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HEADS OF AGENCIES – CMDh

No updates since January 31st 2024.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

12/02/2024	Document: CTIS newsflash - 9 February 2024	New
09/02/2024	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)	Updated
09/02/2024	Document: HMPC: overview of assessment work - priority list	Updated
09/02/2024	PSUSA: PSUSA/00001382/202306 - periodic safety update report single assessment	New
09/02/2024	Page: Evaluation of medicinal products indicated for treatment of bacterial infections - Scientific guideline	Updated
09/02/2024	Document: Minimum inhibitory concentration (MIC) breakpoints	Updated
09/02/2024	Referral: Hydroxyprogesterone-containing medicinal products - referral	Updated
09/02/2024	Herbal: Tribuli terrestris herba - herbal medicinal product	Updated
09/02/2024	Herbal: Matricariae aetheroleum - herbal medicinal product	Updated
09/02/2024	Herbal: Malvae sylvestris flos - herbal medicinal product	Updated
09/02/2024	Herbal: Malvae folium - herbal medicinal product	Updated
09/02/2024	Herbal: Soiae oleum raffinatum - herbal medicinal product	Updated
09/02/2024	Herbal: Lecithinum ex soya - herbal medicinal product	Updated
09/02/2024	Herbal: Fragariae folium - herbal medicinal product	Updated
09/02/2024	Herbal: Combination: Species pectorales - herbal medicinal product	Updated
09/02/2024	Herbal: Cnici benedicti herba - herbal medicinal product	Updated
09/02/2024	Medicine: Tyenne	Updated
09/02/2024	PSUSA: PSUSA/00001594/202306 - periodic safety update report single assessment	New
09/02/2024	PSUSA: PSUSA/00010291/202306 - periodic safety update report single assessment	New
09/02/2024	PSUSA: PSUSA/00010815/202307 - periodic safety update report single assessment	New
09/02/2024	Medicine: Bylvay	Updated

09/02/2024	Document: Meeting summary of the Medicine Shortages (SPOC) Working Party 14 December 2023	New
09/02/2024	Event: European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting	Updated
09/02/2024	Page: Big data	Updated
09/02/2024	News: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 5-8 February 2024	New
09/02/2024	Document: Joint HMA/EMA multi-stakeholder workshop on Patient Registries	Updated
09/02/2024	Event: Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) Multistakeholder workshop on Patient Registries	Updated
08/02/2024	Document: Human medicines highlights - February 2024	New
08/02/2024	Medicine: Jcovden (previously COVID-19 Vaccine Janssen)	Updated
08/02/2024	EU-M4all: Arpraziquantel	Updated
08/02/2024	Medicine: Mometamax Ultra	New
08/02/2024	Document: Questions and answers on EMA pilot offering enhanced support to academic and non- profit developers of Advanced Therapy Medicinal Products (ATMPs)	Updated
08/02/2024	Document: Decision of the Executive Director on fee incentives for scientific advice, marketing authorisation applications and pre-authorisation inspections in the ATMP support pilot for academia	New
08/02/2024	Medicine: Evanovo	New
08/02/2024	Document: Epirubicin: List of nationally authorised medicinal products - PSUSA/00001234/202306	New
08/02/2024	Medicine: DogStem	New
08/02/2024	Medicine: Coxatab	New
08/02/2024	Medicine: Cortaderm	New
08/02/2024	News: Progress update on pilot for academic and non-profit developers of advanced therapy medicines	New
08/02/2024	PSUSA: PSUSA/00001234/202306 - periodic safety update report single assessment	New
08/02/2024	Orphan: EU/3/23/2870 - orphan designation for treatment of amyotrophic lateral sclerosis	New
08/02/2024	Medicine: Rivastigmine Actavis	Updated
08/02/2024	Medicine: Ambirix	Updated
08/02/2024	Medicine: Buccolam	Updated
08/02/2024	Medicine: Elucirem	Updated
08/02/2024	Medicine: Omjjara	Updated
08/02/2024	Medicine: MenQuadfi	Updated
08/02/2024	DHPC: pseudoephedrine - direct healthcare professional communication (DHPC)	New
07/02/2024	Event: Committee for Herbal Medicinal Products (HMPC): 20-22 November 2023	Updated
07/02/2024	Document: Saxenda (liraglutide) supply shortage	Updated
07/02/2024	Medicine: Jardiance	Updated
07/02/2024	Medicine: Uzpruvo	Updated
07/02/2024	Page: Plasma master file certificates	Updated
07/02/2024	Medicine: Bortezomib Fresenius Kabi	Updated
07/02/2024	Medicine: Twinrix Adult	Updated
07/02/2024	Medicine: Twinrix Paediatric	Updated
07/02/2024	Medicine: Strensiq	Updated
07/02/2024	Medicine: Briumvi	Updated
07/02/2024	Medicine: Hemlibra	Updated

07/02/2024	Medicine: Spravato	Updated
07/02/2024	Medicine: Edistride	Updated
07/02/2024	Medicine: Qtern	Updated
07/02/2024	Medicine: Xigduo	Updated
06/02/2024	Document: Cibinqo-H-C-005452-P46-005 : EPAR - Assessment Report - Variation	New
06/02/2024	Medicine: Ebymect	Updated
06/02/2024	Medicine: Forxiga	Updated
06/02/2024	PIP: EMA-002360-PIP02-22 - paediatric investigation plan	New
06/02/2024	PIP: EMA-002597-PIP09-22 - paediatric investigation plan	New
06/02/2024	PSUSA: PSUSA/00001370/202304 - periodic safety update report single assessment	New
06/02/2024	Medicine: Xenpozyme	Updated
06/02/2024	Medicine: Voriconazole Accord	Updated
06/02/2024	Medicine: Brukinsa	Updated
06/02/2024	Medicine: Ayvakyt	Updated
05/02/2024	Document: List of signals discussed at PRAC since September 2012	Updated
05/02/2024	Document: New product information wording – Extracts from PRAC recommendations on signals adopted at the 8-11 January 2024 PRAC	New
05/02/2024	Page: PRIME: priority medicines	Updated
05/02/2024	Document: PRAC recommendations on signals adopted at the 8-11 January 2024 PRAC meeting	New
05/02/2024	Page: Union Product Database	Updated
05/02/2024	Document: List of medicines currently in PRIME scheme	Updated
05/02/2024	Document: Recommendations on eligibility to PRIME scheme adopted at the CHMP meeting of 22-25 January 2024	New
05/02/2024	Event: Sixth EMA-Medicines for Europe bilateral meeting	Updated
05/02/2024	Document: Enpr-EMA newsletter 2023	New
05/02/2024	Document: Production API and registration process - production release version 01.6.42 - Veterinary Medicinal Products Regulation: Union Product Database	Updated
05/02/2024	Medicine: Trumenba	Updated
05/02/2024	Event: First European Medicines Agency (EMA) and IPFA – PPTA bilateral meeting	New
05/02/2024	Document: List of eligible industry stakeholder organisations	Updated

NOTICE TO APPLICANTS

No updates since January 30th 2023.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

09.02.2024	Cobimetinib; Vemurafenib – aphtöses Geschwür, Mundgeschwür, Stomatitis Cobimetinib; Vemurafenib – aphtöses Geschwür, Mundgeschwür, Stomatitis
09.02.2024	Cefotaxim – Arzneimittelexanthem mit Eosinophilie und systemischen Symptomen (DRESS) Cefotaxim – Arzneimittelexanthem mit Eosinophilie und systemischen Symptomen (DRESS)
09.02.2024	Avatrombopag – Antiphospholipidsyndrom Avatrombopag – Antiphospholipidsyndrom
09.02.2024	Amphotericin B, Lipidformulierungen – Hyperkaliämie Amphotericin B, Lipidformulierungen – Hyperkaliämie

09.02.2024	Pharmacovigilance Risk Assessment Committee (PRAC)
	Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 08.01-11.01.2024 behandelt wurden.
09.02.2024	Informationen zu Rote-Hand-Briefen und Informationsbriefen
	Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht neue Hinweise zu anstehenden Rote-Hand-Briefen und Informationsbriefen.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

08.02.2024	Antrag auf Sonderzulassung von Medizinprodukten
	Sonderzulassung von Medizinprodukten

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since November 16th 2023.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeduropa updates will be presented quarterly.

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