TABLE OF CONTENTS

HEADS OF AGENCIES – CMDh

No updates since August 4th, 2026.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
11/09/2026	**Medicine**: Aybintio bevacizumab	Updated
11/09/2026	**Medicine**: Saphnelo anifrolumab	Updated
11/09/2026	**Medicine**: Vyloy zolbetuximab	Updated
11/09/2026	**Medicine**: Repaglinide Accord repaglinide	Updated
11/09/2026	**Medicine**: Bilprevda denosumab	Updated
11/09/2026	**Medicine**: Emgality galcanezumab	Updated
11/09/2026	**Medicine**: Lynkuet elinzanetant	Updated
11/09/2026	**Medicine**: Cirbloc porcine circovirus vaccine (inactivated)	New
11/09/2026	**Medicine**: AviGate S. Typhimurium Salmonella enterica, subsp. enterica, serovar Typhimurium, strain Nal2/Rif9/Rtt, Live	New
11/09/2026	**News**: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 8-10 September 2026	New
11/09/2026	**Post-authorisation**: Firocoxib CP-Pharma - opinion on variation to marketing authorisation firocoxib	New

Date	Content	Status
11/09/2026	**Post-authorisation**: Vectormune HVT-AIV - opinion on variation to marketing authorisation Avian influenza vaccine	New
11/09/2026	**Post-authorisation**: Felpreva - opinion on variation to marketing authorisation emodepside; praziquantel; tigolaner	New
11/09/2026	**Post-authorisation**: Vectra 3D - opinion on variation to marketing authorisation dinotefuran, permethrin, and pyriproxyfen	New
11/09/2026	**Page**: ICH M12 on drug interaction studies - Scientific guideline	Updated
11/09/2026	**Document**: Draft guideline on the investigation of interactions in the gastrointestinal tract	New
10/09/2026	**Event**: HMA / EMA multistakeholder AI and Data forum: Build trustworthy AI on strong data foundations	Updated
10/09/2026	**Referral**: Veterinary medicinal products containing amoxicillin - referral amoxicillin	Updated
10/09/2026	**Medicine**: Xeljanz tofacitinib	Updated
10/09/2026	**Medicine**: Uzpruvo ustekinumab	Updated
10/09/2026	**Medicine**: Zoledronic acid Mylan zoledronic acid	Updated
10/09/2026	**Medicine**: Tagrisso osimertinib	Updated
10/09/2026	**Medicine**: Moventig naloxegol	Updated
10/09/2026	**Event**: First European Medicines Agency (EMA) - International Society for Cell and Gene Therapy (ISCT) bilateral meeting	New
10/09/2026	**Event**: Fifth European Medicines Agency (EMA) - Vaccines Europe bilateral meeting	New
10/09/2026	**Event**: Product Management Service (PMS) public API beta release - Technical overview and live demo	Updated
10/09/2026	**Page**: Clinical investigation of medicinal products for treatment of migraine - Scientific guideline	Updated
10/09/2026	**Document**: Draft guideline on clinical investigation of medicinal products for the treatment of migraine and cluster headache - Revision 2	New
09/09/2026	**PSUSA**: PSUSA/00000405/202601 - periodic safety update report single assessment bezafibrate	New
09/09/2026	**Medicine**: Amvuttra vutrisiran	Updated
09/09/2026	**Page**: Expert panel support for orphan medical devices	Updated
09/09/2026	**Document**: Orphan medical devices regular process: 2027 timetable	New

Date	Content	Status
09/09/2026	**Page**: Scientific advice for high-risk medical devices	Updated
09/09/2026	**Medicine**: Perjeta pertuzumab	Updated
09/09/2026	**Document**: Advice to medical device manufacturers - 2027 Timetable	New
09/09/2026	**Medicine**: Zilbrysq zilucoplan	Updated
09/09/2026	**Medicine**: Zercepac trastuzumab	Updated
09/09/2026	**Medicine**: Colchicine Agepha Pharma colchicine	Updated
09/09/2026	**Event**: EMA Biotech Hub and Technology Transfer Offices (TTOs) engagement workshop	New
09/09/2026	**Document**: Agenda of the PRAC meeting 31 August - 3 September 2026	Updated
09/09/2026	**Document**: Electronic submission of Article 57(2) data: questions and answers	Updated
09/09/2026	**Document**: Chapter 3.II: XEVPRM detailed user guidance on the electronic submission of information on medicinal products for human use by marketing authorisation holders to the EMA	Updated
09/09/2026	**Document**: QRD veterinary Appendix I - Adverse event (PhV) MSs reporting details	Updated
09/09/2026	**Event**: 2026 annual open meeting of the European Network of Paediatric Research at EMA (EnprEMA)	New
09/09/2026	**Document**: Applications for new human medicines under evaluation: September 2026	New
09/09/2026	**Shortage**: Eskazole / Zentel albendazole	New
09/09/2026	**Shortage**: Natpar parathyroid hormone	Updated
09/09/2026	**Medicine**: Qezzaqar catequentinib	Updated
09/09/2026	**Page**: Good pharmacovigilance practices (GVP)	Updated
09/09/2026	**Document**: Guidelines on good pharmacovigilance practices (GVP): Introductory cover note, last updated with revision 2 of Module III on pharmacovigilance inspections	New
09/09/2026	**Document**: Guideline on good pharmacovigilance practices: Module III - Pharmacovigilance inspections (Rev. 2) with tracked changes	New
09/09/2026	**Document**: Guideline on good pharmacovigilance practices: Module III - Pharmacovigilance inspections (Rev. 2)	New
09/09/2026	**Document**: Agenda of the CAT meeting 9-11 September 2026	New

Date	Content	Status
08/09/2026	**Medicine**: Benlysta belimumab	Updated
08/09/2026	**Medicine**: Rinvoq upadacitinib	Updated
08/09/2026	**Medicine**: Sivextro tedizolid phosphate	Updated
08/09/2026	**Medicine**: Suliqua insulin glargine; lixisenatide	Updated
08/09/2026	**Medicine**: Lucentis ranibizumab	Updated
08/09/2026	**Medicine**: Bexsero meningococcal group B Vaccine (rDNA, component, adsorbed)	Updated
08/09/2026	**Medicine**: Vislyfa ranibizumab	Updated
08/09/2026	**Medicine**: Lupkynis voclosporin	Updated
08/09/2026	**Medicine**: Kavigale sipavibart	Updated
08/09/2026	**Medicine**: Rezolsta darunavir; cobicistat	Updated
08/09/2026	**PSUSA**: PSUSA/00003159/202512 - periodic safety update report single assessment antithrombin III	New
08/09/2026	**Document**: Agenda of the CVMP meeting 8-10 September 2026	New
08/09/2026	**PSUSA**: PSUSA/00010710/202601 - periodic safety update report single assessment alitretinoin (oral use)	New
08/09/2026	**Medicine**: Olumiant baricitinib	Updated
08/09/2026	**Document**: Member states contact points for translations review	Updated
08/09/2026	**Medicine**: Gardasil 9 human papillomavirus 9-valent vaccine (recombinant, adsorbed)	Updated
07/09/2026	**Event**: EMA/FVE information session for veterinary students: the importance of pharmacovigilance	New
07/09/2026	**Medicine**: Xolremdi mavorixafor	Updated
07/09/2026	**Document**: Co-ordinating good manufacturing practice (GMP) inspections for centrally authorised products	Updated
07/09/2026	**Medicine**: Fymskina ustekinumab	Updated
07/09/2026	**Document**: Agenda - PDCO agenda of the 8-11 September 2026 meeting	New
07/09/2026	**Medicine**: Arava leflunomide	Updated
07/09/2026	**Medicine**: Nordimet methotrexate	Updated
07/09/2026	**Medicine**: Jylamvo methotrexate	Updated

Date	Content	Status
07/09/2026	**Document**: Agenda of the COMP Meeting 8-10 September 2026	New
07/09/2026	**PSUSA**: PSUSA/00000560/202601 - periodic safety update report single assessment carboprost	New
07/09/2026	**Event**: EMA Methodology Working Party interested parties meeting 2026	New
07/09/2026	**PSUSA**: PSUSA/00000164/202601 - periodic safety update report single assessment aminophylline	New
07/09/2026	**Page**: QRD guidance on the use of adopted abbreviations and pictograms on the packaging of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP), decentralised (DCP), subsequent recognition (SRP) and national procedures	Updated
07/09/2026	**Document**: Guidance on the revised pre-submission interactions model	Updated

NOTICE TO APPLICANTS

No updates since June 24th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
08.09.2026	**Vorläufige Tagesordnung der 99. Routinesitzung am 28. September 2026** Die 99. Routinesitzung nach § 63 AMG wird am 28. September 2026 ab 10:00 Uhr als Videokonferenz stattfinden.
07.09.2026	**Umsetzung des Durchführungsbeschlusses der Europäischen Kommission vom 20.08.2026 zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Methotrexat** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Methotrexat infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
07.09.2026	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 25.06.2026 betreffend die Zulassungen für Humanarzneimittel mit der Wirkstoffkombination Ramipril/Bisoprolol** Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffkombination Ramipril/Bisoprolol infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
08.09.2026	**Vorläufige Tagesordnung der 99. Routinesitzung am 28. September 2026** Die 99. Routinesitzung nach § 63 AMG wird am 28. September 2026 ab 10:00 Uhr als Videokonferenz stattfinden.
08.09.2026	**HIIS-VZ nach § 374a SGB V** Mit dem in Kraft treten von § 374a SGB V stehen Hersteller von Hilfsmitteln und Implantaten gemäß Kabinettsentwurf für ein Gesetz für Daten und digitale Innovation im Gesundheitswesen (GeDIG) ab dem 01.01.2028 in der Verantwortung, interoperable Schnittstellen anzubieten, damit erhobene Gesundheitsdaten an eine DiGA übermittelt werden können.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since August 3rd, 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.