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HEADS OF AGENCIES – CMDh

23 July

[UPDATE - Contact Points](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
24/07/2026	Medicine: Desloratadine Teva desloratadine	Updated
24/07/2026	Document: European Medicines Agency's data protection notice for meeting registration forms via Microsoft Forms	New
24/07/2026	Document: European Medicines Agency's data protection notice for conducting surveys via Microsoft Forms	New
24/07/2026	Document: European Medicines Agency's data protection notice for meeting registration forms via EUSurvey	Updated
24/07/2026	Document: European Medicines Agency's data protection notice for conducting surveys via EUSurvey	Updated
24/07/2026	Document: List of changes to combined Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) list of clinical terms for reporting suspected adverse events in animal and humans to veterinary medicinal products for 2025	Updated
24/07/2026	DHPC: Vyvgart - direct healthcare professional communication (DHPC) efgartigimod alfa	New

Date	Content	Status
24/07/2026	Document: Combined VeDDRA list of clinical terms for reporting suspected adverse events in animals and humans to veterinary medicinal products	Updated
24/07/2026	Document: Antimicrobial Sales and Use (ASU) Platform: Release notes	Updated
24/07/2026	Event: SPOR and XEVMPD status update webinar - Q3 2026	Updated
24/07/2026	Page: Healthcare Professionals' Working Party	Updated
24/07/2026	Document: Summary report - Network Data Steering Group and industry stakeholders annual meeting	New
24/07/2026	Document: Agenda - Network Data Steering Group and industry stakeholders annual meeting	New
24/07/2026	Event: Network Data Steering Group and industry stakeholders annual meeting	New
24/07/2026	Document: Concept paper on the quality and safety aspects of RNA interference and RNA antisense oligonucleotide therapies as veterinary medicinal products	New
24/07/2026	Document: Guideline on data requirements for changes to the strain composition of authorised equine influenza vaccines in line with WOH recommendations - Revision 1	New
24/07/2026	Medicine: Cavoley pegfilgrastim	New
24/07/2026	Medicine: Lynavoy Linerixibat	New
24/07/2026	Medicine: Meplyffa arimoclomol	New
24/07/2026	Medicine: Ubeslo obicetrapib	New
24/07/2026	Medicine: Nezglyal leriglitazone	New
24/07/2026	Medicine: Evlarco obicetrapib; ezetimibe	New
24/07/2026	Medicine: Lyrokaul lerodalcibep	New
24/07/2026	Medicine: Zokovea ensitrelvir	New
24/07/2026	Medicine: Susvimo ranibizumab	New
24/07/2026	Medicine: Azacitidine Adienne azacitidine	New

Date	Content	Status
24/07/2026	Medicine: Qezzaqar catequentinib	New
24/07/2026	Medicine: Icotype icotrokinra hydrochloride	New
24/07/2026	Medicine: KemSu sufentanil; ketamine	New
24/07/2026	News: First oral medicine targeting interleukin-23 receptor recommended for plaque psoriasis	New
24/07/2026	Post-authorisation: Enhertu - opinion on variation to marketing authorisation trastuzumab deruxtecan	New
24/07/2026	Post-authorisation: Riltrava Aerosphere - opinion on variation to marketing authorisation formoterol fumarate dihydrate; glycopyrronium; budesonide	New
24/07/2026	Post-authorisation: Piqray - opinion on variation to marketing authorisation alpelisib	New
24/07/2026	Post-authorisation: Imfinzi - withdrawal of application for variation to marketing authorisation durvalumab	New
24/07/2026	Post-authorisation: Rinvoq - opinion on variation to marketing authorisation upadacitinib	New
24/07/2026	Post-authorisation: Repatha - opinion on variation to marketing authorisation evolocumab	New
24/07/2026	Post-authorisation: Trixeo Aerosphere - opinion on variation to marketing authorisation formoterol; glycopyrronium bromide; budesonide	New
24/07/2026	Medicine: Spikevax (previously COVID-19 Vaccine Moderna) COVID-19 mRNA vaccine	Updated
24/07/2026	Medicine: Comirnaty COVID-19 mRNA vaccine	Updated
24/07/2026	Document: Minutes - HMA-EMA joint Network Data Steering Group meeting - 16 June 2026	New
24/07/2026	Document: Cardiac valves - Notified Body 0344 - 20/12/2025 - Expert decision and opinion in the context of the clinical evaluation consultation procedure (CECP)	Updated

Date	Content	Status
24/07/2026	Document: Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2026	Updated
24/07/2026	Document: Minutes – Ad hoc Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - 12 June 2026	New
24/07/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) – June 2026	Updated
24/07/2026	Document: Concept paper on the revision of the guideline on pharmaceutical fixed combination products (EMA/CVMP/83804/2005-Rev.1)	New
24/07/2026	Document: Guideline on data requirements to support in-use stability claims for veterinary vaccines - Revision 1	New
23/07/2026	Post-authorisation: Trodelvy - opinion on variation to marketing authorisation sacituzumab govitecan	New
23/07/2026	Post-authorisation: Dupixent - withdrawal of application for variation to marketing authorisation dupilumab	New
22/07/2026	Medicine: Kigabeq vigabatrin	Updated
22/07/2026	Medicine: Lumykras sotorasib	Updated
22/07/2026	Document: Lumykras : EPAR - Risk management plan	Updated
22/07/2026	Medicine: Orkambi lumacaftor; ivacaftor	Updated
22/07/2026	Medicine: Opzelura ruxolitinib	Updated
22/07/2026	Medicine: Cometriq cabozantinib	Updated
22/07/2026	Medicine: Ryjunea atropine sulfate	Updated
22/07/2026	Medicine: Voriconazole Accord voriconazole	Updated
22/07/2026	Page: Academia	Updated
22/07/2026	Medicine: Vitrakvi larotrectinib	Updated
22/07/2026	Medicine: Plerixafor Accord plerixafor	Updated

Date	Content	Status
22/07/2026	Medicine: Braftovi encorafenib	Updated
22/07/2026	Medicine: Zeffix lamivudine	Updated
22/07/2026	Medicine: Dimethyl fumarate Mylan dimethyl fumarate	Updated
22/07/2026	Medicine: Nucala mepolizumab	Updated
22/07/2026	Medicine: Zonegran zonisamide	Updated
22/07/2026	Document: Concept paper on revision of: Guideline on similar biological medicinal products, CHMP/437/04 Rev.1	New
22/07/2026	Medicine: Padcev enfortumab vedotin	Updated
21/07/2026	Medicine: Vorango vorasidenib	Updated
21/07/2026	Medicine: Ultomiris ravulizumab	Updated
21/07/2026	Medicine: Takhzyro lanadelumab	Updated
21/07/2026	Medicine: Tecentriq atezolizumab	Updated
21/07/2026	Medicine: Darzalex daratumumab	Updated
21/07/2026	Document: Agenda - PDCO agenda of the 21-24 July 2026 meeting	New
21/07/2026	Medicine: Opdualag relatlimab; nivolumab	Updated
21/07/2026	Medicine: LysaKare arginine; lysine	Updated
21/07/2026	Medicine: Gobivaz golimumab	Updated
21/07/2026	Medicine: Metalyse tenecteplase	Updated
21/07/2026	Medicine: Lutathera lutetium (177Lu) oxodotreotide	Updated
21/07/2026	Medicine: Fetcroja cefiderocol	Updated

Date	Content	Status
21/07/2026	Medicine: Eltrombopag Accord eltrombopag	Updated
21/07/2026	Medicine: Etcamah camizestrant	Updated
21/07/2026	Medicine: Abrysvo respiratory syncytial virus vaccine (bivalent, recombinant)	Updated
21/07/2026	Medicine: Vfend voriconazole	Updated
21/07/2026	Medicine: Tolucombi telmisartan; hydrochlorothiazide	Updated
21/07/2026	Medicine: Fluenz influenza vaccine (live attenuated, nasal)	Updated
21/07/2026	Medicine: Jascayd nerandomilast	Updated
20/07/2026	Medicine: Enhertu trastuzumab deruxtecan	Updated
20/07/2026	Medicine: Retacrit epoetin zeta	Updated
20/07/2026	Medicine: Tafamidis Accord tafamidis	New
20/07/2026	Medicine: Ruxolitinib Viatris ruxolitinib hemifumarate	New
20/07/2026	Medicine: Ogsiveo nirogacestat	Updated
20/07/2026	Medicine: Riociguat Accord riociguat	New
20/07/2026	Medicine: Pluvicto lutetium (¹⁷⁷ Lu) vipivotide tetraxetan	Updated
20/07/2026	Medicine: Scemblix asciminib	Updated
20/07/2026	Medicine: Yondelis trabectedin	Updated
20/07/2026	Page: Questions and answers for biological medicinal products	Updated
20/07/2026	Medicine: Intrarosa prasterone	Updated
20/07/2026	Event: Paediatric Committee (PDCO): 19-22 May 2026	Updated
20/07/2026	Event: Committee for Medicinal Products for Human Use (CHMP): 20-23 July 2026	Updated

Date	Content	Status
20/07/2026	Herbal: Liquiritiae radix - herbal medicinal product Liquorice Root	Updated

NOTICE TO APPLICANTS

No updates since June 27th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
27.07.2026	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
27.07.2026	Informationsbrief zu Eferox (Levothyroxin-Natrium): Tabletten in neuer Zusammensetzung Wirkstoff: Levothyroxin-Natrium Die Firma Aristo Pharma GmbH informiert darüber, dass ab August 2026 eine neue Zusammensetzung der Eferox Tabletten erhältlich sein wird.
24.07.2026	Informationen zu Rote-Hand-Briefen und Informationsbriefen Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht neue Hinweise zu anstehenden Rote-Hand-Briefen und Informationsbriefen (Handreichung: Hilfe bei der Erstellung eines Rote-Hand-Briefes in der Zuständigkeit des BfArM).
22.07.2026	Arzneimittelzulassungen unter Verwendung von Studien der Firma Micro Therapeutic Research Labs in Indien: Ruhen der Zulassungen Wirkstoff: Verschiedene Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) hat mit Bescheid vom 15.07.2026 das Ruhen der Zulassungen verlängert, deren Grundlage Studien der Firma Micro Therapeutic Research Labs (MTR) in Indien waren.
21.07.2026	93. Sitzung (21. Juli 2026 per Videokonferenz) – Kurzprotokoll Sachverständigen-Ausschuss für Verschreibungspflicht nach § 53 Absatz 2 AMG

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
23.07.2026	Webinarreihe DiGA Am 15. September 2026 findet das Webinar "Umsetzung der anwendungsbegleitenden Erfolgsmessung (AbEM)" statt.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
	No updates since July 14 th , 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeducation updates will be presented quarterly.

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