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HEADS OF AGENCIES – CMDh

23 September

- **NEW - PSUR assessment for Iberogast Balance and Iberogast Select**
- **NEW - PSUR assessment for Pyridoxine hydrochloride/ lysozyme hydrochloride**
- **NEW - Recommendations on submission dates in 2027 for Applications of the MRP**
- **NEW - Recommendations on submission dates in 2027 for Applications of the DCP**
- **NEW - Overview of CMDh referral timetables 2027**
- **UPDATE - BPG for the processing of grouped applications in MRP (Chapter 6)**
- **NEW - Report from the meeting held on 15-17 September 2026**

22 September

- **UPDATE - Guidance published by Member States on the implementation of the Falsified Medicines Directive**
- **NEW - 21-22 July CMDh Minutes**

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
25/09/2026	Page: Questions and answers for biological medicinal products	Updated
25/09/2026	PSUSA: PSUSA/00000167/202601 - periodic safety update report single assessment amisulpride	New
25/09/2026	PSUSA: PSUSA/00010430/202511 - periodic safety update report single assessment phenylephrine / tropicamide	New
25/09/2026	PSUSA: PSUSA/00000091/202601 - periodic safety update report single assessment alizapride	New
25/09/2026	Medicine: Tyruko natalizumab	Updated
25/09/2026	Medicine: Celldemic zoonotic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures)	Updated

25/09/2026	Medicine: Incellipan pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures)	Updated
25/09/2026	Medicine: Gobivaz golimumab	Updated
25/09/2026	Medicine: Suboxone buprenorphine; naloxone	Updated
25/09/2026	Medicine: Tolvaptan Accord tolvaptan	Updated
25/09/2026	Medicine: Yuflyma adalimumab	Updated
25/09/2026	Medicine: Rinvoq upadacitinib	Updated
25/09/2026	Page: Data in regulation: Big data and other sources	Updated
25/09/2026	Medicine: Joenja leniolisib	Updated
25/09/2026	Medicine: Skytrofa (previously Lonapegsomatropin Ascendis Pharma) lonapegsomatropin	Updated
25/09/2026	Event: ACT EU workshop on multiplicity in confirmatory clinical trials: From two-arm to platform trials	New
25/09/2026	Document: Start of procedure: Type II Variation - Extension of indication under evaluation by the CHMP (21 August 2026 - 17 September 2026)	New
25/09/2026	Document: Suboxone : EPAR - Procedural steps taken before authorisation	Updated
25/09/2026	Document: Suboxone : EPAR - Scientific Discussion	Updated
24/09/2026	PSUSA: PSUSA/00010431/202510 - periodic safety update report single assessment amlodipine / atorvastatin / perindopril, amlodipine / atorvastatin / ramipril	New
24/09/2026	Medicine: Ruxolitinib Viatris ruxolitinib hemifumarate	Updated
24/09/2026	Medicine: Nezglyal leriglitazone	Updated
24/09/2026	Medicine: Jorveza budesonide	Updated
24/09/2026	Document: Article 57 product data	Updated
24/09/2026	Medicine: Padcev enfortumab vedotin	Updated
24/09/2026	Medicine: Relistor methylnaltrexone bromide	Updated
24/09/2026	Medicine: Degevma denosumab	Updated
24/09/2026	Medicine: Atazanavir Viatris (previously Atazanavir Mylan) atazanavir	Updated
24/09/2026	Medicine: Uzpruvo ustekinumab	Updated
24/09/2026	Medicine: Givlaari givosiran	Updated
24/09/2026	Document: Sponsor guidance: New safety module on the annual safety report	Updated
24/09/2026	Document: Member states guidance: New CTIS safety module on the annual safety report	Updated
24/09/2026	Page: Enpr-EMA priority activities	Updated
24/09/2026	Event: 18th Industry Standing Group (ISG) meeting	Updated

24/09/2026	Medicine: Susvimo ranibizumab	Updated
24/09/2026	Medicine: Pregabalin Viartis Pharma (previously Pregabalin Pfizer) pregabalin	Updated
24/09/2026	Medicine: Tevimbra tislelizumab	Updated
24/09/2026	Medicine: Cometriq cabozantinib	Updated
24/09/2026	Document: PDCO minutes of the 21-24 July 2026 meeting	New
24/09/2026	Document: Member states contact points for review of national implementation of quick response (QR) codes of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP), decentralised procedures (DCP) and national procedures	Updated
24/09/2026	Document: INS-GCP-1 procedure for coordinating good-clinical-practice inspections requested by the CHMP	Updated
24/09/2026	Page: Clinical requirements for medicines intended for the treatment of sickle cell disease	New
24/09/2026	Document: Draft guideline on the clinical requirements for medicines intended for the treatment of sickle cell disease	New
24/09/2026	Page: Clinical requirements for medicines intended for the treatment of thalassaemia	New
24/09/2026	Document: Draft guideline on the clinical requirements for medicines intended for the treatment of thalassaemia	New
23/09/2026	Event: Real-world data collection in Duchenne muscular dystrophy: Joint Heads of Medicines Agencies (HMA) / European Medicines Agency (EMA) multistakeholder workshop	Updated
23/09/2026	Document: Agenda of the HMPC meeting 22-24 September 2026	Updated
23/09/2026	Event: First European Medicines Agency (EMA) and Active Pharmaceutical Ingredients Committee (APIC) bilateral meeting	Updated
24/09/2026	Event: Regulatory perspectives on herbal medicinal / botanical drug product development: Joint FDA / EMA workshop	Updated
23/09/2026	Medicine: Otulfi ustekinumab	Updated
23/09/2026	Medicine: Fintepla fenfluramine	Updated
23/09/2026	Medicine: Dimethyl fumarate Accord dimethyl fumarate	Updated
23/09/2026	Medicine: Onerji levodopa; carbidopa	Updated
23/09/2026	Document: List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment	Updated
23/09/2026	Document: Veterinary Union Pharmacovigilance Database - Best Practice Guide	Updated
23/09/2026	Event: Managing product data quality in PMS: processes, known issues, current status and best practices	Updated
23/09/2026	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
23/09/2026	Document: Minutes of the COMP meeting 14-15 July 2026	New
23/09/2026	Document: List of Union reference dates and frequency of submission of periodic safety update reports (PSURs)	Updated
23/09/2026	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - September 2026	Updated

22/09/2026	Medicine: mCombria influenza mRNA vaccine; COVID-19 mRNA vaccine	Updated
22/09/2026	Medicine: Pegasys peginterferon alfa-2a	Updated
22/09/2026	Medicine: Prevenar 13 pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)	Updated
22/09/2026	Medicine: Blincto blinatumomab	Updated
22/09/2026	Medicine: Xbony denosumab	Updated
22/09/2026	Medicine: Leflunomide Zentiva (previously Leflunomide Winthrop) leflunomide	Updated
22/09/2026	Medicine: Xarelto rivaroxaban	Updated
22/09/2026	Medicine: Icotyde icotrokinra hydrochloride	Updated
22/09/2026	Medicine: Zokve ensitrelvir	Updated
22/09/2026	Medicine: Tacquell Autologous melanoma-derived tumor infiltrating lymphocytes, ex vivo-expanded	Updated
22/09/2026	Page: CHMP opinions on consultation procedures on ancillary substances incorporated in a medical device	Updated
22/09/2026	Document: Records of data processing activity Industry Single Point of Contact (i-SPOC) reporting system	Updated
22/09/2026	Document: European Medicines Agency's privacy statement for the Industry Single Point of Contact (i-SPOC) system	Updated
22/09/2026	Medicine: Yeytuo lenacapavir	Updated
22/09/2026	Medicine: Denosumab Ascend denosumab	Updated
22/09/2026	Page: Assessment templates and guidance	Updated
22/09/2026	Event: SME info day - navigating EMA support: From innovation to marketing authorisation	Updated
22/09/2026	Event: Sixth veterinary big data stakeholder forum	New
22/09/2026	Shortage: Human normal immunoglobulins human normal immunoglobulins	Updated
21/09/2026	Medicine: Mysildec sildenafil	Updated
21/09/2026	Medicine: Onpattro patisiran	Updated
21/09/2026	Medicine: Fruzaqla fruquintinib	Updated
21/09/2026	Medicine: Mounjaro tirzepatide	Updated
21/09/2026	Medicine: Litfulo ritlecitinib	Updated
21/09/2026	Medicine: Wegovy semaglutide	Updated
21/09/2026	Medicine: Entecavir Viartis (previously Entecavir Mylan) entecavir	Updated
21/09/2026	Medicine: Elahere mirvetuximab soravtansine	Updated

21/09/2026	Medicine: Osenvelt denosumab	Updated
21/09/2026	Document: Report on the International Active Pharmaceutical Ingredient Inspection Programme 2017 – 2024	Updated
21/09/2026	Page: Data Analysis and Real World Interrogation Network (DARWIN EU)	Updated
21/09/2026	Page: ICH guideline M13B on bioequivalence for immediate-release solid oral dosage forms - additional strengths biowaiver - Scientific guideline	Updated
21/09/2026	Document: ICH M13B guideline on bioequivalence for immediate-release solid oral dosage forms - additional strengths biowaiver: Questions and Answers - Step 5	New
21/09/2026	Document: ICH M13B guideline on bioequivalence for immediate-release solid oral dosage forms - additional strengths biowaiver - Step 5	New
18/09/2026	Post-authorisation: Pepaxti - opinion on variation to marketing authorisation melphalan flufenamide	New

NOTICE TO APPLICANTS

No updates since July 10th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
24.09.2026	Aktuelle Hinweise zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
23.09.2026	Natriumoxybat: Überprüfung der Anwendung bei Alkoholabhängigkeit Wirkstoff: NatriumoxybatDer CHMP kommt in seinem Gutachten zu dem Schluss, dass der Nutzen von Natriumoxybat bei Menschen mit Alkoholabhängigkeit weiterhin die Risiken überwiegt.
22.09.2026	Ipidacrin: Überprüfung der Wirksamkeit in den zugelassenen Indikationen Wirkstoff: IpidacrinDie Europäische Arzneimittel-Agentur (EMA) schließt die Überprüfung von ipidacrinhaltigen Arzneimitteln ab.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
25.09.2026	Risiko eines vorübergehenden Geräte-Lock-outs bei fehlerhaft initialisierter Echtzeituhr (RTC) Das BfArM informiert über eine fehlerhafte Initialisierung der Echtzeituhr (Real-Time Clock, RTC) bei bestimmten sondenlosen Herzschrittmachern vom Typ Micra™ und über die daraus resultierende Möglichkeit eines vorübergehenden Geräte-Lock-outs.
24.09.2026	Webinarreihe DiGA Am 15. September 2026 fand das Webinar "Umsetzung der anwendungsbegleitenden Erfolgsmessung (AbEM)" statt.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since September 17th, 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedropa updates will be presented quarterly.

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