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HEADS OF AGENCIES – CMDh

08 August

NEW: HaRP assessment reports (Acetylcysteine, Adenosine, Ambroxol, Captopril, Combined Hormonal Contraceptives, Chlormadinone acetate/Ethinylestradiol, Flurbiprofen, Gabapentin, Gliclazide, Lactulose, Levosimendan, Linezolid, Loperamide, Olmesartan/Amlodipine/Hydrochlorthiazide, Piperacillin/Tazobactam, Warfarin)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
08/08/2025	Medicine: Jinarc	Updated
08/08/2025	Medicine: Cystadrops	Updated
08/08/2025	Document: Product Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 2 - track changes	Updated
08/08/2025	Document: Product Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 2	Updated
08/08/2025	Document: Paediatric investigation plan (PIP) - Key elements form	Updated
08/08/2025	Document: Procedural advice on paediatric applications	Updated
08/08/2025	Page: Paediatric medicines: applications and procedures	Updated
08/08/2025	Document: Key elements form: Applicant's proposal for a paediatric-investigation-plan opinion	Updated
08/08/2025	Event: 3Rs Working Party (3RsWP) plenary meeting - Public session on the 2025-2027 work plan	Updated
07/08/2025	Page: Emergency Task Force (ETF)	Updated
07/08/2025	Document: Composition of the Emergency Task Force (ETF) for preparedness	New
07/08/2025	Document: Superseded - Composition of the Emergency Task Force (ETF) for preparedness	Updated
07/08/2025	Medicine: LysaKare	Updated

Date	Content	Status
07/08/2025	Medicine: Brintellix	Updated
07/08/2025	Document: Applications for new human medicines under evaluation: August 2025	New
07/08/2025	Page: Vaccine Monitoring Platform	Updated
07/08/2025	Document: Vaccine Monitoring Platform: List of EMA-funded studies	Updated
07/08/2025	Event: Workshop on a tailored clinical approach in biosimilar development	Updated
07/08/2025	Document: Medicine shortage communication (MSC): Zypadhera (olanzapine pamoate monohydrate <210 mg / 300 mg / 405 mg> powder and solvent for prolonged release suspension for injection)	New
07/08/2025	Document: Agenda - Multi-stakeholder workshop on tailored clinical approach for biosimilars	New
06/08/2025	Document: Ketoprofen: European public maximum-residue-limit assessment report (EPMAR) - CVMP	New
06/08/2025	Medicine: Abecma	Updated
06/08/2025	Medicine: Zebinix	Updated
06/08/2025	Medicine: Enurev Breezhaler	Updated
06/08/2025	Medicine: Adempas	Updated
06/08/2025	Page: Quality guidelines	Updated
06/08/2025	Document: Feedback from European Medicine Agency (EMA) to the EU Commission request to evaluate the feasibility of alternatives to replace titanium dioxide (TiO₂) in medicinal products and its possible impact on medicines' availability	New
06/08/2025	Document: Annex I - Use of titanium dioxide as excipient in human and veterinary medicines and identification of alternatives - Industry feedback to QWP experts / EMA questions - Final report February 2024	New
06/08/2025	Medicine: Tovanor Breezhaler	Updated
06/08/2025	Medicine: Seebri Breezhaler	Updated
06/08/2025	Page: Clinical investigation of medicines for the treatment of Alzheimer's disease - Scientific guideline	Updated
06/08/2025	Document: Concept paper on the need for revision of the guideline on the clinical investigation of medicines for the treatment of Alzheimer's disease	New
06/08/2025	Medicine: Feteroja	Updated
06/08/2025	EU-M4all: Pyramax - opinion on medicine for use outside EU	Updated
06/08/2025	Medicine: Kengrexal	Updated
06/08/2025	Medicine: Tecentriq	Updated
06/08/2025	Document: Marketing authorisation application (MAA) - pre-submission interactions form	Updated
06/08/2025	Medicine: Ayvakyt	Updated
05/08/2025	Document: CHMP-CAT - D80-210 Overview to final EPAR - Rev 07.25 Revamp	Updated
05/08/2025	EU-M4all: Fexinidazole Winthrop - opinion on medicine for use outside EU	Updated
05/08/2025	Medicine: Riximyo	Updated
05/08/2025	Medicine: Rixathon	Updated
05/08/2025	Medicine: Omnitrope	Updated
05/08/2025	Shortage: Quetiapine	Updated
05/08/2025	Shortage: Zypadhera	Updated
05/08/2025	Medicine: Emtricitabine / Tenofovir alafenamide Viartis	Updated
05/08/2025	Medicine: mResvia	Updated
05/08/2025	Medicine: Livtencity	Updated
05/08/2025	PSUSA: PSUSA/00002013/202412 - periodic safety update report single assessment	New

Date	Content	Status
05/08/2025	PSUSA: PSUSA/00002024/202410 - periodic safety update report single assessment	New
05/08/2025	PSUSA: PSUSA/00000997/202410 - periodic safety update report single assessment	New
05/08/2025	Page: Scientific Advisory Group on Immune and Inflammatory Diseases	New
05/08/2025	Document: Declaration of interest form: Public call for Scientific Advisory Group on Immune and Inflammatory Diseases	New
05/08/2025	Document: Public call for expression of interest for experts to become members of the European Medicines Agency's Scientific Advisory Group on Immune and Inflammatory Diseases	New
05/08/2025	Medicine: Glivec	Updated
05/08/2025	Document: Recommendations on eligibility to PRIME scheme adopted at the CHMP meeting of 21-24 July 2025	New
05/08/2025	Page: PRIME: priority medicines	Updated
05/08/2025	Document: List of medicines currently in PRIME scheme	Updated
04/08/2025	Medicine: Darzalex	Updated
04/08/2025	Medicine: Mycamine	Updated
04/08/2025	Page: Eligible patients and consumers organisations	Updated
04/08/2025	Medicine: Docetaxel Kabi	Updated
04/08/2025	Medicine: Vitrakvi	Updated
04/08/2025	Medicine: Kalydeco	Updated
04/08/2025	Page: CHMP opinions on consultation procedures	Updated
04/08/2025	Event: 13th Industry Standing Group (ISG) meeting	Updated
04/08/2025	Document: Highlights - 13th Industry Standing Group (ISG) meeting	New
04/08/2025	Medicine: Rezolsta	Updated
04/08/2025	Document: Scientific advice and protocol assistance adopted during the CHMP meeting 21- 24 July 2025	New
04/08/2025	Document: List of industry subject matter experts and list of planned calls for industry subject matter experts	Updated

NOTICE TO APPLICANTS

No updates since July 07th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
06.08.2025	Thalidomid, Lenalidomid und Pomalidomid: Voraussetzungen für die Verschreibung in Deutschland Wirkstoff: Thalidomid, Lenalidomid, Pomalidomid Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) weist erneut auf die geltenden Sicherheitsvorgaben sowie die Voraussetzungen für eine ordnungsgemäße Verschreibung von Thalidomid, Lenalidomid und Pomalidomid hin.

Date	Title
05.08.2025	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/139606/2025 vom 22.05.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Diclofenac (systemische Darreichungsformen) Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Diclofenac (systemische Darreichungsformen) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
05.08.2025	Vorkommnismeldung durch Hersteller und Bevollmächtigte Vorkommnismeldung durch Hersteller und Bevollmächtigte

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since May 22nd, 2025.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.

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