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HEADS OF AGENCIES – CMDh

31 January

[NEW - 12-14 December 2023 CMDh minutes](#)

[NEW - 15 November 2023 CMDh meeting with representatives of Interested Parties minutes](#)

[UPDATE - List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation](#)

[UPDATE - Practical guidance for procedures related to Brexit for medicinal products for human use approved via MRP/DCP](#)

[UPDATE - Template CMS comments in MRP](#)

[UPDATE - Overview AR Template \(including instructions\)](#)

[NEW - Art. 45 PAR on Diphtheria, Tetanus, Inactivated Poliomyelitis vaccine](#)

[NEW - Art. 46 PAR on Wilate \(Human von Willebrand factor, human coagulation factor VIII\)](#)

[NEW - Report from the meeting held on 23-24 January 2024](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

02/02/2024	Medicine: Actraphane	Updated
02/02/2024	Document: Records of data processing activity (public) for the Antimicrobials Sales and Use (ASU) platform	New
02/02/2024	Page: Opinions and letters of support on the qualification of novel methodologies for medicine development	Updated
02/02/2024	Document: European Medicines Agency's Data Protection Notice for the Antimicrobials Sales and Use platform	New
02/02/2024	Event: Product Management Services (PMS) deep-dive webinar	New

02/02/2024	Document: EVVet3 EVWeb Production – Release notes	Updated
02/02/2024	Document: Membership list: HMA-EMA joint Big Data Steering Group	Updated
02/02/2024	Page: Big data	Updated
02/02/2024	Orphan: EU/3/23/2868 - orphan designation for treatment of peripheral T-cell lymphoma	New
02/02/2024	Orphan: EU/3/23/2869 - orphan designation for treatment of Angelman syndrome	New
02/02/2024	Medicine: Bekemv	Updated
02/02/2024	Orphan: EU/3/23/2863 - orphan designation for treatment of Duchenne muscular dystrophy	New
02/02/2024	Orphan: EU/3/23/2781 - orphan designation for treatment of myotonic disorders	New
02/02/2024	Orphan: EU/3/23/2783 - orphan designation for treatment of Charcot-Marie-Tooth disease	New
02/02/2024	Orphan: EU/3/23/2779 - orphan designation for treatment of neurofibromatosis type 1	New
02/02/2024	Orphan: EU/3/23/2776 - orphan designation for treatment of hypomyelinating leukodystrophy-18	New
02/02/2024	Orphan: EU/3/23/2795 - orphan designation for treatment of systemic sclerosis	New
02/02/2024	Orphan: EU/3/23/2789 - orphan designation for treatment of amyotrophic lateral sclerosis	New
02/02/2024	Orphan: EU/3/23/2788 - orphan designation for treatment of inherited retinal dystrophies	New
02/02/2024	Orphan: EU/3/23/2792 - orphan designation for treatment of soft tissue sarcoma	New
02/02/2024	Orphan: EU/3/23/2794 - orphan designation for treatment of glioma	New
02/02/2024	Orphan: EU/3/23/2790 - orphan designation for treatment of pancreatic cancer	New
02/02/2024	Orphan: EU/3/23/2796 - orphan designation for treatment of myelodysplastic syndromes	New
02/02/2024	Orphan: EU/3/23/2793 - orphan designation for treatment of moderate and severe closed traumatic brain injury	New
02/02/2024	Event: ACT EU Training for non-commercial sponsors: Transitioning trials to the CTR (CTIS)	Updated
02/02/2024	Document: Working instructions for Notified Bodies on the application of Article 54 of Regulation (EU) 2017/745 on medical devices and Article 48 of Regulation (EU) 2017/746 on in vitro diagnostic medical devices	New
02/02/2024	Document: EU-Innovation Network Workplan 2024	New
02/02/2024	Orphan: EU/3/23/2824 - orphan designation for treatment of arrhythmogenic right ventricular cardiomyopathy due to plakophilin-2 gene mutations	New
02/02/2024	Orphan: EU/3/23/2823 - orphan designation for treatment of Pelizaeus-Merzbacher disease	New
02/02/2024	Orphan: EU/3/23/2820 - orphan designation for treatment of glioma	New
02/02/2024	Event: ACT EU Clinical Trials Analytics Workshop - January 2024	Updated
02/02/2024	Orphan: EU/3/23/2819 - orphan designation for treatment of Huntington's disease	New
02/02/2024	Medicine: Methylthioninium chloride Proveblue	Updated
02/02/2024	Event: Paediatric Committee (PDCO): 12-15 December 2023	Updated
01/02/2024	Orphan: EU/3/23/2825 - orphan designation for treatment of myelodysplastic syndromes	New
01/02/2024	Orphan: EU/3/23/2821 - orphan designation for treatment of pancreatic cancer	New

01/02/2024	Orphan: EU/3/23/2818 - orphan designation for treatment in haematopoietic stem cell transplantation	New
01/02/2024	Orphan: EU/3/23/2817 - orphan designation for treatment of in solid organ transplantation	New
01/02/2024	Medicine: Pemetrexed Fresenius Kabi	Updated
01/02/2024	Medicine: Erelzi	Updated
01/02/2024	Document: Union Product Database - FAQs - questions and answers for industry users	Updated
01/02/2024	Orphan: EU/3/23/2859 - orphan designation for treatment of amyotrophic lateral sclerosis	New
01/02/2024	Orphan: EU/3/23/2857 - orphan designation for treatment of ovarian cancer	New
01/02/2024	Orphan: EU/3/23/2852 - orphan designation for treatment of pancreatic cancer	New
01/02/2024	Document: EU Implementation Guide (IG) on veterinary medicines product data - Chapter 2: Format for the electronic submission of veterinary medicinal product information	Updated
01/02/2024	Orphan: EU/3/23/2855 - orphan designation for treatment of Prader-Willi syndrome	New
01/02/2024	Orphan: EU/3/23/2849 - orphan designation for treatment of Gaucher disease	New
01/02/2024	Orphan: EU/3/23/2848 - orphan designation for treatment of patients with light chain (AL) amyloidosis	New
01/02/2024	Orphan: EU/3/23/2850 - orphan designation for treatment of Alport syndrome	New
01/02/2024	Medicine: Ronapreve	Updated
01/02/2024	Orphan: EU/3/23/2862 - orphan designation for treatment of perinatal asphyxia	New
01/02/2024	Orphan: EU/3/23/2867 - orphan designation for treatment of Leigh syndrome	New
01/02/2024	Medicine: Capecitabine Teva	Updated
01/02/2024	Orphan: EU/3/23/2860 - orphan designation for prevention of primary graft dysfunction following lung transplantation	New
01/02/2024	Orphan: EU/3/23/2866 - orphan designation for treatment of haemophilia B	New
01/02/2024	Orphan: EU/3/23/2861 - orphan designation for treatment of soft-tissue sarcoma	New
01/02/2024	Orphan: EU/3/23/2873 - orphan designation for treatment of tenosynovial giant cell tumour, localised and diffuse type	New
01/02/2024	Orphan: EU/3/23/2864 - orphan designation for treatment of follicular lymphoma	New
01/02/2024	Orphan: EU/3/23/2865 - orphan designation for treatment of glioma	New
01/02/2024	Orphan: EMA/OD/0000149115 - orphan designation for treatment of amyotrophic lateral sclerosis	New
01/02/2024	Orphan: EU/3/23/2872 - orphan designation for treatment of ricin poisoning	New
01/02/2024	Document: Questions and answers on quality of herbal medicinal products/traditional herbal medicinal products - Revision 7	New
01/02/2024	Document: European Medicines Agency's data protection notice for grant procedures	New
01/02/2024	Document: Careers at European Medicines Agency (EMA) - Guidance on selection and recruitment	Updated
01/02/2024	Event: Sixth European Medicines Agency (EMA) and EFPIA bilateral meeting	New
01/02/2024	Medicine: Prevymis	Updated
01/02/2024	Medicine: Nepexto	Updated
01/02/2024	Medicine: Lysodren	Updated

01/02/2024	Medicine: Veltassa	Updated
01/02/2024	PSUSA: PSUSA/00009159/202303 - periodic safety update report single assessment	New
01/02/2024	Medicine: Spikevax (previously COVID-19 Vaccine Moderna)	Updated
01/02/2024	Medicine: NexoBrid	Updated
01/02/2024	Medicine: Wakix	Updated
01/02/2024	Medicine: Abevmy	Updated
01/02/2024	Medicine: Albrioza	Updated
01/02/2024	Medicine: Sotyktu	Updated
01/02/2024	Orphan: EU/3/23/2797 - orphan designation for treatment of osteosarcoma	New
01/02/2024	Orphan: EU/3/23/2839 - orphan designation for treatment of amyotrophic lateral sclerosis	New
01/02/2024	Orphan: EU/3/23/2838 - orphan designation for treatment of Duchenne muscular dystrophy	New
01/02/2024	Orphan: EU/3/23/2844 - orphan designation for treatment of myelofibrosis	New
01/02/2024	Orphan: EU/3/23/2806 - orphan designation for treatment of acute myeloid leukaemia	New
01/02/2024	Orphan: EU/3/23/2811 - orphan designation for treatment of ovarian cancer	New
01/02/2024	Orphan: EU/3/23/2772 - orphan designation for treatment of oesophageal atresia	New
01/02/2024	Orphan: EU/3/23/2833 - orphan designation for treatment of acquired hypothalamic obesity	New
01/02/2024	Orphan: EU/3/23/2847 - orphan designation for treatment of CSF1R-related leukoencephalopathy	New
01/02/2024	Orphan: EU/3/23/2840 - orphan designation for treatment of Olmsted syndrome	New
01/02/2024	Orphan: EU/3/23/2846 - orphan designation for treatment of narcolepsy	New
01/02/2024	Orphan: EU/3/23/2809 - orphan designation for treatment of sarcoidosis	New
01/02/2024	Orphan: EU/3/23/2763 - orphan designation for treatment of scedosporiosis	New
01/02/2024	Orphan: EU/3/23/2814 - orphan designation for treatment of sickle cell disease	New
01/02/2024	Orphan: EU/3/23/2827 - orphan designation for treatment of thalassaemia intermedia and major	New
01/02/2024	Orphan: EU/3/23/2771 - orphan designation for treatment of otoferlin gene-mediated hearing loss	New
01/02/2024	Orphan: EU/3/23/2841 - orphan designation for treatment of lymphatic malformations	New
01/02/2024	Orphan: EU/3/23/2807 - orphan designation for treatment of malignant mesothelioma	New
01/02/2024	Orphan: EU/3/23/2765 - orphan designation for treatment of gastrointestinal stromal tumours	New
01/02/2024	Orphan: EU/3/23/2766 - orphan designation for treatment of hereditary haemorrhagic telangiectasia	New
01/02/2024	Orphan: EU/3/23/2812 - orphan designation for treatment of primary ciliary dyskinesia	New
01/02/2024	Page: Concept paper for the development of a reflection paper on a tailored clinical approach in biosimilar development	New
01/02/2024	Orphan: EU/3/23/2810 - orphan designation for treatment in haematopoietic stem cell transplantation	New
01/02/2024	Orphan: EU/3/23/2767 - orphan designation for treatment of gastrointestinal stromal tumours	New
01/02/2024	Orphan: EU/3/23/2801 - orphan designation for treatment of congenital diaphragmatic hernia	New

01/02/2024	Orphan: EU/3/23/2808 - orphan designation for treatment of Alport syndrome	New
01/02/2024	Orphan: EU/3/23/2834 - orphan designation for treatment of pancreatic cancer	New
01/02/2024	Orphan: EU/3/23/2813 - orphan designation for treatment of spinal muscular atrophy	New
01/02/2024	Orphan: EU/3/23/2769 - orphan designation for treatment of primary CTLA-4 checkpoint related immunodeficiencies	New
01/02/2024	Orphan: EU/3/23/2831 - orphan designation for treatment of Leigh syndrome	New
01/02/2024	Orphan: EU/3/23/2815 - orphan designation for treatment in haematopoietic stem cell transplantation	New
01/02/2024	Orphan: EU/3/23/2804 - orphan designation for treatment of nontuberculous mycobacterial lung disease	New
01/02/2024	PIP: EMA-002999-PIP01-21 - paediatric investigation plan	Updated
31/01/2024	Orphan: EU/3/23/2816 - orphan designation for treatment of primary membranous nephropathy	New
31/01/2024	Orphan: EU/3/23/2799 - orphan designation for treatment of congenital myasthenic syndromes	New
31/01/2024	Document: List of medicinal products under additional monitoring	Updated
31/01/2024	Document: List of medicinal products under additional monitoring	Updated
31/01/2024	Orphan: EU/3/23/2803 - orphan designation for treatment of myelofibrosis	New
31/01/2024	Orphan: EU/3/23/2832 - orphan designation for treatment of Smith-Magenis syndrome	New
31/01/2024	Orphan: EU/3/23/2768 - orphan designation for treatment of CDKL5 deficiency disorder	New
31/01/2024	Orphan: EU/3/23/2764 - orphan designation for treatment of vanishing white matter disease	New
31/01/2024	Orphan: EU/3/23/2770 - orphan designation for treatment of fragile X syndrome	New
31/01/2024	Orphan: EU/3/23/2774 - orphan designation for treatment of soft tissue sarcoma	New
31/01/2024	Orphan: EU/3/23/2853 - orphan designation for treatment of medium-chain acyl-coenzyme A dehydrogenase deficiency	New
31/01/2024	Medicine: Thyrogen	Updated
31/01/2024	Medicine: Saphnelo	Updated
31/01/2024	Orphan: EU/3/23/2858 - orphan designation for treatment of Menkes disease	New
31/01/2024	Medicine: Gencebok	Updated
31/01/2024	News: Clinical trials' transition to new EU system - one year left	New
31/01/2024	Medicine: Rimmyrah	Updated
31/01/2024	Orphan: EU/3/23/2851 - orphan designation for treatment of narcolepsy	New
31/01/2024	Orphan: EU/3/23/2854 - orphan designation for treatment of ovarian cancer	New
31/01/2024	Medicine: Vipdomet	Updated
31/01/2024	Medicine: Alkindi	Updated
30/01/2024	Document: Products Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 7	Updated
30/01/2024	Medicine: Zykadia	Updated
30/01/2024	Orphan: EU/3/23/2791 - orphan designation for treatment of Alport syndrome	New
30/01/2024	Orphan: EU/3/23/2786 - orphan designation for treatment of sickle cell disease	New

30/01/2024	PSUSA: PSUSA/00002602/202303 - periodic safety update report single assessment	New
30/01/2024	Document: Labelling flexibilities for COVID-19 therapeutics	Updated
30/01/2024	Document: Questions and answers on labelling flexibilities for COVID-19 vaccines	Updated
30/01/2024	Orphan: EU/3/23/2800 - orphan designation for treatment of Leigh syndrome	New
30/01/2024	Orphan: EU/3/23/2798 - orphan designation for treatment of primary biliary cholangitis	New
30/01/2024	Orphan: EU/3/23/2805 - orphan designation for treatment of inclusion body myositis	New
30/01/2024	Medicine: Caelyx pegylated liposomal	Updated
30/01/2024	Event: European Medicines Agency (EMA) and Federation of Veterinarians of Europe (FVE) info session on the UPD public portal	New
30/01/2024	Medicine: Tezspire	Updated
30/01/2024	Orphan: EU/3/23/2826 - orphan designation for treatment of Danon disease	New
30/01/2024	Medicine: Lopinavir/Ritonavir Mylan	Updated
30/01/2024	Medicine: Chanaxin	New
30/01/2024	PIP: EMA-001676-PIP01-14-M05 - paediatric investigation plan	Updated
30/01/2024	PIP: EMA-001695-PIP01-14-M05 - paediatric investigation plan	Updated
30/01/2024	Medicine: Prevenar 13	Updated
30/01/2024	Medicine: Exjade	Updated
30/01/2024	Medicine: Increlex	Updated
30/01/2024	Document: Final programming document 2024-2026	New
30/01/2024	Medicine: Brukinsa	Updated
30/01/2024	Page: Annual reports and work programmes	Updated
30/01/2024	Medicine: Filsuvez	Updated
29/01/2024	Medicine: Jardiance	Updated
29/01/2024	Document: Production API and registration process - production release version 01.6.42 - Veterinary Medicinal Products Regulation: Union Product Database	New
29/01/2024	Document: PRAC work plan 2024	New
29/01/2024	Document: CTIS newsflash - 26 January 2024	New
29/01/2024	Page: Data protection and privacy	Updated
29/01/2024	Document: European Medicines Agency's data protection notice for the Security Operation Centre (SOC)	New
29/01/2024	Event: Update webinar on Regulatory Procedure Management for Product Lifecycle Management on IRIS	New
29/01/2024	Document: Highlights from the 12th meeting of the Nitrosamine Implementation Oversight Group (NIOG)	New
29/01/2024	Document: Highlights from the 6th meeting of the Nitrosamine Implementation Oversight Group (NIOG) industry partners (IP)	New
29/01/2024	Document: Getting started with CTIS: Sponsor quick guide	Updated
29/01/2024	Document: Antimicrobial Sales and Use (ASU) technical implementation protocol	New
29/01/2024	Document: Antimicrobial Sales and Use (ASU) - Animal population data template	New
29/01/2024	Document: Antimicrobial Sales and Use (ASU) Power BI Application	New
29/01/2024	Document: Antimicrobial Sales and Use (ASU) - Use data template	Updated
29/01/2024	Medicine: Livmarli	Updated
29/01/2024	Document: Antimicrobial Sales and Use (ASU) - Sales data template	Updated
29/01/2024	Referral: Ocaliva - referral	Updated
29/01/2024	Document: Antimicrobial Sales and Use (ASU) Platform User Guide	New

NOTICE TO APPLICANTS

No updates since January 30th 2023.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

30.01.2024	Informationen zu Rote-Hand-Briefen und Informationsbriefen Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht neue Hinweise zu anstehenden Rote-Hand-Briefen und Informationsbriefen.
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BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since December 28th 2023.

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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