	Page: Type-IA variations: questions and answers	Updated
15/07/2025	Document: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure	Updated
15/07/2025	Document: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure: document with tracked changes	Updated
15/07/2025	Document: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure	Updated
15/07/2025	Document: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure: document with track changes	Updated
15/07/2025	Medicine: Yesintek	Updated
15/07/2025	Document: Checklist for the submission of product information annexes and Annex A (if applicable) for minor procedures without linguistic review - human	Updated
15/07/2025	Document: Template - Application for transfer of marketing authorisation from transferor to transferee - cover letter (human)	Updated
15/07/2025	Medicine: Trabectedin Accord	Updated
15/07/2025	Document: Article 57 product data	Updated
15/07/2025	Document: Agenda of the CAT meeting 16-18 July 2025	New
15/07/2025	Page: Clinical pharmacology and pharmacokinetics: questions and answers	Updated
15/07/2025	Event: European Platform for Regulatory Science Research meeting	New

Date	Content	Status
15/07/2025	Page: Submission dates	Updated
15/07/2025	Medicine: Calquence	Updated
15/07/2025	Medicine: Natpar	Updated
15/07/2025	Document: Agenda of the COMP meeting 15-17 July 2025	New
15/07/2025	Document: Expected publication dates of PRAC recommendations on safety signals	Updated
15/07/2025	Document: Agenda of the CVMP meeting 15-17 July 2025	New
15/07/2025	Medicine: Taltz	Updated
15/07/2025	Medicine: Scenesse	Updated
15/07/2025	Medicine: Zejula	Updated
14/07/2025	Medicine: Sunlenca	Updated
14/07/2025	Medicine: Tevimbra	Updated
14/07/2025	Medicine: Evrysdi	Updated
14/07/2025	Medicine: Vabysmo	Updated
14/07/2025	Medicine: Pomalidomide Krka	Updated
14/07/2025	Event: EMA Information Day on submission predictability of initial marketing authorisation December 2025	New
14/07/2025	Medicine: Plavix	Updated
14/07/2025	PSUSA: PSUSA/00000699/202411 - periodic safety update report single assessment	New
14/07/2025	Medicine: Ruxience	Updated
14/07/2025	PSUSA: PSUSA/00009247/202411 - periodic safety update report single assessment	New
14/07/2025	PSUSA: PSUSA/00001021/202411 - periodic safety update report single assessment	New
14/07/2025	Document: IRIS guide for applicants - How to create, submit and manage IRIS applications, for industry and individual applicants	Updated
14/07/2025	Medicine: Axumin	Updated
14/07/2025	Medicine: Tepezza	Updated
14/07/2025	Medicine: Flucelvax	Updated
14/07/2025	Medicine: Fluad	Updated
14/07/2025	Medicine: Fluenz	Updated
14/07/2025	Medicine: Febuxostat Viatris (previously Febuxostat Mylan)	Updated
14/07/2025	Medicine: Waylivra	Updated
14/07/2025	Event: Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) multistakeholder workshop on Patient Registries for Alzheimer's disease	New
14/07/2025	Medicine: Vfend	Updated
14/07/2025	PSUSA: PSUSA/00009326/202411 - periodic safety update report single assessment	New

NOTICE TO APPLICANTS

No updates since 07. July 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
18.07.2025	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien
15.07.2025	91. Sitzung (15. Juli 2025 per Videokonferenz) – Kurzprotokoll Sachverständigen-Ausschuss für Verschreibungspflicht nach § 53 Absatz 2 AMG

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
17.07.2025	Falten- und Volumenbehandlung durch Filler: Allgemeine Hinweise und Risiken Die Falten- und Volumenbehandlung wird in den letzten Jahren immer beliebter. Oft wird dabei unterschätzt, dass es sich um einen invasiven Eingriff mit entsprechenden Risiken handelt. Das BfArM möchte daher einen Beitrag dazu leisten, dass Personen, die sich einer solchen Behandlung unterziehen möchten, die damit verbundenen Konsequenzen und Risiken besser kennenlernen.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since May 22nd, 2025.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedeuropa updates will be presented quarterly.

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