

TABLE OF CONTENTS

| | |
|--|---|
| HEADS OF AGENCIES – CMDH..... | 1 |
| HEADS OF AGENCIES – PAEDIATRIC REGULATION | 1 |
| EUROPEAN MEDICINES AGENCY (EMA) | 1 |
| NOTICE TO APPLICANTS..... | 6 |
| BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)..... | 6 |
| BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY) | 7 |
| PEI - VIGILANZ (SPECIFIC FOR GERMANY) | 7 |
| PHARMEUROPA TEXTS FOR COMMENT..... | 7 |

HEADS OF AGENCIES – CMDh

13 February

[Update - Q&A on Generics](#)

10 February

[NEW - Art. 46 PAR Elvanse \(lisdexamfetamine dimesylate\)](#)

[NEW - Art. 46 PAR Pneumovax and associated names \(pneumococcal polysaccharide vaccine\)](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

| Date | Content | Status |
|------------|--|---------|
| 16/02/2026 | PSUSA: PSUSA/00000080/202506 - periodic safety update report single assessment alfacalcidol | New |
| 16/02/2026 | Herbal: Ribis nigri folium - herbal medicinal product Blackcurrant Leaf | Updated |
| 16/02/2026 | Document: Draft European Union herbal monograph on Ribes nigrum L., folium - Revision 2 | New |
| 13/02/2026 | Medicine: Emepax maropitant | New |
| 13/02/2026 | News: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 10-12 February 2026 | New |
| 13/02/2026 | Post-authorisation: Suvaxyn PRRS MLV - opinion on variation to marketing authorisation porcine respiratory and reproductive syndrome virus, live | New |
| 13/02/2026 | Post-authorisation: Bluevac BTV (previously Bluevac BTV8) - opinion on variation to marketing authorisation | New |

| Date | Content | Status |
|------------|---|---------|
| 13/02/2026 | Document: Concept paper for the revision of the guideline on veterinary good pharmacovigilance practices (VGVP) Module: Signal Management (EMA/522332/2021) | New |
| 13/02/2026 | Document: Highlights - 6th EMA-AESGP bilateral meeting | New |
| 13/02/2026 | Document: Medicinal products for human use: monthly figures - January 2026 | New |
| 13/02/2026 | Medicine: Emtricitabine / Rilpivirine / Tenofovir Alafenamide Viatrix emtricitabine; rilpivirine; tenofovir alafenamide | Updated |
| 13/02/2026 | Medicine: Xerava eravacycline | Updated |
| 13/02/2026 | Referral: Levamisole-containing medicinal products - referral levamisole | Updated |
| 13/02/2026 | News: EMA recommends withdrawal of marketing authorisations for levamisole medicines | New |
| 13/02/2026 | News: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 9 - 12 February 2026 | New |
| 13/02/2026 | Page: Medicine shortage communications (MSC) | Updated |
| 13/02/2026 | Document: Medicine shortage communication (MSC): Natpar (parathyroid hormone) (25, 50, 75 and 100 micrograms/dose powder and solvent for solution for injection) | New |
| 13/02/2026 | Shortage: Ifosfamide ifosfamide | New |
| 13/02/2026 | Page: Clinical investigation of medicinal products in the treatment of Myasthenia Gravis | New |
| 13/02/2026 | Document: Concept paper on the need of a guideline on clinical investigation of medicinal products in the treatment of Myasthenia Gravis | New |
| 12/02/2026 | Page: Paediatric investigation plans: questions and answers | Updated |
| 12/02/2026 | Document: Review of the stepwise paediatric investigation plan (sPIP) pilot: Outcomes and future perspectives | New |
| 12/02/2026 | Page: Paediatric investigation plans | Updated |
| 12/02/2026 | Medicine: Vantavo (previously Alendronate sodium and colecalciferol, MSD) alendronic acid; colecalciferol | Updated |
| 12/02/2026 | Medicine: Palforzia defatted powder of Arachis hypogaea L., semen (peanuts) | Updated |
| 12/02/2026 | Event: Quarterly System Demo - Q1 2026 | Updated |
| 12/02/2026 | PSUSA: PSUSA/00002076/202506 - periodic safety update report single assessment mitoxantrone | New |
| 12/02/2026 | PSUSA: PSUSA/00000812/202506 - periodic safety update report single assessment clonazepam | New |
| 12/02/2026 | PSUSA: PSUSA/00002639/202507 - periodic safety update report single assessment rifabutin | New |
| 12/02/2026 | Event: Q&A clinic on Substance, Organisation, Referentials Management Services - March 2026 | Updated |

| Date | Content | Status |
|------------|--|---------|
| 12/02/2026 | Document: Guidance for applicants for the preparation of the precise scope section of the variation application form | Updated |
| 12/02/2026 | Medicine: Infanrix Hexa diphtheria (D), tetanus (T), pertussis (acellular, component) (Pa), hepatitis B (rDNA) (HBV), poliomyelitis (inactivated) (IPV) and Haemophilus influenzae type-b (Hib) conjugate vaccine (adsorbed) | Updated |
| 12/02/2026 | Medicine: Retsevmo selpercatinib | Updated |
| 12/02/2026 | Medicine: Adroavance alendronic acid; colecalciferol | Updated |
| 12/02/2026 | PSUSA: PSUSA/00001516/202506 - periodic safety update report single assessment ganciclovir | New |
| 12/02/2026 | PSUSA: PSUSA/00010291/202506 - periodic safety update report single assessment misoprostol (gastrointestinal indication) | New |
| 12/02/2026 | PSUSA: PSUSA/00001499/202502 - periodic safety update report single assessment gabapentin | Updated |
| 12/02/2026 | Event: Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPPD) service - March 2026 | Updated |
| 12/02/2026 | Medicine: Glyxambi empagliflozin; linagliptin | Updated |
| 12/02/2026 | Medicine: Jentaduetto linagliptin; metformin hydrochloride | Updated |
| 12/02/2026 | Page: CVMP recommendations on limited market classification and eligibility for authorisation under Article 23 | Updated |
| 12/02/2026 | Medicine: Trajenta linagliptin | Updated |
| 12/02/2026 | Event: 16th Industry Standing Group (ISG) meeting | New |
| 12/02/2026 | Medicine: Foscan temoporfin | Updated |
| 12/02/2026 | Medicine: Fosavance alendronic acid; colecalciferol | Updated |
| 12/02/2026 | Medicine: Kyinsu insulin icodec; semaglutide | Updated |
| 12/02/2026 | Document: Minutes of the PRAC meeting 24 - 27 November 2025 | New |
| 12/02/2026 | Event: SPOR and XEVMPPD status update webinar - Q1 2026 | Updated |
| 12/02/2026 | Medicine: Kapruvia difelikefalin | Updated |
| 12/02/2026 | Document: Antimicrobial Sales and Use (ASU) Platform: Release notes | Updated |
| 12/02/2026 | Document: Organisation chart: Human Medicines | Updated |
| 12/02/2026 | PSUSA: PSUSA/00002908/202412 - periodic safety update report single assessment testosterone (topical use) | New |
| 11/02/2026 | Event: Committee for Medicinal Products for Human Use (CHMP): 21-24 July 2025 | Updated |
| 11/02/2026 | Document: Annex to 21-24 July 2025 CHMP Minutes | New |

| Date | Content | Status |
|------------|---|---------|
| 11/02/2026 | Document: Minutes of the CHMP meeting 21-24 July 2025 | New |
| 11/02/2026 | Event: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party | Updated |
| 11/02/2026 | Document: Minutes - 2025 annual internal meeting of the members and Coordinating Group of the European network of paediatric research at the EMA (EnprEMA) | New |
| 11/02/2026 | Medicine: Siklos hydroxycarbamide | Updated |
| 11/02/2026 | PSUSA: PSUSA/00000662/202503 - periodic safety update report single assessment chlorhexidine | New |
| 11/02/2026 | Herbal: Oenotherae oleum - herbal medicinal product Evening primrose oil | Updated |
| 11/02/2026 | Herbal: Cimicifugae rhizoma - herbal medicinal product Black Cohosh | Updated |
| 11/02/2026 | Medicine: Imjudo tremelimumab | Updated |
| 11/02/2026 | Medicine: Steglatro ertugliflozin | Updated |
| 11/02/2026 | Medicine: Sephience sepiapterin | Updated |
| 11/02/2026 | Medicine: Romvimza vimseltinib | Updated |
| 11/02/2026 | Medicine: Qinlock ripretinib | Updated |
| 11/02/2026 | Medicine: Lumark lutetium (177Lu) chloride | Updated |
| 11/02/2026 | Medicine: HyQvia human normal immunoglobulin | Updated |
| 11/02/2026 | Page: Extended Eudra Vigilance medicinal product dictionary (XEVMPD) training | Updated |
| 11/02/2026 | Medicine: Plegridy peginterferon beta-1a | Updated |
| 11/02/2026 | Shortage: Norditropin FlexPro / Norditropin NordiFlex somatropin | Updated |
| 11/02/2026 | Page: ICH M15 guideline on general principles for model-informed drug development - Scientific guideline | Updated |
| 11/02/2026 | Document: ICH M15 Guideline on general principles for model-informed drug development - Step 5 | New |
| 10/02/2026 | Medicine: Adenuric febuxostat | Updated |
| 10/02/2026 | Event: Healthcare Professionals' Working Party (HCPWP) plenary meeting February 2026 | Updated |
| 10/02/2026 | Medicine: Qaialdo spironolactone | Updated |
| 10/02/2026 | Medicine: Elucirem gadopiclenol | Updated |

| Date | Content | Status |
|------------|---|---------|
| 10/02/2026 | Medicine: Vueway gadopiclenol | Updated |
| 10/02/2026 | Page: Aliskiren product-specific bioequivalence guidance | Updated |
| 10/02/2026 | Document: PhV non-compliance notification contact points at National Competent Authority (NCA) level | Updated |
| 10/02/2026 | Document: Agenda of the CVMP meeting 10-12 February 2026 | New |
| 10/02/2026 | Medicine: Winlevi clascoterone | Updated |
| 10/02/2026 | Document: Annex to 16-19 June 2025 CHMP Minutes | New |
| 10/02/2026 | Medicine: Imfinzi durvalumab | Updated |
| 10/02/2026 | Document: Minutes of the CHMP meeting 16-19 June 2025 | New |
| 10/02/2026 | Medicine: Carvykti ciltacabtagene autoleucel | Updated |
| 10/02/2026 | Document: Article 57 product data | Updated |
| 10/02/2026 | Document: List of eligible industry stakeholder organisations | Updated |
| 10/02/2026 | Document: Members of the Coordinating group of European network of paediatric research at the European Medicines Agency (Enpr-EMA) | Updated |
| 10/02/2026 | Page: Ledipasvir/sofosbuvir product-specific bioequivalence guidance | Updated |
| 10/02/2026 | Event: Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting | Updated |
| 10/02/2026 | Medicine: Piasky crovalimab | Updated |
| 10/02/2026 | Document: Validation checklist for Type II quality variations | Updated |
| 09/02/2026 | Medicine: Datroway datopotamab deruxtecan | Updated |
| 09/02/2026 | Medicine: Lytenava bevacizumab | Updated |
| 09/02/2026 | Document: Agenda of the PRAC meeting 9-12 February 2026 | New |
| 09/02/2026 | Page: Plasma master file certificates | Updated |
| 09/02/2026 | DHPC: Arixtra - direct healthcare professional communication (DHPC) fondaparinux sodium | New |
| 09/02/2026 | Shortage: Tresiba insulin degludec | Updated |
| 09/02/2026 | Document: Minutes of the COMP meeting 2-3 December 2025 | New |
| 09/02/2026 | Medicine: Zypadhera olanzapine | Updated |
| 09/02/2026 | Medicine: Azopt brinzolamide | Updated |
| 09/02/2026 | Medicine: Xadago safinamide | Updated |
| 09/02/2026 | Event: Third European Medicines Agency (EMA) and IPFA - PPTA global bilateral meeting | Updated |
| 09/02/2026 | Document: PRAC recommendations on signals adopted at the 12-15 January 2026 PRAC meeting | New |

| Date | Content | Status |
|------------|--|---------|
| 09/02/2026 | Document: New product information wording: extracts from PRAC recommendations on signals adopted at the 12-15 January 2026 PRAC | New |
| 09/02/2026 | Document: Concept paper on the revision of the guidelines on Good Manufacturing Practice for medicinal products - Annex 15 - Qualification and validation | New |
| 09/02/2026 | Document: List of signals discussed at PRAC since September 2012 | Updated |
| 09/02/2026 | Medicine: Uptravi selexipag | Updated |

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

| Date | Title |
|------------|--|
| 13.02.2026 | <p>Pharmacovigilance Risk Assessment Committee (PRAC)</p> <p>Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 09.02.-12.02.2026 behandelt wurden.</p> |
| 13.02.2026 | <p>Levamisol: Überprüfung des Risikos für eine Leukoenzephalopathie</p> <p>Wirkstoff: Levamisol</p> <p>Der für Pharmakovigilanzfragen bei Humanarzneimitteln zuständige Ausschuss der EMA (PRAC) hat den Widerruf der Zulassung levamisolhaltiger Arzneimittel und die Marktrücknahme empfohlen, da eine Leukoenzephalopathie eine seltene aber schwerwiegende Nebenwirkung darstellt und der Nutzen dieses Arzneimittel bei der Behandlung parasitärer Wurminfektionen bei Erwachsenen und Kindern die Risiken nicht mehr überwiegt.</p> |
| 10.02.2026 | <p>Umsetzung des Durchführungsbeschlusses der Kommission vom 30.01.2026 zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Testosteron (topische Anwendung)</p> <p>Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Testosteron (topische Anwendung) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.</p> |
| 10.02.2026 | <p>Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 11.12.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Cytarabin</p> <p>Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Cytarabin des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.</p> |

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since January 27th, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

| Date | Title |
|-------------|--|
| 13.02.2026 | Influenza-Impfstoff Influxac mit italienischer Beschriftung in Deutschland verfügbar |

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedeuropa updates will be presented quarterly.

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