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20 July

NEW - 21-22 July CMDh agenda

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
20/07/2026	**Event**: Cancer Medicines Forum: June 2026	New
20/07/2026	**Document**: Signal assessment report on neurodevelopmental disorders with paternal exposure to valproate and related substances	New
17/07/2026	**Document**: Advice on the influenza virus on request from the Medical Device Coordination Group	Updated
17/07/2026	**Document**: Veterinary pharmacovigilance cluster - Terms of reference	New
17/07/2026	**Document**: Veterinary medicinal products cluster - Terms of reference	New
17/07/2026	**Document**: Terms of reference for the European Medicines Agency, Health Canada and United States Food and Drugs Administration cluster on vaccines	New
17/07/2026	**Document**: Terms of reference for the European Medicines Agency – United States Food and Drugs Administration – Health Canada cluster on	New

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	real world data	
17/07/2026	**Document**: Terms of reference for the rare diseases cluster	New
17/07/2026	**Document**: Terms of reference for the cluster on pregnancy and lactation	New
17/07/2026	**Document**: Pharmacovigilance cluster – Terms of Reference	New
17/07/2026	**Document**: Pharmacometrics cluster – Terms of Reference	New
17/07/2026	**Document**: Pediatric cluster terms of reference	New
17/07/2026	**Document**: Terms of reference for the European Medicines Agency, United States Food and Drugs Administration and Health Canada cluster on patient engagement	New
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17/07/2026	**Document**: Terms of Reference for the Non-Clinical Oncology European Medicines Agency and United States Food and Drug Administration Cluster	New
17/07/2026	**Document**: Neuroscience Cluster – Terms of Reference	New
17/07/2026	**Document**: Terms of reference for the European Medicines Agency and United States Food and Drugs Administration cardiovascular cluster	New
17/07/2026	**Document**: Dual chamber leadless pacemaker - Notified Bodfy 123 - 28/03/2024 - Expert decision and opinion in the context of the clinical evaluation consultation procedure (CECP)	New
17/07/2026	**PSUSA**: PSUSA/00010532/202509 - periodic safety update report single assessment lisinopril, lisinopril / hydrochlorothiazide	New

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17/07/2026	**PSUSA**: PSUSA/00000421/202509 - periodic safety update report single assessment bivalirudin	New
17/07/2026	**Medicine**: Inaqovi cedazuridine; decitabine	Updated
17/07/2026	**Document**: List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment	Updated
17/07/2026	**Document**: Terms of reference for the European Medicines Agency, Health Canada and United States Food and Drug Administration cluster on blood products	New
17/07/2026	**Document**: Biostatistics cluster – Terms of Reference	New
17/07/2026	**Document**: Antivirals cluster – Terms of Reference	New
17/07/2026	**Document**: Terms of reference for biosimilars cluster	New
17/07/2026	**Medicine**: Anzupgo delgocitinib	Updated
17/07/2026	**Document**: Terms of reference for the advanced therapy medicinal products cluster	New
17/07/2026	**Medicine**: Kefdensis denosumab	Updated
17/07/2026	**Document**: Guiding principles for the EMA - US FDA cluster teleconferences on Artificial Intelligence in Pharmacovigilance	New
17/07/2026	**Medicine**: Hukyndra adalimumab	Updated
17/07/2026	**Medicine**: Fluenz influenza vaccine (live attenuated, nasal)	Updated
17/07/2026	**Medicine**: Flucelvax influenza vaccine (surface antigen, inactivated, prepared in cell cultures)	Updated
17/07/2026	**Medicine**: Fluad influenza vaccine (surface antigen, inactivated, adjuvanted)	Updated
17/07/2026	**Document**: Minutes of the HMPC meeting 4-6 May 2026	New

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17/07/2026	**PSUSA**: PSUSA/00002798/202411 - periodic safety update report single assessment sufentanil	New
17/07/2026	**Referral**: Veterinary medicinal products containing amoxicillin - referral amoxicillin	Updated
17/07/2026	**DHPC**: Tavneos - direct healthcare professional communication (DHPC) avacopan	New
17/07/2026	**Orphan**: EU/3/26/3236 - orphan designation for treatment of Kawasaki disease infliximab	New
17/07/2026	**Orphan**: EU/3/26/3238 - orphan designation for treatment of non-syndromic inherited retinal dystrophies of the rod-dominant phenotype allogeneic human induced pluripotent stem cell-derived photoreceptor precursor cells	New
17/07/2026	**Orphan**: EU/3/26/3237 - orphan designation for treatment of Charcot-Marie-Tooth disease allogeneic human Wharton's jelly-derived mesenchymal stem cells	New
17/07/2026	**Orphan**: EU/3/26/3234 - orphan designation for treatment of pulmonary neuroendocrine carcinoma humanised IgG1 monoclonal antibody against delta-like ligand 3, octakis(thioether) with N-[6-(2-mercapto-5-pyrimidinyl)-1-oxo-5-hexyn-1-yl]-L-valyl-N6,N6-dipropyl-L-lysyl-N-[[3-[(7S)-7-ethyl-7,8,11,13-tetrahydro-7-hydroxy-8,11-dioxo-10H-1,3-dioxolo[4,5-g]pyrano[3',4':6,7]indolizino[1,2-b]quinolin-14-yl]propoxy]methyl]glycinamide	New
17/07/2026	**Orphan**: EU/3/26/3230 - orphan designation for treatment of inherited retinal dystrophies due to mutation in the PRPF31 gene peptide-oligonucleotide conjugate against CNOT3 mRNA	New
17/07/2026	**Medicine**: Enhertu trastuzumab deruxtecan	Updated
17/07/2026	**News**: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 14-16 July 2026	New
17/07/2026	**Orphan**: EU/3/26/3242 - orphan designation for treatment of in solid organ transplantation allogeneic peripheral blood mononuclear cells incubated in vitro with mitomycin C	New
17/07/2026	**Medicine**: Bexatil Bexagliflozin	New
17/07/2026	**Document**: Clinical Trial Information System (CTIS) - Sponsor handbook	Updated

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17/07/2026	**Document**: Highlights - European Medicines Agency (EMA) / European Chemicals Agency (ECHA) joint meeting with industry stakeholders	New
17/07/2026	**Page**: Horizon scanning: Identifying emerging trends	New
17/07/2026	**Event**: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - July 2026	Updated
16/07/2026	**Medicine**: Bimervax COVID-19 Vaccine (recombinant, adjuvanted)	Updated
16/07/2026	**Medicine**: Inhixa enoxaparin sodium	Updated
16/07/2026	**Medicine**: Vaxneuvance pneumococcal polysaccharide conjugate vaccine (adsorbed)	Updated
16/07/2026	**Medicine**: Zemcelpro allogeneic umbilical cord-derived CD34- cells, non-expanded; dorocubicel	Updated
16/07/2026	**Medicine**: Elocta efmoroctocog alfa	Updated
16/07/2026	**Medicine**: Trodelvy sacituzumab govitecan	Updated
16/07/2026	**Medicine**: Xeljanz tofacitinib	Updated
16/07/2026	**Page**: Questions and answers: Article 13 referral procedures	Updated
16/07/2026	**Document**: Questions and answers on Article 20 non-pharmacovigilance procedures	Updated
16/07/2026	**Medicine**: Benlysta belimumab	Updated
16/07/2026	**Document**: Questions and answers on Article 13 referral procedures	Updated
16/07/2026	**PSUSA**: PSUSA/00001521/202505 - periodic safety update report single assessment gemfibrozil	New
16/07/2026	**Medicine**: Hympavzi marstacimab	Updated
16/07/2026	**Page**: Questions and answers: Article 29(4) referral procedures	Updated

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16/07/2026	**Medicine**: Xervyteg Allogeneic faecal microbiota, pooled	Updated
16/07/2026	**PIP**: EMA/PE/0000228512 - paediatric investigation plan satralizumab	Updated
16/07/2026	**Document**: Questions and answers on Article 29(4) referral procedures	Updated
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15/07/2026	**Page**: Questions and answers: Article 30 referral procedures	Updated
15/07/2026	**Medicine**: Maviret glecaprevir; pibrentasvir	Updated
15/07/2026	**Document**: Questions and answers on Article 30 referral procedures	Updated
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15/07/2026	**Medicine**: Veyvondi vonicog alfa	Updated
15/07/2026	**Medicine**: Erbitux cetuximab	Updated
15/07/2026	**Page**: Questions and answers: Article 31 non-pharmacovigilance referrals	Updated
15/07/2026	**Document**: Questions and answers on Article 31 non-pharmacovigilance referrals	Updated
15/07/2026	**Document**: Recommendations of the Executive Steering Group on the Shortages and Safety of Medicinal Products on shortages of intravenous ifosfamide and cyclophosphamide	Updated
15/07/2026	**Medicine**: Yartemlea Narsoplimab	Updated
15/07/2026	**News**: EMA and EISMEA boost cooperation to accelerate health innovations	New
15/07/2026	**Page**: ICH E6 Good clinical practice - Scientific guideline	Updated

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15/07/2026	**Medicine**: Rinvoq upadacitinib	Updated
15/07/2026	**PSUSA**: PSUSA/00000148/202506 - periodic safety update report single assessment amiloride, amiloride / furosemide, amiloride / hydrochlorothiazide, amiloride / hydrochlorthiazide / timolol, amiloride / bumetanide, amiloride / chlortalidone	New
15/07/2026	**PSUSA**: PSUSA/00000444/202512 - periodic safety update report single assessment brotizolam	New
15/07/2026	**Document**: Draft reflection paper on particulars for safety signals for (traditional) herbal medicinal products	New
15/07/2026	**Page**: Quality Working Party	Updated
15/07/2026	**News**: Executive Director Emer Cooke's speech at the European Parliament's Committee on Public Health	New
15/07/2026	**Document**: Concept paper on the revision of the guidelines on Good Manufacturing Practice for medicinal products - Annex 15 - Qualification and validation - Corrigendum	Updated
15/07/2026	**Medicine**: Rozlytrek entrectinib	Updated
15/07/2026	**Medicine**: PecFent fentanyl	Updated
15/07/2026	**Page**: EU Innovation Network (EU-IN)	Updated
15/07/2026	**Document**: Severe cutaneous adverse reactions - standard template wording for product information	Updated
15/07/2026	**Document**: Scientific advice and protocol assistance adopted during the CHMP meeting 22-25 June 2026	New
15/07/2026	**Document**: List of substances and products subject to worksharing for signal management	Updated
15/07/2026	**PSUSA**: PSUSA/00002275/202512 - periodic safety update report single assessment pancuronium	New

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15/07/2026	**PSUSA**: PSUSA/00002801/202511 - periodic safety update report single assessment sulbutiamine	New
14/07/2026	**Document**: Meeting report of the EMA cancer medicines forum 14 November 2025	New
14/07/2026	**Medicine**: Poulvac Procerta HVT-ND Marek's disease and Newcastle disease vaccine (live recombinant)	Updated
14/07/2026	**PIP**: EMA/PE/0000235924 - paediatric investigation plan Mitazalimab	New
14/07/2026	**PIP**: EMA/PE/0000240621 - paediatric investigation plan lunsekimig	New
14/07/2026	**PIP**: EMA/PE/0000241250 - paediatric investigation plan trilaciclib (dihydrochloride)	New
14/07/2026	**PIP**: EMA/PE/0000182809 - paediatric investigation plan afimkibart	New
14/07/2026	**PIP**: EMA/PE/0000232767 - paediatric investigation plan ve303-07: bacilli, strain from cluster xvii, (closest relative: clostridium_aq innocuum) liveve303-07; ve303-06: clostridia, strain from cluster xiva, (closest relative: dorea_a longicatena) live; ve303-05: clostridia, strain from cluster xiva, (closest relative: blautia sp001304935) live; ve303-03: clostridia, strain from cluster xiva, (closest relative: sellimonas intestinalis) live; ve303-02: clostridia, strain from cluster iv, (closest relative: anaerotruncus colihominis) liveve303-02; ve303-01: clostridia, strain from cluster xiva (closest relative: enterocloster bolteae) live; ve303-08: clostridia, strain from cluster iv, (closest relative: flavonifractor plautii), live; ve303-04: clostridia, strain from cluster xiva, (closest relative: clostridium_q symbiosum) live (ve303)	New
14/07/2026	**PIP**: EMEA-002828-PIP01-20 - paediatric investigation plan firsocostat; cilofexor	New
14/07/2026	**PIP**: EMEA-002004-PIP04-23 - paediatric investigation plan atacicept	New
14/07/2026	**PIP**: EMA/PE/0000232778 - paediatric investigation plan duvakitug	New
14/07/2026	**PIP**: EMA/PE/0000232777 - paediatric investigation plan zosurabalpin	New
14/07/2026	**PIP**: EMA/PE/0000232760 - paediatric investigation plan riliprubart	New
14/07/2026	**PIP**: EMA/PE/0000236704 - paediatric investigation plan nucresiran	New

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14/07/2026	**PIP**: EMA/PE/0000242278 - paediatric investigation plan betula pollen extract	Updated
14/07/2026	**PIP**: EMA/PE/0000226166 - paediatric investigation plan sparsentan	Updated
14/07/2026	**PIP**: EMA/PE/0000244768 - paediatric investigation plan darvadstrocel	Updated
14/07/2026	**PIP**: EMA/PE/0000242923 - paediatric investigation plan Lerodalcibep	Updated
14/07/2026	**Medicine**: Ekterly sebetralstat	Updated
14/07/2026	**PSUSA**: PSUSA/00000485/202511 - periodic safety update report single assessment caffeine / ergotamine	New
14/07/2026	**PSUSA**: PSUSA/00000313/202511 - periodic safety update report single assessment benazepril	New
14/07/2026	**PSUSA**: PSUSA/00003041/202512 - periodic safety update report single assessment carbaethopendecinium bromide / trimecaine hydrochloride	New
14/07/2026	**Medicine**: Qaialdo spironolactone	Updated
14/07/2026	**Medicine**: Tuznue trastuzumab	Updated
14/07/2026	**Medicine**: Hemgenix etranacogene dezaparvovec	Updated
14/07/2026	**Medicine**: Bildyos denosumab	Updated
14/07/2026	**Event**: Industry webinar on new electronic application form (eAF) version	New
14/07/2026	**Medicine**: Bilprevda denosumab	Updated
14/07/2026	**PSUSA**: PSUSA/00010504/202512 - periodic safety update report single assessment ascorbic acid / rutoside, ascorbic acid / rutoside / alfatocopherol	New
14/07/2026	**PSUSA**: PSUSA/00000227/202511 - periodic safety update report single assessment apomorphine	New

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14/07/2026	**PSUSA**: PSUSA/00003167/202512 - periodic safety update report single assessment dienogest	New
14/07/2026	**Document**: PRIME eligibility requests: 2027 deadlines for submission and timetable for assessment	New
14/07/2026	**PIP**: EMA/PE/0000184114 - paediatric investigation plan duvakitug	New
14/07/2026	**PIP**: EMA/PE/0000242080 - paediatric investigation plan luveltamab tazevibulin	New
14/07/2026	**Medicine**: Dyrupeg pegfilgrastim	Updated
14/07/2026	**PIP**: EMA/PE/0000221389 - paediatric investigation plan darovasertib	New
14/07/2026	**Medicine**: Zefylti filgrastim	Updated
14/07/2026	**Page**: Changing the labelling and package leaflet (Article 61(3) notifications)	Updated
14/07/2026	**PIP**: EMA/PE/0000232449 - paediatric investigation plan sodium 2-(3'(-3-(1-(4-(tert-butyl)benzyl)-4-ethyl-5-oxo-4,5-dihydro-1H-1,2,4-triazol-3-yl)propyl)-4-ethoxy-[1,1'-biphenyl]-3-yl)acetate	New
14/07/2026	**PIP**: EMA/PE/0000232782 - paediatric investigation plan (1r,2s)-1-(6-bromo-2-methoxyquinolin-3-yl)-2-(2,6-dimethoxypyridin-4-yl)-4-(dimethylamino)-1-(2,3,6-trimethoxypyridin-4-yl)butan-2-ol tartrate	New
14/07/2026	**PIP**: EMA/PE/0000232780 - paediatric investigation plan probenecid	New
14/07/2026	**PIP**: EMA/PE/0000239504 - paediatric investigation plan zabilugene almadenorepvec	New
14/07/2026	**Medicine**: Vitrakvi larotrectinib	Updated
14/07/2026	**PIP**: EMA/PE/0000241614 - paediatric investigation plan calcium carbonate; cholecalciferol; risedronate sodium	New
14/07/2026	**Document**: Agenda of the CVMP meeting 14-16 July 2026	New
14/07/2026	**Document**: Applications for new human medicines under evaluation: July 2026	New

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14/07/2026	**Document**: Medicinal products for human use: monthly figures - June 2026	New
14/07/2026	**Page**: Clinical pharmacology and pharmacokinetics: questions and answers	Updated
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14/07/2026	**PIP**: EMA/PE/0000242940 - paediatric investigation plan buloxibutid sodium	New
14/07/2026	**Medicine**: Acvybra denosumab	Updated
14/07/2026	**PIP**: EMA/PE/0000245434 - paediatric investigation plan setmelanotide	Updated
14/07/2026	**PIP**: EMA/PE/0000233998 - paediatric investigation plan sebetralstat	Updated
14/07/2026	**PIP**: EMA/PE/0000241034 - paediatric investigation plan Lebrikizumab	Updated
14/07/2026	**PIP**: EMA/PE/0000240529 - paediatric investigation plan cagrilintide; semaglutide	Updated
14/07/2026	**Page**: Semaglutide and FlexTouch solution for injection in pre-filled pen product-specific bioequivalnce guidance - various strengths	New
14/07/2026	**Document**: Semaglutide and FlexTouch solution for injection in pre-filled pen product-specific bioequivalence guidance - various strengths	New
14/07/2026	**DHPC**: Ixchiq - direct healthcare professional communication (DHPC) Chikungunya virus, strain CHIKV LR2006-OPY1, live attenuated	New
13/07/2026	**Document**: Decision of the Executive Director on rules governing the traineeship programme at the EMA	Updated
13/07/2026	**Event**: SME info day - navigating EMA support: From development to market authorisation	Updated
13/07/2026	**Medicine**: Hetronifly serplulimab	Updated
13/07/2026	**PSUSA**: PSUSA/00000810/202512 - periodic safety update report single assessment clomifene	New

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13/07/2026	**Document**: Minutes of the COMP meeting 11-12 May 2026	New
13/07/2026	**PSUSA**: PSUSA/00001731/202511 - periodic safety update report single assessment indapamide	New
13/07/2026	**Page**: Open letters	Updated
13/07/2026	**Document**: Joint response from European Medicines Regulatory Network to letter from Health Action International and other health groups on missing clinical trial results in CTIS	New
13/07/2026	**Medicine**: Libmyris adalimumab	Updated
13/07/2026	**PSUSA**: PSUSA/00002298/202512 - periodic safety update report single assessment caffeine / paracetamol / propyphenazone, paracetamol / propyphenazone	New
13/07/2026	**PSUSA**: PSUSA/00001720/202511 - periodic safety update report single assessment idarubicin	New
13/07/2026	**PSUSA**: PSUSA/00000409/202512 - periodic safety update report single assessment biclotymol / enoxolone / muramidase hydrochloride	New
13/07/2026	**Medicine**: Idacio adalimumab	Updated
13/07/2026	**PSUSA**: PSUSA/00003102/202511 - periodic safety update report single assessment vecuronium bromide	New
13/07/2026	**PIP**: EMEA-003356-PIP01-22 - paediatric investigation plan Inhibitor of receptor-interacting protein kinase 1 (ABBV-668)	Updated
13/07/2026	**Medicine**: Kostaive zapomeran	Updated
13/07/2026	**Medicine**: Humalog insulin lispro	Updated
13/07/2026	**PSUSA**: PSUSA/00002117/202511 - periodic safety update report single assessment naltrexone	New
13/07/2026	**PSUSA**: PSUSA/00002829/202511 - periodic safety update report single assessment sultamicillin	New

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13/07/2026	**Medicine**: Abasaglar (previously Abasria) insulin glargine	Updated
13/07/2026	**PSUSA**: PSUSA/00003135/202512 - periodic safety update report single assessment yellow fever vaccine (live)	New
13/07/2026	**Event**: European platform for regulatory science research meeting: June 2026	Updated
13/07/2026	**Document**: Guidance for applicants for the preparation of the precise scope section of the variation application form	Updated
13/07/2026	**Document**: Pre-notification check for type IB Variations	Updated
13/07/2026	**Document**: Template - Application for transfer of marketing authorisation from transferor to transferee - cover letter (human)	Updated
13/07/2026	**Document**: Pre-notification check for type IA/IAIN variations	Updated
13/07/2026	**Medicine**: Lyumjev (previously Liumjev) insulin lispro	Updated
13/07/2026	**Document**: Agenda - EMA/HMA European platform for regulatory science research platform meeting	Updated
13/07/2026	**Page**: Grouping of variations: questions and answers	Updated
13/07/2026	**Page**: Pre-authorisation guidance	Updated
13/07/2026	**Document**: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure	Updated
13/07/2026	**Document**: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure: document with tracked changes	Updated
13/07/2026	**Document**: Template - Application for transfer of marketing authorisation from transferor to transferee, attachment 1	Updated
13/07/2026	**Page**: Transfer of marketing authorisation: questions and answers	Updated

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13/07/2026	**Page**: Guidance on good manufacturing practice and good distribution practice: Questions and answers	Updated
13/07/2026	**Page**: Extensions of marketing authorisations: questions and answers	Updated
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13/07/2026	**Medicine**: Paxlovid nirmatrelvir; ritonavir	Updated
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13/07/2026	**Page**: Type-II variations: questions and answers	Updated
13/07/2026	**Document**: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure	Updated
13/07/2026	**Document**: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure: document with tracked changes	Updated

NOTICE TO APPLICANTS

No updates since June 24th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
20.07.2026	**Informationen zu Einreichung und Genehmigung von Schulungsmaterial** Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
16.07.2026	**Rote-Hand-Brief zu Tavneos (Avacopan): Empfehlung zum Widerruf der Zulassung in der EU** Wirkstoff: Avacopan Empfehlung zum Widerruf der Zulassung in der EU aufgrund eines ungünstigen Nutzen-Risiko Verhältnisses.

Date	Title
15.07.2026	**Rote-Hand-Brief zu Mykronor 5 Mikrogramm/ml Injektions-/Infusionslösung: Risiko von Medikationsfehlern** Wirkstoff: Norepinephrin, Noradrenalin Die Firma Aguettant Deutschland GmbH informiert über das Risiko von Medikationsfehlern bei der Anwendung von Mykronor 5 Mikrogramm/ml Injektions-/Infusionslösung.
13.07.2026	**Informationen zu Rote-Hand-Briefen und Informationsbriefen** Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht neue Hinweise zu anstehenden Rote-Hand-Briefen und Informationsbriefen.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
15.07.2026	**DiPA-Leitfaden (Stand 15.07.2026, Version 1.3)** Mit dem Leitfaden bietet das BfArM insbesondere Herstellern von DiPA, aber auch Nutzenden und allen anderen Interessierten eine möglichst verständliche, zusammenfassende Darstellung der Regelungen, die an verschiedenen Stellen im SGB XI, in der Digitale Pflegeanwendungen-Verordnung (DiPAV) und in den Anlagen zur DiPAV zu finden sind.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
14.07.2026	**Rote-Hand-Brief: Ixchiq (Chikungunya-Impfstoff)**

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.