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04 February

NEW - Report from the meeting held on 27-28 January 2026

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NEW - 09-11 December CMDh minutes

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
06/02/2026	**Document**: Guideline on good pharmacovigilance practices (GVP): Product- or population-specific considerations III: Pregnant and breastfeeding women and their children exposed in utero or via breastmilk - with tracked changes	New
06/02/2026	**Document**: Comments received from public consultation on good pharmacovigilance practices (GVP) Product- or Population-Specific Considerations III: Pregnant and breastfeeding women (EMA/653036/2019)	New
06/02/2026	**Document**: Guidelines on good pharmacovigilance practices (GVP): Introductory cover note, last updated with final considerations on pregnant and breastfeeding women and their children exposed in utero or via breastmilk	New
06/02/2026	**Document**: Guideline on good pharmacovigilance practices (GVP): Product- or population-specific considerations III: Pregnant and breastfeeding women and their children exposed in utero or via breastmilk	New
06/02/2026	**Page**: Good pharmacovigilance practices (GVP)	Updated
06/02/2026	**Page**: Archive of development of good pharmacovigilance practices	Updated
06/02/2026	**Page**: Fees for veterinary medicines	Updated
06/02/2026	**Page**: Fees for human medicines	Updated

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06/02/2026	**Document**: Highlights – 1st European Medicine Agency (EMA) and European Respiratory Society (ERS) bilateral meeting	New
06/02/2026	**Medicine**: Bildyos denosumab	Updated
06/02/2026	**Medicine**: Tepkinly epcoritamab	Updated
06/02/2026	**Medicine**: Helicobacter Test INFAI 13C-urea	Updated
06/02/2026	**Medicine**: Tuznue trastuzumab	Updated
06/02/2026	**Medicine**: Cibinqo abrocitinib	Updated
06/02/2026	**Medicine**: Exforge HCT amlodipine besilate; valsartan; hydrochlorothiazide	Updated
06/02/2026	**Medicine**: Alymsys bevacizumab	Updated
06/02/2026	**Medicine**: Dafiro HCT amlodipine besilate; valsartan; hydrochlorothiazide	Updated
06/02/2026	**Medicine**: Copalia HCT amlodipine; valsartan; hydrochlorothiazide	Updated
06/02/2026	**Page**: Other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices	Updated
06/02/2026	**Page**: Combination Products Operational Group: agendas and highlight reports	Updated
06/02/2026	**Page**: Annual fees payable to the European Medicines Agency	Updated
06/02/2026	**Document**: Agenda - Combination products operational group, In vitro diagnostics (IVD) stream, 9 February 2026	New
06/02/2026	**Medicine**: Retsevmo selpercatinib	Updated
06/02/2026	**Document**: Agenda - Combination products operational group, Medical devices (MD) stream, 12 February 2026	New
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06/02/2026	**Document**: Overview of (invented) names reviewed in November 2025 by the Name Review Group (NRG) adopted at the CHMP meeting of 11 December 2025	Updated
06/02/2026	**Medicine**: Rayvow lasmiditan	Updated
06/02/2026	**Page**: Medicine shortages and availability issues	Updated
06/02/2026	**Page**: Drug Shortages Global Regulatory Working Group	Updated
06/02/2026	**Medicine**: Mounjaro tirzepatide	Updated
06/02/2026	**PSUSA**: PSUSA/00003006/202503 - periodic safety update report single assessment tranexamic acid	New
06/02/2026	**Medicine**: Insulin aspart Sanofi insulin aspart	Updated

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06/02/2026	**Medicine**: Kisunla donanemab	Updated
06/02/2026	**Document**: Agenda - Webinar on the use of platform technologies in the non-clinical and clinical domains	Updated
06/02/2026	**Medicine**: Xerava eravacycline	Updated
06/02/2026	**Page**: COVID-19 vaccines: key facts	Updated
06/02/2026	**Event**: LinkedIn Live: How EMA supports innovation in medicine development	New
06/02/2026	**Page**: Medicines during pregnancy and breastfeeding	Updated
06/02/2026	**Medicine**: Azarga brinzolamide; timolol	Updated
06/02/2026	**Document**: Drug Shortages Global Regulatory Working Group: Group statement published on behalf of the Working Group by EMA	New
05/02/2026	**Medicine**: Eltrombopag Viatris eltrombopag	Updated
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05/02/2026	**Medicine**: Dasatinib Accord Healthcare dasatinib	Updated
05/02/2026	**Medicine**: Kesimpta ofatumumab	Updated
05/02/2026	**Medicine**: Clopidogrel Zentiva (previously Clopidogrel Winthrop) clopidogrel	Updated
05/02/2026	**Medicine**: Entyvio vedolizumab	Updated
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05/02/2026	**Document**: Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 26-29 January 2026	Updated
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05/02/2026	**Medicine**: Yuvanci macitentan; tadalafil	Updated
05/02/2026	**Medicine**: Vazkepa icosapent ethyl	Updated
05/02/2026	**Medicine**: Lyxumia lixisenatide	Updated
05/02/2026	**Medicine**: Yuflyma adalimumab	Updated
05/02/2026	**Event**: Committee for Advanced Therapies (CAT): 3-5 December 2025	Updated
05/02/2026	**Document**: Applications for new human medicines under evaluation: February 2026	New
05/02/2026	**Event**: Third European Medicines Agency (EMA) and IPFA - PPTA global bilateral meeting	New
05/02/2026	**Medicine**: DuoTrav travoprost; timolol	Updated
05/02/2026	**Document**: List of medicines currently in PRIME scheme	Updated

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05/02/2026	**Medicine**: Spevigo spesolimab	Updated
05/02/2026	**Document**: Procedural advice for vaccine platform technology master file (vPTMF) certification	Updated
05/02/2026	**Document**: Procedural advice for veterinary vaccine antigen master file (VAMF) certification	Updated
05/02/2026	**Medicine**: Wegovy semaglutide	Updated
05/02/2026	**Medicine**: Tocilizumab STADA (previously Tofidence) tocilizumab	Updated
05/02/2026	**Document**: HMPC meeting report on European Union herbal monographs, guidelines and other activities - 19-21 January 2026	New
05/02/2026	**Document**: European Medicines Agency's data protection notice for EudraVigilance Human (EV)	Updated
05/02/2026	**Medicine**: Prevenar 13 pneumococcal polysaccharide conjugate vaccine (13-valent, adsorbed)	Updated
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04/02/2026	**Document**: Start of procedure: Type II Variation - Extension of indication under evaluation by the CHMP (12 December 2025 - 29 January 2026)	New
04/02/2026	**Event**: Industry stakeholder webinar on revised environmental risk assessment guideline for medicinal products for human use - 1 year experience	Updated
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04/02/2026	**Medicine**: Sugammadex Amomed sugammadex	Updated
04/02/2026	**Page**: Epidemiological data on blood transmissible infections - Scientific guideline	Updated
04/02/2026	**Document**: Committee for Advanced Therapies (CAT): Work Plan 2026	New
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04/02/2026	**Document**: Hearing the Association of the European Self-Medication Industry (AESGP) during the HMPC November 2025 meeting	New
04/02/2026	**Document**: PRAC rapporteur post-authorisation-safety-study-protocol assessment-report template	Updated
04/02/2026	**Document**: Template PRAC assessment report of an non-interventional imposed PASS final study report	Updated
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04/02/2026	**Page**: National competent authorities (human)	Updated
04/02/2026	**Medicine**: Imraldi adalimumab	Updated

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04/02/2026	**Document**: List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs)	Updated
04/02/2026	**Document**: Plasma Master File (PMF) requirements - questions and answers for PMF holders	Updated
03/02/2026	**Document**: List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment	Updated
03/02/2026	**Medicine**: Sapropterin Dipharma sapropterin	Updated
03/02/2026	**Medicine**: Gilenya fingolimod	Updated
03/02/2026	**Document**: Three-year work plan for the Quality Drafting Group (QDG) of the Committee on Herbal Medicinal Products (HMPC)	Updated
03/02/2026	**Document**: CHMP work plan 2026	New
03/02/2026	**Medicine**: Uzpruvo ustekinumab	Updated
03/02/2026	**Medicine**: Trazimera trastuzumab	Updated
03/02/2026	**Medicine**: GalliaPharm gallium (68Ga) chloride; germanium (68Ge) chloride	Updated
02/02/2026	**Document**: Training module EV-M8 - Considerations on the international transfer of personal (health) data in ICSRs -SUSARs originating in the EU	Updated
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02/02/2026	**Document**: COMP work plan 2026	New
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02/02/2026	**Event**: EMA Veterinary Medicines Info Day 2026	Updated
02/02/2026	**Document**: Minutes – Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - 17 December 2025	New
02/02/2026	**Event**: 15th industry stakeholder platform on research and development support	Updated
02/02/2026	**Document**: Recommended submission dates for veterinary medicinal products	Updated
02/02/2026	**Event**: SPOR and XEVMPD status update webinar - Q1 2026	Updated
02/02/2026	**Document**: Union Product Database (UPD) registration guide for UI and API users	Updated
02/02/2026	**Page**: Human Medicines	Updated
02/02/2026	**Page**: EU enlargement	Updated
02/02/2026	**Document**: Organisation chart: Human Medicines	Updated

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
06.02.2026	**Erklärung zur Vorlage von Schulungsmaterial (Educational Material) für Parallelvertreiber und Parallelimporteure - Anhang zur Bekanntmachung vom 16.05.2013 über die Modalitäten der elektronischen Erst- und Folgeeinreichung sowie über die Bearbeitung von Schulungs- und Informationsmaterialien**
06.02.2026	**Rote-Hand-Brief zu Arixtra: Schwerwiegender Qualitätsmangel im Zusammenhang mit der Nadel in der vorgefüllten Spritze** Wirkstoff: Fondaparinux Natrium Die Firma Viatris Healthcare Limited informiert über Fälle von braunen Verfärbungen sowie Verstopfungen der Nadel bei dem Arzneimittel Arixtra Injektionslösung in einer Fertigspritze.
04.02.2026	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 11.12.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Linezolid** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Linezolid infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
04.02.2026	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 11.12.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Nefopam** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Nefopam infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
04.02.2026	**Ergebnisprotokoll der 97. Routinesitzung nach § 63 AMG am 11. November 2025** Das BfArM gibt das Ergebnisprotokoll der 97. Routinesitzung vom 11. November 2025 bekannt.
03.02.2026	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 11.12.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Isotretinoin (orale Darreichungsformen)** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Isotretinoin (orale Darreichungsformen) des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

Date	Title
02.02.2026	**Informationsbrief zu Kisqali 200 mg Filmtabletten der Firma Novartis: Änderung der Lagerungsbedingungen und Haltbarkeit** Wirkstoff: Ribociclib Die Firma Novartis Pharma GmbH informiert über Änderungen bei den Lagerungsbedingungen und der Haltbarkeit für Kisqali 200 mg.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since January 27th, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
05.02.2026	Chikungunya-Impfstoff Vimkunya mit französischer Beschriftung erneut in Deutschland verfügbar

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.