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HEADS OF AGENCIES – CMDh

No updates since April 3rd 2024.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
12/04/2024	Event: Committee for Advanced Therapies (CAT) meeting with interested parties, May 2023	New
12/04/2024	Medicine: Darzalex	Updated
12/04/2024	Medicine: Zeposia	Updated
12/04/2024	Event: Cancer Medicines Forum: February 2024	New
12/04/2024	Page: Big data	Updated
12/04/2024	Document: Guidance on real-world evidence provided by EMA: support for regulatory decision-making	New
12/04/2024	Document: Minutes of the 122nd meeting of the Management Board, 13-14 December 2023	New
12/04/2024	PSUSA: PSUSA/00002506/202308 - periodic safety update report single assessment	New
12/04/2024	PSUSA: PSUSA/00000858/202307 - periodic safety update report single assessment	New
12/04/2024	PSUSA: PSUSA/00001850/202307 - periodic safety update report single assessment	New
12/04/2024	PSUSA: PSUSA/00001040/202307 - periodic safety update report single assessment	New
12/04/2024	PSUSA: PSUSA/00003134/202305 - periodic safety update report single assessment	New
12/04/2024	Medicine: Eladynos	Updated
12/04/2024	News: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 8-11 April 2024	New
12/04/2024	PSUSA: PSUSA/00002411/202303 - periodic safety update report single assessment	New
12/04/2024	PSUSA: PSUSA/00010178/202308 - periodic safety update report single assessment	New

12/04/2024	Document: Emend (aprepitant) supply shortage	New
12/04/2024	Page: Pharmaceutical quality of inhalation and nasal products - Scientific guideline	Updated
12/04/2024	Document: Draft guideline on the pharmaceutical quality of inhalation and nasal medicinal products	New
12/04/2024	Document: Draft revised Heads of Medicines Agency / European Medicines Agency guidance document on the identification of personal data and commercially confidential information within the structure of the marketing authorisation application dossier	New
12/04/2024	Document: Draft guideline on the requirements for demonstrating therapeutic equivalence between orally inhaled products (OIP) for asthma and chronic obstructive pulmonary disease (COPD)	New
11/04/2024	PIP: EMEA-000727-PIP01-09-M07 - paediatric investigation plan	Updated
11/04/2024	Medicine: Wegovy	Updated
11/04/2024	Medicine: Rybelsus	Updated
11/04/2024	Medicine: Ozempic	Updated
11/04/2024	PSUSA: PSUSA/00001392/202308 - periodic safety update report single assessment	New
11/04/2024	Orphan: EU/3/16/1714 - orphan designation for treatment of mucopolysaccharidosis type I	Updated
11/04/2024	Orphan: EU/3/14/1236 - orphan designation for treatment of epidermolysis bullosa	Updated
11/04/2024	Document: Membership list: HMA-EMA joint Big Data Steering Group	Updated
11/04/2024	Orphan: EU/3/23/2873 - orphan designation for treatment of tenosynovial giant cell tumour, localised and diffuse type	Updated
11/04/2024	Orphan: EU/3/17/1861 - orphan designation for treatment of pulmonary arterial hypertension	Updated
11/04/2024	Orphan: EU/3/22/2723 - orphan designation for treatment of ovarian cancer	Updated
11/04/2024	Orphan: EU/3/20/2265 - orphan designation for treatment of acute myeloid leukaemia	Updated
11/04/2024	Orphan: EU/3/15/1515 - orphan designation for treatment of cutaneous T-cell lymphoma	Updated
11/04/2024	Orphan: EU/3/19/2184 - orphan designation for treatment of neurofibromatosis type 1	Updated
11/04/2024	Orphan: EU/3/05/317 - orphan designation for treatment of graft-versus-host disease	Updated
11/04/2024	Medicine: Yorvipath	Updated
11/04/2024	Orphan: EU/3/10/756 - orphan designation for prevention of scarring post glaucoma filtration surgery	Updated
11/04/2024	Orphan: EU/3/20/2311 - orphan designation for treatment of mitochondrial encephalomyopathy, lactic acidosis and stroke-like episodes	Updated
11/04/2024	Orphan: EU/3/20/2319 - orphan designation for treatment of long-chain 3-hydroxyacyl-coenzyme A dehydrogenase deficiency	Updated
11/04/2024	Orphan: EU/3/18/2010 - orphan designation for treatment of spinal muscular atrophy	Updated
11/04/2024	Event: Focus group on veterinary pharmacovigilance reporting in aquaculture	Updated
11/04/2024	Medicine: Myclausen	Updated
11/04/2024	Orphan: EU/3/17/1938 - orphan designation for treatment of epidermolysis bullosa	Updated
11/04/2024	Orphan: EU/3/18/2080 - orphan designation for treatment of haemophilia B	Updated
11/04/2024	Medicine: Febuxostat Viartis (previously Febuxostat Mylan)	Updated

11/04/2024	Orphan: EU/3/24/2897 - orphan designation for treatment of focal segmental glomerulosclerosis	New
11/04/2024	Medicine: Lacosamide UCB	Updated
11/04/2024	Orphan: EU/3/24/2901 - orphan designation for treatment of fibrodysplasia ossificans progressiva	New
11/04/2024	Event: Clinical Trials Information System (CTIS): Walk-in clinic - March 2024	Updated
11/04/2024	Orphan: EU/3/24/2890 - orphan designation for treatment of ovarian cancer	New
11/04/2024	Orphan: EU/3/24/2892 - orphan designation for treatment of small cell lung cancer	New
11/04/2024	Medicine: CellCept	Updated
11/04/2024	Orphan: EU/3/24/2891 - orphan designation for treatment of glioma	New
11/04/2024	Orphan: EU/3/24/2899 - orphan designation for treatment of acute respiratory distress syndrome (ARDS)	New
11/04/2024	Medicine: Padcev	Updated
11/04/2024	Document: Final Minutes – HMA-EMA joint Big Data Steering Group teleconference - 22 March 2024	New
11/04/2024	Orphan: EU/3/24/2898 - orphan designation for treatment of hereditary angioedema	New
11/04/2024	Orphan: EU/3/24/2900 - orphan designation for treatment of AL amyloidosis	New
11/04/2024	Page: Procurement	Updated
11/04/2024	Orphan: EU/3/24/2896 - orphan designation for treatment of ATTR amyloidosis	New
11/04/2024	Event: Eighth Industry Standing Group (ISG) meeting	Updated
11/04/2024	Orphan: EU/3/23/2887 - orphan designation for treatment of recurrent respiratory papillomatosis	New
11/04/2024	Orphan: EU/3/23/2888 - orphan designation for treatment of mucopolysaccharidosis type IIIA (Sanfilippo A syndrome)	New
11/04/2024	Orphan: EU/3/23/2881 - orphan designation for treatment of acute myeloid leukaemia	New
11/04/2024	Orphan: EU/3/23/2877 - orphan designation for treatment of amyotrophic lateral sclerosis	New
11/04/2024	Orphan: EU/3/23/2884 - orphan designation for treatment of Rett syndrome	New
11/04/2024	Orphan: EU/3/23/2883 - orphan designation for alpha-thalassaemia X-linked intellectual disability syndrome (due to mutations in the ATRX gene)	New
11/04/2024	Orphan: EU/3/23/2876 - orphan designation for treatment of small cell lung cancer	New
11/04/2024	Medicine: Glivec	Updated
11/04/2024	Medicine: Fampridine Accord	Updated
11/04/2024	Medicine: Xromi	Updated
11/04/2024	Medicine: Entecavir Viatris (previously Entecavir Mylan)	Updated
11/04/2024	Orphan: EU/3/23/2885 - orphan designation for treatment of patients undergoing haematopoietic stem cell transplantation	New
11/04/2024	Orphan: EU/3/23/2889 - orphan designation for treatment of thalassaemia intermedia and major	New
11/04/2024	Orphan: EU/3/23/2875 - orphan designation for diagnosis of glioma	New
11/04/2024	Orphan: EU/3/23/2879 - orphan designation for treatment of insulinoma	New
11/04/2024	Orphan: EU/3/23/2882 - orphan designation for treatment of eosinophilic granulomatosis with polyangiitis	New

11/04/2024	Orphan: EU/3/23/2878 - orphan designation for treatment of diffuse large B-cell lymphoma	New
11/04/2024	Orphan: EU/3/23/2886 - orphan designation for treatment of acquired factor X deficiency	New
11/04/2024	Orphan: EU/3/23/2874 - orphan designation for treatment of systemic sclerosis	New
11/04/2024	Orphan: EU/3/24/2894 - orphan designation for treatment of cystic fibrosis	New
11/04/2024	Event: Cancer Medicines Forum workshop: April 2024	Updated
11/04/2024	Medicine: Gardasil 9	Updated
11/04/2024	Medicine: Zaltrap	Updated
11/04/2024	Medicine: Spikevax (previously COVID-19 Vaccine Moderna)	Updated
11/04/2024	Medicine: Ambrisentan Mylan	Updated
11/04/2024	Medicine: Takhzyro	Updated
11/04/2024	Medicine: Tessie	Updated
11/04/2024	Page: Scientific publications	Updated
10/04/2024	Event: EMA/FVE info session on restrictions of certain antimicrobials	New
10/04/2024	Medicine: Myfenax	Updated
10/04/2024	Medicine: Mycophenolate mofetil Teva	Updated
10/04/2024	Medicine: Ranexa (previously Latixa)	Updated
10/04/2024	Medicine: Venclyxto	Updated
10/04/2024	Document: Members of the Coordinating group of European network of paediatric research at the European Medicines Agency (Enpr-EMA)	Updated
10/04/2024	Medicine: Cancidas (previously Caspofungin MSD)	Updated
10/04/2024	Medicine: Gavreto	Updated
10/04/2024	Medicine: Nivestim	Updated
10/04/2024	Medicine: Abilify Maintena	Updated
10/04/2024	Medicine: Sarclisa	Updated
10/04/2024	Medicine: Kyprolis	Updated
10/04/2024	Medicine: Aerinaze	Updated
09/04/2024	Medicine: Ninlaro	Updated
09/04/2024	Medicine: Tepadina	Updated
09/04/2024	Medicine: Dupixent	Updated
09/04/2024	Medicine: Lunsumio	Updated
09/04/2024	Event: Update webinar on Regulatory Procedure Management for Product Lifecycle Management on IRIS	Updated
09/04/2024	Page: Variations not requiring assessment (veterinary medicines)	Updated
09/04/2024	Event: Focus group on veterinary pharmacovigilance reporting in poultry	Updated
09/04/2024	Orphan: EU/3/18/2090 - orphan designation for treatment of haemophilia B	Updated
09/04/2024	Orphan: EU/3/10/830 - orphan designation for treatment of ovarian cancer	Updated
09/04/2024	Orphan: EU/3/14/1265 - orphan designation for treatment of ovarian cancer	Updated
09/04/2024	Orphan: EU/3/11/902 - orphan designation for treatment of neuroblastoma	Updated
09/04/2024	Orphan: EU/3/16/1808 - orphan designation for treatment of systemic sclerosis	Updated
09/04/2024	Orphan: EU/3/20/2334 - orphan designation for treatment of aspartylglucosaminuria	Updated
09/04/2024	Orphan: EU/3/16/1736 - orphan designation for treatment of cystic fibrosis	Updated
09/04/2024	Orphan: EU/3/18/2070 - orphan designation for treatment of dermatomyositis	Updated
09/04/2024	Orphan: EU/3/20/2324 - orphan designation for treatment of von Hippel-Lindau disease	Updated

09/04/2024	Orphan: EU/3/20/2309 - orphan designation for treatment of idiopathic pulmonary fibrosis	Updated
09/04/2024	Orphan: EU/3/09/632 - orphan designation for treatment of acute intermittent porphyria	Updated
09/04/2024	Orphan: EU/3/12/974 - orphan designation for treatment of primary hyperoxaluria type 1	Updated
09/04/2024	Orphan: EU/3/09/663 - orphan designation for treatment of Duchenne muscular dystrophy	Updated
09/04/2024	Orphan: EU/3/16/1631 - orphan designation for diagnosis of glioma	Updated
09/04/2024	Orphan: EU/3/16/1632 - orphan designation for diagnosis of hepatocellular carcinoma	Updated
09/04/2024	Orphan: EU/3/22/2593 - orphan designation for treatment of phenylalanine hydroxylase deficiency	Updated
09/04/2024	Orphan: EU/3/20/2341 - orphan designation for treatment of Fabry disease	Updated
09/04/2024	Orphan: EU/3/18/2015 - orphan designation for treatment of haemophilia A	Updated
09/04/2024	Orphan: EU/3/20/2326 - orphan designation for treatment of Gaucher disease	Updated
09/04/2024	Medicine: Komboglyze	Updated
09/04/2024	Medicine: Myozyme	Updated
09/04/2024	Medicine: Braftovi	Updated
09/04/2024	Document: Minutes of the PRAC meeting 5-8 February 2024	New
09/04/2024	Event: EMA multi-stakeholder workshop on psychedelics – Towards an EU regulatory framework	Updated
08/04/2024	Medicine: Bondronat	Updated
08/04/2024	Medicine: Bonviva	Updated
08/04/2024	Medicine: Xydalba	Updated
08/04/2024	Orphan: EU/3/19/2135 - orphan designation for treatment of DiGeorge syndrome	Updated
08/04/2024	Orphan: EU/3/19/2136 - orphan designation for treatment of CHARGE syndrome	Updated
08/04/2024	Orphan: EU/3/21/2568 - orphan designation for prevention of bronchopulmonary dysplasia	Updated
08/04/2024	Orphan: EU/3/19/2183 - orphan designation for treatment of WHIM syndrome	Updated
08/04/2024	Document: Agenda of the PRAC meeting 8-11 April 2024	New
08/04/2024	Orphan: EU/3/20/2271 - orphan designation for treatment in haematopoietic stem cell transplantation	Updated
08/04/2024	Orphan: EU/3/15/1534 - orphan designation for treatment of Rett syndrome	Updated
08/04/2024	Orphan: EU/3/15/1529 - orphan designation for treatment of fragile X syndrome	Updated
08/04/2024	Orphan: EU/3/19/2203 - orphan designation for treatment of Netherton syndrome	Updated
08/04/2024	Orphan: EU/3/19/2214 - orphan designation for treatment of soft tissue sarcoma	Updated
08/04/2024	Orphan: EU/3/21/2511 - orphan designation for treatment of Krabbe disease	Updated
08/04/2024	Orphan: EU/3/16/1759 - orphan designation for treatment of Duchenne muscular dystrophy	Updated
08/04/2024	Orphan: EU/3/21/2563 - orphan designation for treatment of invasive Scopulariopsis	Updated
08/04/2024	Orphan: EU/3/12/978 - orphan designation for treatment of perinatal asphyxia	Updated

08/04/2024	Orphan: EU/3/21/2407 - orphan designation for treatment of cystinosis	Updated
08/04/2024	Orphan: EU/3/21/2449 - orphan designation for treatment of pulmonary arterial hypertension	Updated
08/04/2024	Orphan: EU/3/07/434 - orphan designation for treatment of Leber's hereditary optic neuropathy	Updated
08/04/2024	Orphan: EU/3/20/2354 - orphan designation for treatment of microvillus inclusion disease	Updated
08/04/2024	Orphan: EU/3/22/2606 - orphan designation for treatment of haemophilia A	Updated
08/04/2024	Orphan: EU/3/19/2232 - orphan designation for treatment of amyotrophic lateral sclerosis	Updated
08/04/2024	Orphan: EU/3/22/2715 - orphan designation for treatment of spinocerebellar ataxia	Updated
08/04/2024	Medicine: Viagra	Updated
08/04/2024	Page: Contacts at the European Medicines Agency	Updated
08/04/2024	Page: Services and databases	Updated
08/04/2024	Medicine: Enjaymo	Updated
08/04/2024	News: EMA systems disruption expected from 11 to 17 April	New
08/04/2024	Post-authorisation: Orencia - withdrawal of application for variation to marketing authorisation	Updated
08/04/2024	PIP: EMEA-001821-PIP01-15-M06 - paediatric investigation plan	Updated
08/04/2024	PIP: EMEA-002063-PIP01-16-M02 - paediatric investigation plan	Updated
08/04/2024	PIP: EMEA-002070-PIP01-16-M07 - paediatric investigation plan	Updated
08/04/2024	PIP: EMEA-002079-PIP01-16-M03 - paediatric investigation plan	Updated
08/04/2024	PIP: EMEA-003170-PIP01-21-M01 - paediatric investigation plan	Updated
08/04/2024	Medicine: Cibinqo	Updated

NOTICE TO APPLICANTS

No updates since January 30th 2023.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

12.04.2024	GLP-1-Rezeptor-Agonisten: Keine Evidenz für einen Zusammenhang mit Suizidgedanken und Selbstverletzungsgedanken GLP-1-Rezeptor-Agonisten
12.04.2024	Abemaciclib; Palbociclib; Ribociclib – Erythema multiforme Abemaciclib; Palbociclib; Ribociclib – Erythema multiforme
12.04.2024	Pharmacovigilance Risk Assessment Committee (PRAC) Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 04.03-07.03.2024 behandelt wurden.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since April 3rd 2024.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since February 27th 2024.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.

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