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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)

19/02/2024	Document: Article 57 product data	Updated
19/02/2024	Medicine: Dynastat	Updated
16/02/2024	Document: Orphan medicines figures 2000-2023	Updated
16/02/2024	Document: Annual report on the use of the special contribution for orphan medicinal products - 2023	New
16/02/2024	News: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 13-14 February 2024	New
16/02/2024	Medicine: Divence Penta	New
16/02/2024	Medicine: Lexylan	New
16/02/2024	Medicine: Mupleo (previously Lusutrombopag Shionogi)	Updated
16/02/2024	Medicine: Viagra	Updated
16/02/2024	Document: Organisation chart: Veterinary Medicines	Updated
16/02/2024	Page: Biostatistics	Updated
16/02/2024	Page: Non-inferiority and equivalence comparisons in clinical trials - Scientific guideline	New
16/02/2024	Document: Procedural advice to applicants/marketing authorisation holders on re-examination of CVMP opinions (according to Regulation (EU) 2019/6)	Updated
16/02/2024	Medicine: Rayvow	Updated
15/02/2024	Medicine: Hemgenix	Updated
15/02/2024	Page: Procurement	Updated
15/02/2024	Document: Records of data processing activity (public) for the HMA-EMA Catalogue of real-world data sources (and networks and institutions)	New
15/02/2024	Document: European Medicines Agency's Data Protection Notice for the HMA-EMA Catalogue of real-world data sources (and networks and institutions)	New

15/02/2024	Document: European Medicines Agency's Data Protection Notice for the HMA-EMA Catalogue of real-world data studies	New
15/02/2024	Medicine: Prolevare	New
15/02/2024	Medicine: CircoMax	New
15/02/2024	Medicine: Brucellin Aquilon	Updated
15/02/2024	Medicine: Rubraca	Updated
15/02/2024	Medicine: Vectormune ND	Updated
15/02/2024	Medicine: Suprelorin	Updated
15/02/2024	Medicine: Oncaspar	Updated
15/02/2024	Medicine: AdTab (previously Lotilaner Elanco)	Updated
15/02/2024	Referral: Synapse - referral	Updated
15/02/2024	Medicine: Besponsa	Updated
15/02/2024	Medicine: Mevlyq	Updated
15/02/2024	Page: Safety of COVID-19 vaccines	Updated
15/02/2024	Page: COVID-19 vaccines: key facts	Updated
15/02/2024	PSUSA: PSUSA/00010956/202307 - periodic safety update report single assessment	New
15/02/2024	Medicine: Praluent	Updated
15/02/2024	Herbal: Cimicifugae rhizoma - herbal medicinal product	Updated
15/02/2024	Page: Paediatric Formulation Operational Expert Group	Updated
15/02/2024	Herbal: Ribis nigri folium - herbal medicinal product	Updated
15/02/2024	Herbal: Echinaceae purpureae herba - herbal medicinal product	Updated
15/02/2024	Herbal: Echinaceae purpureae radix - herbal medicinal product	Updated
15/02/2024	Herbal: Echinaceae pallidae radix - herbal medicinal product	Updated
15/02/2024	Herbal: Echinaceae angustifoliae radix - herbal medicinal product	Updated
15/02/2024	Herbal: Plantaginis ovatae seminis tegumentum - herbal medicinal product	Updated
15/02/2024	Herbal: Agni casti fructus - herbal medicinal product	Updated
15/02/2024	Herbal: Polypodii rhizoma - herbal medicinal product	Updated
15/02/2024	Herbal: Plantaginis ovatae semen - herbal medicinal product	Updated
15/02/2024	Herbal: Oleae folium - herbal medicinal product	Updated
15/02/2024	Event: Multi-stakeholder webinar on the HMA-EMA Catalogues of real-world data sources and studies	New
15/02/2024	Page: Big data	Updated
15/02/2024	News: Launch of new HMA-EMA catalogues of real-world data sources and studies	New
15/02/2024	Page: Notifying EMA of changes to contact persons (veterinary medicines)	Updated
15/02/2024	Event: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	Updated
15/02/2024	Medicine: Myozyme	Updated
15/02/2024	Page: Procedures for monograph and list entry establishment	Updated
14/02/2024	Document: Guidance on the electronic submission of information on investigational medicinal products for human use in the Extended EudraVigilance medicinal product dictionary (XEVMPD)	Updated
14/02/2024	Document: Oncology Working Party (ONCWP) work plan: Priorities for 2024	New
14/02/2024	Document: Non-clinical domain work plan: Priorities for 2024	New
14/02/2024	PIP: EMEA-000335-PIP01-08-M15 - paediatric investigation plan	Updated
14/02/2024	PIP: EMEA-000597-PIP02-10-M09 - paediatric investigation plan	Updated
14/02/2024	PIP: EMEA-001032-PIP01-10-M05 - paediatric investigation plan	Updated
14/02/2024	PIP: EMEA-001079-PIP01-10-M06 - paediatric investigation plan	Updated
14/02/2024	PIP: EMEA-001136-PIP01-11-M02 - paediatric investigation plan	Updated
14/02/2024	Document: Vaccine Working Party (VWP) work plan 2022-2024	Updated

14/02/2024	Document: Consolidated 3-year work plan for the Rheumatology and Immunology Working Party (RIWP) 2024-2026	New
14/02/2024	PIP: EMA-002709-PIP01-19-M01 - paediatric investigation plan	Updated
14/02/2024	Document: 3-year work plan for the joint CHMP/CVMP Quality Working Party 2024-2026	New
14/02/2024	Document: 3-year work plan for the Quality Innovation Group 2024-2026	New
14/02/2024	Document: Consolidated 3-year work plan for the Infectious Disease Working Party (IDWP)	Updated
14/02/2024	Document: Draft revised consolidated 3-year work plan for the Methodology Working Party (MWP)	Updated
14/02/2024	Document: Haematology Working Party (HWP) work plan 2022-2024	Updated
14/02/2024	Document: Cardiovascular Working Party (CVSWP) work plan 2022-2024	Updated
14/02/2024	Document: Central Nervous System Working Party (CNSWP) work plan 2022-2024	Updated
14/02/2024	PIP: EMA-002240-PIP02-17-M02 - paediatric investigation plan	Updated
14/02/2024	Document: 3-year work plan for Biosimilar Medicinal Products Working Party (BMWP) 2024-2026	New
14/02/2024	Document: 3-year work plan for the Biologics Working Party (BWP) 2024-2026	New
14/02/2024	PIP: EMA-002320-PIP01-17-M03 - paediatric investigation plan	Updated
14/02/2024	Document: Reflection paper on investigation of pharmacokinetics in the obese population - Scientific guideline	New
14/02/2024	Medicine: Nezglyal	Updated
14/02/2024	PIP: EMA-001864-PIP03-19-M01 - paediatric investigation plan	Updated
14/02/2024	PIP: EMA-003212-PIP01-22 - paediatric investigation plan	New
14/02/2024	PIP: EMA-003207-PIP01-22 - paediatric investigation plan	New
14/02/2024	PIP: EMA-003177-PIP01-21 - paediatric investigation plan	New
14/02/2024	Medicine: Orserdu	Updated
14/02/2024	PIP: EMA-002283-PIP01-17-M04 - paediatric investigation plan	Updated
14/02/2024	PIP: EMA-003122-PIP01-21-M01 - paediatric investigation plan	Updated
14/02/2024	Document: European Medicines Agency mid-year report 2022 (January-June 2022)	Updated
14/02/2024	Document: European Medicines Agency mid-year report 2021 (January-June 2021)	Updated
14/02/2024	Document: Annual activity report 2022	Updated
14/02/2024	Document: CHMP rules of procedure	Updated
14/02/2024	Document: Agenda of the CAT meeting 14-16 February 2024	New
13/02/2024	PIP: EMA-003144-PIP01-21 - paediatric investigation plan	New
13/02/2024	Event: Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) meeting - April 2024	New
13/02/2024	PIP: EMA-003125-PIP02-21 - paediatric investigation plan	New
13/02/2024	Page: Health technology assessment bodies	Updated
13/02/2024	Document: Record of data processing activity relating to Security Access Control System (public)	Updated
13/02/2024	Event: Update webinar on Regulatory Procedure Management for Product Lifecycle Management on IRIS	Updated
13/02/2024	Event: Multi-stakeholder workshop on Data Quality Framework for Adverse Drug Reaction reporting	Updated
13/02/2024	Medicine: VidPrevtyl Beta	Updated
13/02/2024	Event: Technical Webinar: Regulatory Procedure Management for PLM in IRIS for Network Users	New
13/02/2024	Event: Orphan medicines development - ask the European regulator	Updated
13/02/2024	Medicine: Dupixent	Updated
13/02/2024	Document: Agenda of the CVMP meeting 13-15 February 2024	New

13/02/2024	Medicine: Fabrazyme	Updated
13/02/2024	Document: HMPC meeting report on European Union herbal monographs, guidelines and other activities - 29-31 January 2024	New
13/02/2024	Medicine: Zutectra	Updated
13/02/2024	Medicine: Remsima	Updated
13/02/2024	Medicine: Fasenra	Updated
13/02/2024	Medicine: Protopic	Updated
13/02/2024	Medicine: Rolufta Ellipta (previously Rolufta)	Updated
13/02/2024	Document: Scientific recommendations on classification of advanced therapy medicinal products	Updated
13/02/2024	Medicine: Catiolanze	Updated
13/02/2024	Medicine: Incruse Ellipta (previously Incruse)	Updated
13/02/2024	Medicine: Vueway	Updated
13/02/2024	PIP: EMA-001142-PIP02-16 - paediatric investigation plan	Updated
13/02/2024	Page: Questions and Answers on how to use a CEP in the context of a Marketing Authorisation Application or a Marketing Authorisation Variation	New
13/02/2024	PIP: EMA-003077-PIP01-21 - paediatric investigation plan	Updated
13/02/2024	PIP: EMA-001625-PIP04-22 - paediatric investigation plan	New
13/02/2024	Medicine: MenQuadfi	Updated
12/02/2024	Medicine: Jayempi	Updated
12/02/2024	Event: EMA Veterinary Medicines Info Day 2024	Updated
12/02/2024	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - March 2024	New
12/02/2024	Document: List of industry subject matter experts and list of planned calls for industry subject matter experts	Updated
12/02/2024	Medicine: Kymriah	Updated
12/02/2024	Document: Applications for new human medicines under evaluation: February 2024	New
12/02/2024	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - February 2024	New
12/02/2024	Page: Website outages and upgrades	Updated
12/02/2024	PSUSA: PSUSA/00010667/202306 - periodic safety update report single assessment	New
12/02/2024	Medicine: Roclanda	Updated
12/02/2024	Medicine: Voraxaze	Updated
12/02/2024	Medicine: Lumykras	Updated
12/02/2024	Document: Committee on Herbal Medicinal Products (HMPC): Work Plan 2024	New
12/02/2024	Event: Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) Multistakeholder workshop on Patient Registries	Updated
12/02/2024	PSUSA: PSUSA/00000101/202306 - periodic safety update report single assessment	New
12/02/2024	Medicine: Tecentriq	Updated
12/02/2024	Document: Joint HMA/EMA multi-stakeholder workshop on Patient Registries	Updated

NOTICE TO APPLICANTS

No updates since January 30th 2023.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

19.02.2024	Rote-Hand-Brief zu Valproat: Mögliches Risiko für neurologische Entwicklungsstörungen bei Kindern, deren Väter mit Valproat behandelt wurden Wirkstoff: Valproat Die Zulassungsinhaber von valproathaltigen Arzneimitteln informieren über neue Maßnahmen in Bezug auf das mögliche Risiko für neurologische Entwicklungsstörungen bei Kindern von Vätern, die in den drei Monaten vor der Zeugung mit Valproat behandelt wurden.
15.02.2024	Pseudoephedrin: Risiko für posteriores reversibles Enzephalopathiesyndrom und reversibles zerebrales Vasokonstriktionssyndrom Wirkstoff: Pseudoephedrin Unter der Anwendung von pseudoephedrinhaltigen Arzneimitteln wurden wenige Fälle eines posterioren reversiblen Enzephalopathiesyndroms (PRES) und eines reversiblen zerebralen Vasokonstriktionssyndroms (RCVS) berichtet.
15.02.2024	Gadoliniumhaltige Kontrastmittel: Gadoliniumablagerungen im Gehirn und anderen Geweben Wirkstoff: Gadolinium Für gadoliniumhaltige Kontrastmittel ist das Ruhen der Zulassungen bis zum 28.02.2026 verlängert worden
13.02.2024	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 Pharmedeuropa updates will be presented quarterly.

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