TABLE OF CONTENTS

HEADS OF AGENCIES – CMDh

25 July
UPDATE - Contact Points

24 July
NEW - Minutes of the 19 June 2025 meeting with Interested Parties
NEW - 17-19 June CMDh minutes

21 July
NEW - 22-23 July CMDh agenda

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
25/07/2025	Medicine: Spikevax (previously COVID-19 Vaccine Moderna)	Updated
25/07/2025	Medicine: Exjade	Updated
25/07/2025	Medicine: Vildagliptin / Metformin hydrochloride Accord	Updated
25/07/2025	Document: Substances considered as not falling within the scope of Regulation (EC) No. 470/2009, with regard to residues of veterinary medicinal products in foodstuffs of animal origin	Updated
25/07/2025	Document: IRIS guide for applicants - How to create, submit and manage IRIS applications, for industry and individual applicants	Updated
25/07/2025	Shortage: Saxenda	Updated
25/07/2025	Page: ICH Guideline M13B on bioequivalence for immediate-release solid oral dosage forms - additional strengths biowaiver - Scientific guideline	Updated
25/07/2025	Document: Overview of comments received on ICH M13B guideline on bioequivalence for immediate-release solid oral dosage forms - additional strengths biowaiver (EMA/CHMP/ICH/85092/2025)	New
25/07/2025	Medicine: Hetronifly	Updated
25/07/2025	Medicine: Tezspire	Updated
25/07/2025	Medicine: Olumiant	Updated
25/07/2025	Medicine: Ifinwil	New
25/07/2025	Event: Committee for Advanced Therapies (CAT) workshop on gene editing	Updated

Date	Content	Status
25/07/2025	Document: HMPC meeting report on European Union herbal monographs, guidelines and other activities - 07-09 July 2025	New
25/07/2025	Medicine: Comirnaty	Updated
25/07/2025	Document: Regulatory Procedure Management (RPM) for the Product Lifecycle Management (PLM) - Frequently asked questions	Updated
25/07/2025	Event: European shortages monitoring platform (ESMP): updates and question and answer (Q&A) clinic for marketing authorisation holders (MAHs)	Updated
25/07/2025	Document: European Union Member State Public Holidays Recorded in CTIS (year: 2026)	New
25/07/2025	Event: EU Medicines Assessment - Opportunities for expert involvement	Updated
25/07/2025	Page: Signal management	Updated
25/07/2025	Document: Questions and answers on Implementing Regulation (EU) 2025/1466: Amendment of Regulation (EU) No 520/2012 and Conclusion of the Signal Detection in EudraVigilance Pilot by marketing authorisation holders	New
25/07/2025	Page: Development of a reflection paper on the use of external controls for evidence generation in regulatory decision-making - Scientific guideline	Updated
25/07/2025	Document: Table of decisions of labelling exemption requests falling under article 63 of Directive 2001/83/EC examined by the Quality Review of Documents (QRD) Group	Updated
25/07/2025	Page: Demonstration of efficacy for veterinary medicinal products containing anticoccidial substances - Scientific guideline	Updated
25/07/2025	Orphan: EU/3/25/3077 - orphan designation for treatment of congenital adrenal hyperplasia	New
25/07/2025	Orphan: EU/3/25/3076 - orphan designation for treatment of glioma	New
25/07/2025	Orphan: EU/3/25/3070 - orphan designation for treatment of multifocal motor neuropathy	New
25/07/2025	Orphan: EU/3/25/3075 - orphan designation for treatment of multiple system atrophy	New
25/07/2025	Orphan: EU/3/25/3073 - orphan designation for treatment of mucopolysaccharidosis type IIIB (Sanfilippo B syndrome)	New
25/07/2025	Orphan: EU/3/25/3081 - orphan designation for treatment of Rett syndrome	New
25/07/2025	Document: Questions and answers on the outcome of assessment on use of Neuraceq to monitor treatment response	New
25/07/2025	Orphan: EU/3/25/3072 - orphan designation for treatment of Netherton syndrome	New
25/07/2025	Orphan: EU/3/25/3069 - orphan designation for treatment of osteogenesis imperfecta	New
25/07/2025	Orphan: EU/3/25/3065 - orphan designation for treatment of mastocytosis	New
25/07/2025	Orphan: EU/3/25/3071 - orphan designation for treatment of primary sclerosing cholangitis	New
25/07/2025	Orphan: EU/3/25/3068 - orphan designation for treatment of radiation induced maculopathy	New
25/07/2025	Orphan: EU/3/25/3079 - orphan designation for treatment of acute myeloid leukaemia	New
25/07/2025	News: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 21-24 July 2025	New
25/07/2025	News: First reformulation of an inhaled medicine with environmentally friendly gas propellant	New
25/07/2025	Post-authorisation: Baqsimi - opinion on variation to marketing authorisation	New
25/07/2025	Post-authorisation: Sirturo - opinion on variation to marketing authorisation	New

Date	Content	Status
25/07/2025	Post-authorisation: Clopidogrel Zentiva (previously Clopidogrel Winthrop) - opinion on variation to marketing authorisation	New
25/07/2025	Post-authorisation: Tevimbra - opinion on variation to marketing authorisation	New
25/07/2025	News: New injection for easier prevention of HIV infection in the EU and worldwide	New
25/07/2025	Orphan: EU/3/25/3078 - orphan designation for treatment of lymphoplasmacytic lymphoma	New
25/07/2025	Post-authorisation: Invokana - opinion on variation to marketing authorisation	New
25/07/2025	Medicine: Elevidys	New
25/07/2025	Medicine: Nurzigma	New
25/07/2025	Medicine: Usrenty	New
25/07/2025	Post-authorisation: Alhemo - opinion on variation to marketing authorisation	New
25/07/2025	Post-authorisation: Taltz - opinion on variation to marketing authorisation	New
25/07/2025	Post-authorisation: mResvia - opinion on variation to marketing authorisation	New
25/07/2025	Medicine: Eyluxvi	New
25/07/2025	Medicine: Jelrix	New
25/07/2025	Medicine: Macitentan Accord	New
25/07/2025	Medicine: Macitentan AccordPharma	New
25/07/2025	Medicine: Ekterly	New
25/07/2025	Medicine: Zurzuvae	New
25/07/2025	Medicine: Voranigo	New
25/07/2025	Medicine: Romvimza	New
25/07/2025	Medicine: Bildyos	New
25/07/2025	Medicine: Bilprevda	New
25/07/2025	Medicine: Yeytuo	New
25/07/2025	Medicine: Aplidin	New
25/07/2025	Medicine: Nidlegy	New
25/07/2025	Medicine: Kisunla	Updated
25/07/2025	Referral: Tecovirimat SIGA - referral	New
25/07/2025	Referral: Ixchiq - referral	Updated
25/07/2025	EU-M4all: Lenacapavir Gilead - opinion on medicine for use outside EU	New
25/07/2025	News: Ixchiq: temporary restriction on vaccinating people 65 years and older to be lifted	New
25/07/2025	Orphan: EU/3/23/2858 - orphan designation for treatment of Menkes disease	New
25/07/2025	Orphan: EU/3/21/2458 - orphan designation for treatment of biliary tract cancer	New
25/07/2025	Medicine: Xoterna Breezhaler	Updated
25/07/2025	Referral: Oxbryta - referral	Updated
25/07/2025	Medicine: Ondexxya	Updated
25/07/2025	Medicine: Volibris	Updated
25/07/2025	Medicine: Mysimba	Updated
25/07/2025	Medicine: Ultibro Breezhaler	Updated
25/07/2025	Medicine: Armisarte (previously Pemetrexed Actavis)	Updated
25/07/2025	Medicine: Ulunar Breezhaler	Updated
24/07/2025	Medicine: Cresemba	Updated
24/07/2025	Page: CHMP opinions on consultation procedures	Updated
24/07/2025	Page: Portfolio and technology meetings	Updated
24/07/2025	Page: Innovation Task Force briefing meetings	Updated

Date	Content	Status
24/07/2025	Document: Innovation Task Force (ITF) briefing meeting report	New
24/07/2025	Document: Innovation Task Force (ITF) briefing meeting request form	Updated
24/07/2025	Page: Risk minimisation measures (RMM)	New
24/07/2025	Medicine: Pyzchiva	Updated
24/07/2025	Medicine: Vitrakvi	Updated
24/07/2025	Page: Good pharmacovigilance practices (GVP)	Updated
24/07/2025	Document: Guidelines on good pharmacovigilance practices (GVP): Introductory cover note, last updated with new Addendum II to Module VI on masking of personal data in individual case safety reports submitted to EudraVigilance	New
24/07/2025	Document: Guideline on good pharmacovigilance practices (GVP) - Module VI Addendum II – Masking of personal data in individual case safety reports submitted to EudraVigilance	New
24/07/2025	News: EMA Paediatric Committee elects Sabine Scherer as its new chair	New
24/07/2025	Medicine: Amlodipine / Valsartan Mylan	Updated
24/07/2025	Page: Safety and residue data requirements for the establishment of maximum residue limits in minor species - Scientific guideline	Updated
24/07/2025	Medicine: Opdualag	Updated
24/07/2025	Shortage: Trulicity	Updated
24/07/2025	Document: LifeGlobal Media - Procedural steps and scientific information after initial consultation (archive)	Updated
24/07/2025	Medicine: Poteligeo	Updated
24/07/2025	Event: HMA/EMA multi-stakeholder workshop on artificial intelligence	Updated
24/07/2025	Page: Parallel scientific advice and special development aspects or product types	Updated
24/07/2025	Document: EU Repurposing pilot	New
24/07/2025	Medicine: Nubeqa	Updated
24/07/2025	Medicine: Sugammadex Amomed	Updated
24/07/2025	Page: Pharmaceutical quality of inhalation and nasal products - Scientific guideline	Updated
24/07/2025	Document: Guideline on the pharmaceutical quality of inhalation and nasal medicinal products - Revision 1	Updated
24/07/2025	Medicine: Benepali	Updated
24/07/2025	Document: HMA-EMA joint Network Data Steering Group meeting 27 June 2025	New
24/07/2025	Document: HMA-EMA joint Network Data Steering Group meeting - 28 May 2025	New
24/07/2025	Referral: Veterinary medicinal products containing albendazole as a single active substance presented as oral suspension in sheep - referral	Updated
24/07/2025	Document: CooperSurgical Inc ART Media - Procedural steps and scientific information after initial consultation (archive)	Updated
24/07/2025	Document: Origio - Procedural steps and scientific information after initial consultation (archive)	Updated
24/07/2025	Medicine: Skyrizi	Updated
23/07/2025	Medicine: Apixaban Accord	Updated
23/07/2025	Medicine: Afqlir	Updated
23/07/2025	Medicine: Supemtek Tetra (previously Supemtek)	Updated
23/07/2025	Medicine: Tafinlar	Updated
23/07/2025	Medicine: Blincyto	Updated
23/07/2025	Medicine: Inrebic	Updated
23/07/2025	Event: Workshop on the use of external controls for evidence generation in regulatory decision-making	Updated

Date	Content	Status
23/07/2025	Document: Questions and answers (Q&As) on the external guidance of Policy 0070 on clinical data publication (CDP)	Updated
23/07/2025	Document: Marketing authorisation application (MAA) - pre-submission interactions form	Updated
23/07/2025	Medicine: Tyenne	Updated
23/07/2025	Document: New fee regulation: General questions and answers for all applicants	Updated
23/07/2025	Medicine: Celsentri	Updated
23/07/2025	Medicine: Rhokiinsa	Updated
23/07/2025	Medicine: Rivaroxaban Viatris (previously Rivaroxaban Mylan)	Updated
23/07/2025	Event: 5th Veterinary Big Data Stakeholder Forum	New
23/07/2025	Document: Anti-t lymphocyte immunoglobulin for human use, rabbit : List of nationally authorised medicinal products - PSUSA/00010252/202406	Updated
22/07/2025	Medicine: Taltz	Updated
22/07/2025	Medicine: Sondelbay	Updated
22/07/2025	Medicine: Axitinib Accord	Updated
22/07/2025	Medicine: Efient	Updated
22/07/2025	Medicine: Incruse Ellipta (previously Incruse)	Updated
22/07/2025	Medicine: Yescarta	Updated
22/07/2025	Medicine: Lynozyfic	Updated
22/07/2025	Medicine: Zyclara	Updated
22/07/2025	Medicine: Pylclari	Updated
22/07/2025	Medicine: Ponvory	Updated
22/07/2025	Document: Agenda - PDCO agenda of the 22-25 July 2025 meeting	New
22/07/2025	Medicine: Kaftrio	Updated
22/07/2025	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) – July 2025	Updated
22/07/2025	Document: Agenda – Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - 23 July 2025	New
22/07/2025	Event: EMA multi-stakeholder workshop on the clinical evaluation of therapeutic radiopharmaceuticals in oncology	New
22/07/2025	Event: Q&A clinic on web-based electronic Application Form (eAF) functionalities for CAPs and non-CAPs variations	Updated
22/07/2025	Event: Refresher training webinar on post-authorisation procedure management in IRIS for marketing authorisation holders	New
22/07/2025	Document: Network Data Steering Group workplan 2025-2028	Updated
22/07/2025	Document: Medicinal products for human use: monthly figures - June 2025	New
21/07/2025	Medicine: Elrexfio	Updated
21/07/2025	Medicine: Zirabev	Updated
21/07/2025	Medicine: Menveo	Updated
21/07/2025	Page: Requirements for demonstrating therapeutic equivalence between orally inhaled products (OIP) for asthma and chronic obstructive pulmonary disease (COPD) - Scientific guideline	Updated
21/07/2025	Medicine: Aybintio	Updated
21/07/2025	Document: Guideline on the requirements for demonstrating therapeutic equivalence between orally inhaled products (OIP) for asthma and chronic obstructive pulmonary disease (COPD) - Revision 2	New
21/07/2025	Document: Annex to 21-24 July 2025 CHMP Agenda	New
21/07/2025	Document: Agenda of the CHMP meeting 21-24 July 2025	New
21/07/2025	Event: Thirteenth Nitrosamine Implementation Oversight Group (NIOG) meeting	New

Date	Content	Status
21/07/2025	Document: Highlights from the 13th meeting of the Nitrosamine Implementation Oversight Group (NIOG)	New
21/07/2025	Page: 30th anniversary scientific conference highlights	New

NOTICE TO APPLICANTS

No updates since 07. July 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
25.07.2025	**Tecovirimat SIGA: Überprüfung der Wirksamkeit bei der Behandlung von Mpox** Wirkstoff: TecovirimatDie Europäische Arzneimittel-Agentur (EMA) hat eine Überprüfung von Tecovirimat SIGA (Tecovirimat) eingeleitet, nachdem neue Daten aus aktuellen klinischen Studien darauf hindeuten, dass das Arzneimittel bei der Behandlung von Mpox nicht wirksam ist.
25.07.2025	**Informationen zu Rote-Hand-Briefen und Informationsbriefen** Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht neue Hinweise zu anstehenden Rote-Hand-Briefen und Informationsbriefen.
23.07.2025	**Nitrosaminverunreinigungen - Informationen für Zulassungsinhaber: Aktuelle Informationen zur Einreichung von Schritt 3** Wirkstoff: VerschiedeneNitrosaminverunreinigungen - Informationen für Zulassungsinhaber: Aktuelle Informationen zur Einreichung von Schritt 3
22.07.2025	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/155373/2025 vom 22.05.2024 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Sumatriptan und der Wirkstoffkombination Naproxen/Sumatriptan** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Sumatriptan und die Wirkstoffkombination Naproxen/Sumatriptan infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
24.07.2025	**Rückruf-Meldung** Rückruf melden

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since May 22nd, 2025.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.

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