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23 March 2026

NEW - 24-26 March CMDh agenda

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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EUROPEAN MEDICINES AGENCY (EMA)

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27/03/2026	**Orphan**: EU/3/25/3174 - orphan designation for treatment of myelofibrosis amsulostat	New

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27/03/2026	**Medicine**: Wakix pitolisant	Updated
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27/03/2026	**Referral**: Levamisole-containing medicinal products - referral levamisole	Updated
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27/03/2026	**Document**: EU implementation strategy of ICH E2D(R1) Guideline - Post-approval safety data: Definitions and standards for management and reporting of individual case safety reports	Updated
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27/03/2026	**Page**: Data quality framework for medicines regulation	Updated
27/03/2026	**Page**: Risk management plans (RMP) in post-authorisation phase: questions and answers	Updated
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27/03/2026	**Document**: Outcome of the public consultation on the Data Quality Framework for EU Medicines Regulation: application to Real-World Data	New
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27/03/2026	**Page**: Worksharing: questions and answers	Updated
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27/03/2026	**Document**: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure	Updated
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27/03/2026	**Orphan**: EU/3/20/2339 - orphan designation for treatment of activated phosphoinositide 3-kinase delta syndrome Leniolisib	Updated
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27/03/2026	**Post-authorisation**: Tafinlar - opinion on variation to marketing authorisation dabrafenib	New
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26/03/2026	**Orphan**: EU/3/25/3163 - orphan designation for treatment of oesophageal cancer zimberelimab	New
26/03/2026	**Orphan**: EU/3/25/3165 - orphan designation for treatment of alpha-mannosidosis autologous peripheral blood-derived CD34+ haematopoietic stem and progenitor cells transduced with a lentiviral vector containing the human MAN2B1 gene	New

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26/03/2026	**Medicine**: Axumin fluciclovine (18F)	Updated
26/03/2026	**Orphan**: EU/3/25/3168 - orphan designation for treatment of oesophageal cancer domvanalimab	New
26/03/2026	**Orphan**: EU/3/25/3161 - orphan designation for treatment of autosomal dominant polycystic kidney disease humanised IgG1 kappa monoclonal antibody against pregnancy-associated plasma protein A	New
26/03/2026	**Orphan**: EU/3/25/3172 - orphan designation for treatment of biotin-thiamine-responsive basal ganglia disease (BTBGD) biotin	New
26/03/2026	**Orphan**: EU/3/25/3164 - orphan designation for treatment of cutaneous T-cell lymphoma human IgG1 monoclonal antibody against tumor necrosis factor receptor superfamily member 1B	New
26/03/2026	**Orphan**: EU/3/25/3167 - orphan designation for treatment of gastric cancer zimberelimab	New
26/03/2026	**Orphan**: EU/3/25/3160 - orphan designation for treatment of idiopathic pulmonary fibrosis adeno-associated virus vector serotype 6.2 containing human TERT gene	New
26/03/2026	**Medicine**: Ritonavir Viatris (previously Ritonavir Mylan) ritonavir	Updated
26/03/2026	**Orphan**: EU/3/25/3175 - orphan designation for treatment of glioma iniparib	New
26/03/2026	**Orphan**: EU/3/25/3176 - orphan designation for treatment in solid organ transplantation potravitug	New
26/03/2026	**Page**: Vaccine-preventable diseases: key facts	Updated
26/03/2026	**Page**: Vaccine Essentials: Supporting vaccine literacy	New
26/03/2026	**Document**: Vaccine Essentials: Meningococcal group B vaccines - facts and figures overview	New
26/03/2026	**Medicine**: Xtandi enzalutamide	Updated
26/03/2026	**Page**: Pharmaceutical quality system (PQS) effectiveness pilot project	New
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26/03/2026	**Page**: Clinical Trials Information System (CTIS): training and support	Updated
26/03/2026	**Document**: Clinical Trial Information System (CTIS) - Sponsor Frequently Asked Questions (FAQ)	New
26/03/2026	**Document**: Clinical Trial Information System (CTIS) - Sponsor handbook	Updated
25/03/2026	**Orphan**: EU/3/25/3183 - orphan designation for treatment idiopathic pulmonary fibrosis deupirfenidone	New
25/03/2026	**Orphan**: EU/3/25/3182 - orphan designation for treatment of hypoparathyroidism canvuparatide	New

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25/03/2026	**Orphan**: EU/3/25/3185 - orphan designation for treatment of autosomal dominant polycystic kidney disease human IgG1 kappa monoclonal antibody against pappalysin-1	New
25/03/2026	**Orphan**: EU/3/25/3178 - orphan designation for treatment of myelofibrosis navtemadlin	New
25/03/2026	**Orphan**: EU/3/25/3194 - orphan designation for treatment of fibrodysplasia ossificans progressiva saracatinib	New
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25/03/2026	**Orphan**: EU/3/25/3184 - orphan designation for treatment of follicular lymphoma surovatamig	New
25/03/2026	**Orphan**: EU/3/25/3116 - orphan designation for treatment of tuberculosis alpibectir; ethionamide	New
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25/03/2026	**Medicine**: SomaKit TOC edotreotide	Updated
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25/03/2026	**Document**: HMPC meeting report on European Union herbal monographs, guidelines and other activities - 2-4 March 2026	New
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25/03/2026	**Document**: QRD Appendix V - Adverse-drug-reaction reporting details	Updated
25/03/2026	**Document**: QRD Appendix II - Medical Dictionary for Regulatory Activities terminology to be used in section 4.8 'undesirable effects' of the summary of product characteristics (Cover page)	Updated
25/03/2026	**Document**: QRD Appendix II - Medical Dictionary for Regulatory Activities terminology to be used in section 4.8 'undesirable effects' of the summary of product characteristics	Updated
25/03/2026	**Document**: Names of the European Union / European Economic Area countries	Updated
25/03/2026	**Document**: Tables of non-standard abbreviations to be used in the summary of product characteristics	Updated
25/03/2026	**Document**: List of official languages per country	Updated

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25/03/2026	**PIP**: EMEA-003318-PIP01-22 - paediatric investigation plan modRNA encoding 4 influenza HA antigens (2 for influenza A and 2 for influenza B strains) (qIRV)	Updated
25/03/2026	**PIP**: EMEA-001484-PIP01-13-M01 - paediatric investigation plan Elobixibat	Updated
25/03/2026	**PIP**: EMEA-000814-PIP01-09 - paediatric investigation plan birch pollen; alder pollen; hazel pollen	Updated
25/03/2026	**PIP**: EMEA-000811-PIP01-09 - paediatric investigation plan grass pollen; rye pollen; birch pollen	Updated
25/03/2026	**PIP**: EMEA-000815-PIP01-09-M01 - paediatric investigation plan Dermatophagoides pteronyssinus and Dermatophagoides farinae extracts (50%/50%)	Updated
25/03/2026	**PIP**: EMEA-000808-PIP01-09-M01 - paediatric investigation plan Birch, hazel and alder pollen extracts	Updated
25/03/2026	**Page**: Changing the (invented) name of a centrally authorised medicine: questions and answers	Updated
25/03/2026	**PIP**: EMEA-000806-PIP01-09 - paediatric investigation plan 12 Grass Pollen Extract and Cultivated Rye Pollen Extract	Updated
25/03/2026	**PIP**: EMEA-000807-PIP01-09 - paediatric investigation plan Dermatophagoides pteronyssinus and Dermatophagoides farinae extracts (50%/50%)	Updated
25/03/2026	**PIP**: EMEA-000812-PIP01-09 - paediatric investigation plan 12 grass pollen extract, cultivated rye pollen extract and birch/alder/hazel pollen extract	Updated
25/03/2026	**PIP**: P/28/2010 - paediatric investigation plan dalcetrapib	Updated
25/03/2026	**PIP**: EMEA-002101-PIP02-18-M01 - paediatric investigation plan iodine (131-I) murine IgG1 monoclonal antibody against B7-H3 (131I-omburtamab)	Updated
25/03/2026	**PIP**: EMEA-001964-PIP02-19 - paediatric investigation plan cannabidiol	Updated
25/03/2026	**Medicine**: Bemfola follitropin alfa	Updated
25/03/2026	**PIP**: EMEA-001964-PIP03-21 - paediatric investigation plan cannabidiol	Updated
25/03/2026	**PIP**: EMEA-002142-PIP01-17 - paediatric investigation plan trazodone (hydrochloride)	Updated
25/03/2026	**PIP**: EMEA-000977-PIP01-10 - paediatric investigation plan house dust mites allergen extract from Dermatophagoides pteronyssinus and Dermatophagoides farinae (50/50)	Updated
25/03/2026	**PIP**: EMEA-003277-PIP02-23 - paediatric investigation plan live attenuated respiratory syncytial virus (RSV)	Updated
25/03/2026	**PSUSA**: PSUSA/00000535/202504 - periodic safety update report single assessment captopril	New
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25/03/2026	**Document**: Member states contact points for translations review	Updated
25/03/2026	**Document**: 2025 European Medicines Agency annual report on independence	New
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24/03/2026	**Medicine**: MenQuadfi meningococcal group A, C, W-135 and Y conjugate vaccine	Updated
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24/03/2026	**Medicine**: Kadcyla trastuzumab emtansine	Updated
24/03/2026	**Medicine**: Noxafil posaconazole	Updated
24/03/2026	**Event**: Committee for Advanced Therapies (CAT): 18-20 February 2026	Updated
24/03/2026	**Document**: Bioabsorbable orthopaedic screws - Notified body 0344 - 14/05/2024 - Expert decision and opinion in the context of the clinical evaluation consultation procedure (CECP)	New
24/03/2026	**Medicine**: Grasustek pegfilgrastim	Updated
24/03/2026	**Medicine**: Qaialdo spironolactone	Updated
24/03/2026	**Document**: Minutes – Ad hoc Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - 5 March 2026	New
24/03/2026	**Medicine**: Vafseo vadadustat	Updated
24/03/2026	**Medicine**: Artesunate Amivas artesunate	Updated
24/03/2026	**Medicine**: Roclanda latanoprost / netarsudil	Updated
24/03/2026	**Medicine**: Jardiance empagliflozin	Updated
24/03/2026	**Medicine**: Velphoro sucroferric oxyhydroxide	Updated
24/03/2026	**Medicine**: Zynyz retifanlimab	Updated
24/03/2026	**Page**: Medicine shortage communications (MSC)	Updated
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24/03/2026	**Document**: Recommendations of the Executive Steering Group on the Shortages and Safety of Medicinal Products on shortages of intravenous ifosfamide and cyclophosphamide	New
24/03/2026	**Document**: Medicine Shortage Communication (MSC): Endoxan / Sendoxan / Genoxal (cyclophosphamide), 100 mg, 200 mg, 500 mg, 1 g and 2 g, powder for solution for injection or infusion	New
24/03/2026	**Document**: Medicine Shortage Communication (MSC): Holoxan / Tronoxal / Mitoxana (ifosfamide), 500 mg, 1 g and 2 g powder for solution for injection	New
24/03/2026	**PSUSA**: PSUSA/00000777/202507 - periodic safety update report single assessmentcisatracurium	New
24/03/2026	**Event**: Meeting of the Executive Steering Group on Shortages of Medical Devices (MDSSG)	Updated
24/03/2026	**Document**: Cardiac valves - Notified Body 0344 - 07/12/2021 - Expert decision and opinion in the context of the clinical evaluation consultation procedure (CECP)	New
24/03/2026	**Document**: Medicinal products for human use: monthly figures - February 2026	New
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24/03/2026	**Event**: Paediatric Committee (PDCO): 24-27 March 2026	Updated
24/03/2026	**Page**: Guidance on good manufacturing practice and good distribution practice: Questions and answers	Updated
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24/03/2026	**Document**: European Medicines Agency's data protection notice for the handling of data subjects' requests	Updated
24/03/2026	**PSUSA**: PSUSA/00001456/202508 - periodic safety update report single assessment flutrimazole	New
24/03/2026	**PSUSA**: PSUSA/00010803/202508 - periodic safety update report single assessment copper chloride dihydrate / manganese chloride tetrahydrate / potassium iodide / sodium fluoride / sodium selenite anhydrous / zinc chloride	New
24/03/2026	**PSUSA**: PSUSA/00010163/202508 - periodic safety update report single assessment human plasma protease C1 inhibitor (nationally authorised products)	New
24/03/2026	**Page**: Website outages and upgrades	Updated
23/03/2026	**Shortage**: Eli Lilly insulin (various forms)	New
23/03/2026	**Document**: Medicine Shortage Communication (MSC): Insulin (human insulin) (various short-, rapid-, intermediate-, mixed- and long-acting forms) 2026	New
23/03/2026	**Page**: Good Manufacturing Practice (GMP) / Good Distribution Practice (GDP) Inspectors Working Group	Updated
23/03/2026	**Medicine**: Shingrix herpes zoster vaccine (recombinant, adjuvanted)	Updated
23/03/2026	**Medicine**: Sondelbay teriparatide	Updated
23/03/2026	**Medicine**: Qutenza capsaicin	Updated

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23/03/2026	**Medicine**: Arexvy recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E	Updated
23/03/2026	**Medicine**: Vaborem meropenem; vaborbactam	Updated
23/03/2026	**Medicine**: Tremfya guselkumab	Updated
23/03/2026	**Medicine**: Opzelura ruxolitinib	Updated
23/03/2026	**Medicine**: Waylivra volanesorsen	Updated
23/03/2026	**Medicine**: Rxulti brexpiprazole	Updated
23/03/2026	**Document**: Outcome of written procedures finalised during the period from 4 December 2025 to 3 March 2026	New

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
27.03.2026	**Tecovirimat SIGA: Überprüfung der Wirksamkeit bei der Behandlung von Mpox** Wirkstoff: TecovirimatDer Ausschuss für Humanarzneimittel (CHMP) der EMA hat empfohlen, Tecovirimat SIGA nicht länger zur Behandlung von Mpox anzuwenden.
27.03.2026	**Levamisol: Überprüfung des Risikos für eine Leukoenzephalopathie** Wirkstoff: LevamisolDie Europäische Arzneimittel-Agentur (EMA) empfiehlt den Widerruf der Zulassungen levamisolhaltiger Arzneimittel.
27.03.2026	**Rote-Hand-Brief zu Accupaque Injektionslösung und Visipaque Injektionslösung: Risiko von Partikeln** Wirkstoff: Iohexol, IodixanolDie Firma GE Healthcare Buchler GmbH & Co. KG informiert über das mögliche Risiko von Partikeln in bestimmten Chargen der beiden Arzneimittel Accupaque Injektionslösung und Visipaque Injektionslösung.
25.03.2026	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 29.01.2026 betreffend die Zulassungen für Humanarzneimittel mit den Wirkstoffkombinationen Coffein/Codein/Paracetamol/Propyphenazon und Acetylsalicylsäure/Coffein/Codein/Paracetamol** Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffkombinationen Coffein/Codein/Paracetamol/Propyphenazon und Acetylsalicylsäure/Coffein/Codein/Paracetamol infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

Date	Title
25.03.2026	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 29.01.2026 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Cefixim** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Cefixim infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
24.03.2026	**Feststellung des rechtlichen Status und Klassifizierung** Zur Feststellung des rechtlichen Status sowie der Klassifizierung von Medizinprodukten werden die EU-Verordnungen 2017/745 (MDR) bzw. für In-vitro-Diagnostika die EU-Verordnung 2017/746 (IVDR) herangezogen. Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) entscheidet gemäß § 6 des Medizinprodukterecht-Durchführungsgesetzes (MPDG) auf Antrag unter anderem über die Klassifizierung und den rechtlichen Status von Produkten. Für die Entscheidungsfindung können auch weitere Quellen wie beispielsweise die MDCG-Dokumente der Europäischen Kommission Hilfestellungen bieten.
23.03.2026	**Registrierung von Medizinprodukten: Übergang vom DMIDS zu EUDAMED** Ab dem 28. Mai 2026 müssen neue Produkte verpflichtend in EUDAMED registriert werden, weiter in Verkehr gebrachte Produkte müssen bis zum 28. November in EUDAMED registriert sein. Die Pflicht zur Registrierung von Produkten im DMIDS entfällt.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
24.03.2026	Informationsschreiben von Biotest Pharma GmbH: Yimmugo

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.