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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)

23/02/2024	Document: Eldisine (vindesine) supply shortage	New
23/02/2024	Page: Allergen products development for immunotherapy and allergy diagnosis in moderate to low-sized study populations - Scientific guideline	New
23/02/2024	Document: Clinical Trial Information System (CTIS) evaluation timelines	Updated
23/02/2024	Document: CTIS Training materials - Latest updates	Updated
23/02/2024	Medicine: Aripiprazole Zentiva	Updated
23/02/2024	Medicine: Kesimpta	Updated
23/02/2024	Medicine: Arexvy	Updated
23/02/2024	Event: SPOR Status Update	New
23/02/2024	Document: Membership list: HMA-EMA joint Big Data Steering Group	Updated
23/02/2024	Medicine: Fuzeon	Updated
23/02/2024	Medicine: Vaxneuvance	Updated
23/02/2024	Medicine: Febuxostat Krka	Updated
23/02/2024	Medicine: Temodal	Updated
23/02/2024	Medicine: Ravicti	Updated
23/02/2024	Document: Infographic - Orphan Medicines in the EU	Updated
23/02/2024	Page: Signal Management Review Technical (SMART) Working Group	New
23/02/2024	Page: Pharmacovigilance-related recommendations to product information for centrally authorised veterinary medicines	Updated
23/02/2024	Post-authorisation: Carvykti - opinion on variation to marketing authorisation	New
23/02/2024	Medicine: Apremilast Accord	New
23/02/2024	Medicine: Pyzchiva	New
23/02/2024	Medicine: Incellipan	New
23/02/2024	Medicine: Tizveni	New
23/02/2024	Medicine: Zynyz	New
23/02/2024	Medicine: Filspari	New

23/02/2024	Medicine: Cellademic	New
23/02/2024	Medicine: Nintedanib Accord	New
23/02/2024	Medicine: Voydeya	New
23/02/2024	Medicine: Qalsody	New
23/02/2024	Post-authorisation: Kalydeco - opinion on variation to marketing authorisation	New
23/02/2024	Post-authorisation: Cibinqo - opinion on variation to marketing authorisation	New
23/02/2024	Post-authorisation: Reblozyl - opinion on variation to marketing authorisation	New
23/02/2024	Post-authorisation: Xromi - opinion on variation to marketing authorisation	New
23/02/2024	Post-authorisation: Keytruda - opinion on variation to marketing authorisation	New
23/02/2024	News: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 19-22 February 2024	New
23/02/2024	News: First oral treatment against residual haemolytic anaemia in patients with paroxysmal nocturnal haemoglobinuria	New
23/02/2024	News: New treatment for rare motor neurone disease recommended for approval	New
23/02/2024	Document: Start of Union reviews adopted during the CHMP meeting of 19-22 February 2024	New
23/02/2024	Event: Committee for Medicinal Products for Veterinary Use (CVMP): 16-18 January 2024	Updated
23/02/2024	Event: Multi-stakeholder webinar on the HMA-EMA Catalogues of real-world data sources and studies	Updated
23/02/2024	Referral: Ibuprofen NVT - referral	New
22/02/2024	Medicine: Bylvay	Updated
22/02/2024	Medicine: Glivec	Updated
22/02/2024	Medicine: Cibinqo	Updated
22/02/2024	Medicine: Beovu	Updated
22/02/2024	Medicine: Mounjaro	Updated
22/02/2024	Page: Non-clinical and clinical evaluation of antiviral medicinal products and monoclonal antibodies for the prevention and treatment of COVID-19 - Scientific guideline	New
22/02/2024	PIP: EMA-001757-PIP02-15-M03 - paediatric investigation plan	Updated
22/02/2024	Document: Procedural advice on the accelerated assessment of marketing authorisation applications pursuant to Article 44 (3) of Regulation (EU) No 2019/6	Updated
22/02/2024	Medicine: Herceptin	Updated
21/02/2024	Page: Outcomes of imposed non-interventional post-authorisation safety studies	Updated
21/02/2024	Document: Valproate : PRAC non-interventional imposed PASS final study report assessment report - EMA/H/N/PSR/J/0043	New
21/02/2024	Document: Valproate : CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - EMA/H/N/PSR/J/0043	New
21/02/2024	Document: Valproate : List of nationally authorised medicinal products - EMA/H/N/PSR/J/0043	New
21/02/2024	Medicine: Jayempi	Updated
21/02/2024	Medicine: Trecondi	Updated
21/02/2024	Herbal: Fumariae herba - herbal medicinal product	Updated
21/02/2024	Medicine: Besremi	Updated
21/02/2024	Medicine: Tysabri	Updated
21/02/2024	Medicine: Veltassa	Updated

21/02/2024	Page: Public-health advice during COVID-19 pandemic	Updated
21/02/2024	Medicine: Reblozyl	Updated
21/02/2024	Document: Simplified summary - EMA/ECDC/EFSA fourth joint report on the integrated analysis of the antimicrobial agent consumption and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals in the EU/EEA (JIACRA IV)	New
21/02/2024	Event: European Medicines Agency (EMA) and Federation of Veterinarians of Europe (FVE) info session on the UPD public portal	Updated
21/02/2024	News: Multi-agency report highlights importance of reducing antibiotic use	New
21/02/2024	Document: EMA/ECDC/EFSA fourth joint report on the integrated analysis of the antimicrobial agent consumption and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals in the EU/EEA (JIACRA IV)	New
21/02/2024	Medicine: Opdualag	Updated
21/02/2024	Page: Analysis of antimicrobial consumption and resistance ('JIACRA' reports)	Updated
21/02/2024	Medicine: Velsipity	New
21/02/2024	Medicine: Vizimpro	Updated
21/02/2024	Medicine: Zinforo	Updated
21/02/2024	Medicine: Atazanavir Mylan	Updated
20/02/2024	PIP: EMA-002058-PIP01-16-M01 - paediatric investigation plan	Updated
20/02/2024	Medicine: Tecartus	Updated
20/02/2024	Medicine: Vantavo (previously Alendronate sodium and colecalciferol, MSD)	Updated
20/02/2024	PIP: EMA-003098-PIP01-21 - paediatric investigation plan	Updated
20/02/2024	Medicine: Fosavance	Updated
20/02/2024	Medicine: Adrovance	Updated
20/02/2024	Medicine: VidPrevtyn Beta	Updated
20/02/2024	Medicine: Zavicefta	Updated
20/02/2024	Event: Clinical Trials Information System Webinar: Last Year of Transition	New
20/02/2024	Event: Cancer Medicines Forum workshop: April 2024	Updated
20/02/2024	PIP: EMA-001352-PIP01-12-M01 - paediatric investigation plan	Updated
20/02/2024	Medicine: Ervebo	Updated
20/02/2024	Event: Paediatric Committee (PDCO): 20-23 February 2024	Updated
20/02/2024	PIP: EMA-001656-PIP01-14 - paediatric investigation plan	Updated
20/02/2024	PIP: EMA-002938-PIP01-20 - paediatric investigation plan	Updated
20/02/2024	Page: Clinical Trials Information System: training and support	Updated
19/02/2024	Medicine: HorStem	Updated
19/02/2024	Medicine: Briumvi	Updated
19/02/2024	Medicine: Slenyto	Updated
19/02/2024	Page: Opinions and letters of support on the qualification of novel methodologies for medicine development	Updated
19/02/2024	Document: Regulatory Procedure Management (RPM) for the Product Lifecycle Management (PLM) - Frequently asked questions	Updated
19/02/2024	Event: Update webinar on Regulatory Procedure Management for Product Lifecycle Management on IRIS	Updated
19/02/2024	Medicine: Calquence	Updated
19/02/2024	Event: Network users training for Regulatory Procedure Management 1st roll-out on IRIS	Updated
19/02/2024	Page: Fees payable to the European Medicines Agency	Updated

19/02/2024	Document: Questions and answers on the European Union framework for (traditional) herbal medicinal products, including those from a 'non-European' tradition	Updated
19/02/2024	Medicine: DaTSCAN	Updated
19/02/2024	Page: Scientific publications	Updated
19/02/2024	Event: Committee for Medicinal Products for Human Use (CHMP): 19-22 February 2024	Updated
19/02/2024	Medicine: Lonquex	Updated
19/02/2024	Document: Extended EudraVigilance Medicinal Product Report Message step-by-step guide: Insert of a development medicinal product	Updated
19/02/2024	Medicine: Pelmeg	Updated
19/02/2024	Medicine: Brinavess	Updated

NOTICE TO APPLICANTS

No updates since January 30th 2023.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

23.02.2024	Rote-Hand-Brief zu kombinierten hormonalen Kontrazeptiva mit Chlormadinonacetat/Ethinylestradiol: Leicht erhöhtes Risiko für venöse Thromboembolien Wirkstoff: Chlormadinonacetat, Ethinylestradiol Die Zulassungsinhaber von kombinierten hormonalen Kontrazeptiva, die Chlormadinonacetat und Ethinylestradiol enthalten, informieren über ein leicht erhöhtes Risiko für venöse Thromboembolien.
23.02.2024	Informationen zu Rote-Hand-Briefen und Informationsbriefen Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht neue Hinweise zu anstehenden Rote-Hand-Briefen und Informationsbriefen.
23.02.2024	Venöse Thromboembolien und kombinierte hormonale Kontrazeptiva Im Januar 2024 wurde das bisher unbekannte Risiko für eine venöse Thromboembolie für die Kombination aus Chlormadinon und Ethinylestradiol auf Grundlage der Ergebnisse einer retrospektiven Kohortenstudie bestimmt und ergänzt.
20.02.2024	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktuelle Hinweise für pharmazeutische Unternehmen zu Pomalidomid wurden veröffentlicht.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since February 8th 2024.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since November 16th 2023.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.

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