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NEW - Art. 45 PAR Pheniramine maleate, naphazoline hydrochloride

NEW - Overview referral timetables 2026

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UPDATE - RMS Validation Checklist for human medicinal products in DCP

UPDATE - Common request form for RMS in DCP

NEW - 22-23 July CMDh minutes

NEW - Q1-Q2 2025 Statistics for New Applications (MRP/DCP), Variations, Referrals and Paediatric Worksharing procedures

24 September

NEW - Report from the meeting held on 16-18 September 2025

UPDATE - List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation

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UPDATE - Guidance on the application of the revised variations framework

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
26/09/2025	Medicine: Ibandronic acid Accord	Updated
26/09/2025	Medicine: Tigecycline Accord	Updated
26/09/2025	Document: Minutes of the COMP meeting 15-17 July 2025	New
26/09/2025	Medicine: Dovato	Updated
26/09/2025	Event: Enpr-EMA Coordinating Group and networks meeting June 2025	New
26/09/2025	Page: List of medicines under additional monitoring	Updated
26/09/2025	Medicine: Prasugrel Viatris (previously Prasugrel Mylan)	Updated
26/09/2025	Medicine: Hizentra	Updated
26/09/2025	Medicine: Voranigo	Updated
26/09/2025	Document: Minutes - PDCO minutes of the 22-25 July 2025 meeting	New
26/09/2025	Document: List of medicinal products under additional monitoring	Updated
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26/09/2025	Medicine: Eylea	Updated
26/09/2025	Event: Industry stakeholder webinar on revised environmental risk assessment guideline for medicinal products for human use - 1 year experience	New
26/09/2025	Medicine: Grastofil	Updated
26/09/2025	Event: European Platform for Regulatory Science Research meeting September 2025	Updated
26/09/2025	Page: PRIME: priority medicines	Updated
26/09/2025	Document: Recommendations on eligibility to PRIME scheme adopted at the CHMP meeting of 15-18 September 2025	New
26/09/2025	Document: List of medicines currently in PRIME scheme	Updated
25/09/2025	Medicine: Alhemo	Updated
25/09/2025	PSUSA: PSUSA/00010312/202501 - periodic safety update report single assessment	New
25/09/2025	Medicine: Zoledronic acid Teva	Updated
25/09/2025	Page: Innovation Task Force briefing meetings	Updated
25/09/2025	Document: List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs)	Updated
25/09/2025	Shortage: Ecalta	Updated
25/09/2025	Page: Medicine Shortages Single Point of Contact (SPOC) Working Party	Updated

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25/09/2025	PIP: EMEA-002944-PIP02-22 - paediatric investigation plan	New
25/09/2025	Medicine: Revolade	Updated
25/09/2025	Medicine: Equilis EHV 1+4	New
25/09/2025	Medicine: Imlygic	Updated
25/09/2025	Medicine: Xaluprine (previously Mercaptopurine Nova Laboratories)	Updated
25/09/2025	Medicine: Kisqali	Updated
25/09/2025	Medicine: Karvezide	Updated
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25/09/2025	PIP: EMEA-002740-PIP03-24 - paediatric investigation plan	New
25/09/2025	Medicine: Padcev	Updated
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25/09/2025	Medicine: Riulvy	Updated
25/09/2025	Medicine: Lacosamide Adroiq	Updated
25/09/2025	Medicine: Sugammadex Adroiq	Updated
25/09/2025	Medicine: Emtricitabine / Rilpivirine / Tenofovir Alafenamide Viatris	Updated
25/09/2025	Document: Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2025	Updated
25/09/2025	Page: Product-specific bioequivalence guidance	Updated
25/09/2025	Document: Eltrombopag film-coated tablets 12.5 mg, 25 mg, 50 mg, 75 mg and powder for oral suspension 25 mg product-specific bioequivalence guidance	New
25/09/2025	Document: Melatonin prolonged release tablets 2 mg product-specific bioequivalence guidance	New
24/09/2025	Document: Members of the Coordinating group of European network of paediatric research at the European Medicines Agency (Enpr-EMA)	Updated
24/09/2025	Document: Procedural advice on publication of information on withdrawals of marketing authorisation and variation applications for veterinary medicinal products	New
24/09/2025	Medicine: Ixchiq	Updated
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24/09/2025	Medicine: Korjuny	Updated
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24/09/2025	Medicine: Rinvoq	Updated
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24/09/2025	Medicine: Stoboclo	Updated
24/09/2025	Document: Timetable: Post-authorisation measure (PAM) assessed by PRAC	Updated
24/09/2025	Document: Timetable: Post-authorisation measure (PAM) assessed by CAT	Updated
24/09/2025	Document: Timetable: Post-authorisation measure (PAM) Paediatric art. 46 submission - ATMP	Updated
24/09/2025	Document: Timetable: Post-authorisation measure (PAM) Paediatric art. 46 submission	Updated
24/09/2025	Document: Timetable: Post-authorisation measures (PAMs) assessed by PRAC - ATMP	Updated
24/09/2025	Document: Timetable: Post-authorisation measure (PAM) assessed by CHMP	Updated
24/09/2025	Page: Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)	Updated
24/09/2025	Document: Mandate and objectives for the Working Group of the MSSG on the European Shortages Monitoring Platform (ESMP)	New
24/09/2025	Document: Mandate and objectives for the Working Group of the MSSG on the Voluntary Solidarity Mechanism and Policy	New
24/09/2025	Document: Mandate and objectives for the Working Group of the MSSG on the Vulnerability Analysis Methodology	New
24/09/2025	Document: Minutes of the 128th meeting of the EMA Management Board: 11-12 June 2025	New
24/09/2025	Document: Categorisation of antibiotics in the European Union - Answer to the request from the European Commission for updating the scientific advice on the impact on public health and animal health of the use of antibiotics in animals	Updated

Date	Content	Status
24/09/2025	Document: Infographic - Categorisation of antibiotics for use in animals for prudent and responsible use	Updated
23/09/2025	Document: Scientific recommendations on classification of advanced therapy medicinal products	Updated
23/09/2025	Medicine: Olanzapine Apotex	Updated
23/09/2025	Event: Quarterly System Demo – Q3 2025	Updated
23/09/2025	Event: Committee for Advanced Therapies (CAT) workshop on gene editing	Updated
23/09/2025	PSUSA: PSUSA/00001413/202412 - periodic safety update report single assessment	New
23/09/2025	DHPC: Ixchiq - direct healthcare professional communication (DHPC)	New
23/09/2025	Document: Inclusion/exclusion criteria for the Important Medical Events (IME) list	Updated
23/09/2025	PSUSA: PSUSA/00001587/202501 - periodic safety update report single assessment	New
23/09/2025	Document: Timetable: Post-authorisation safety study (PASS) protocols and final results	Updated
23/09/2025	Document: Timetable: Periodic safety update report (PSUR) and PSUR single assessment (PSUSA)	Updated
23/09/2025	Document: Timetable: Periodic safety update report (PSUR) and PSUR single assessment (PSUSA) - Advanced therapy medicinal products (ATMPs)	Updated
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23/09/2025	Document: Start of procedure: Type II variation - Extension of indication under evaluation by the CHMP (22 August 2025 - 18 September 2025)	New
23/09/2025	Document: Request to the CVMP for classification of a veterinary medicinal product as intended for a limited market according to Article 4(29) and for eligibility for authorisation according to Article 23 (Applications for limited markets)	Updated
23/09/2025	Document: Engineered living materials for in situ production of therapeutics - EU-IN Horizon Scanning Report	New
23/09/2025	Medicine: Vizamyl	Updated
23/09/2025	Medicine: Gilenya	Updated
23/09/2025	Medicine: Pelmeg	Updated
23/09/2025	Medicine: Cegfila (previously Pegfilgrastim Mundipharma)	Updated
23/09/2025	News: New targets for clinical trials in Europe	New
23/09/2025	News: Use of paracetamol during pregnancy unchanged in the EU	New

Date	Content	Status
23/09/2025	Document: MedDRA important medical event terms list - version 28.1	Updated
22/09/2025	Event: Training session on human variations web-based electronic application form (eAF) for CAPs	Updated
22/09/2025	News: New variations guidelines to streamline lifecycle management of medicines	Updated
22/09/2025	Page: Guidance on the application of the revised variations framework	Updated
22/09/2025	Document: Agenda of the HMPC meeting 22-24 September 2025	New
22/09/2025	Medicine: Romvimza	Updated
22/09/2025	Medicine: Pyzchiva	Updated
22/09/2025	Medicine: Jayempi	Updated
22/09/2025	Document: CHMP PROM minutes for the meeting on 17 March 2025	New
22/09/2025	Event: Q&A clinic on web-based electronic application form (eAF) functionalities for CAPs and non-CAPs	Updated
22/09/2025	Document: Agenda – Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - 24 September 2025	New
22/09/2025	Herbal: Combination: Species pectorales - herbal medicinal product	Updated
22/09/2025	Referral: Oxbryta - referral	Updated
22/09/2025	Document: Mandate, objectives, and rules of procedure for working parties under the quality, non-clinical, methodology, clinical and veterinary domains	New

NOTICE TO APPLICANTS

No updates since September 03rd, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
25.09.2025	**Testosteronhaltige Arzneimittel: Möglicher Hinweis auf die Anwendung außerhalb der zugelassenen Indikation** Wirkstoff: Testosteron Eine vom BfArM initiierte Studie zeigt einen deutlichen Anstieg der Verordnungsprävalenz von testosteronhaltigen Arzneimitteln zulasten gesetzlicher Krankenkassen in Deutschland. Dabei könnte es sich teilweise um die Anwendung außerhalb der zugelassenen Indikation handeln.

Date	Title
25.09.2025	**Informationen zu Einreichung und Genehmigung von Schulungsmaterial** Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien
23.09.2025	**Umsetzung des Durchführungsbeschlusses der Europäischen Kommission vom 17.09.2025 zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Azathioprin** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Azathioprin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
22.09.2025	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 24.07.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Hydromorphon** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Hydromorphon infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
22.09.2025	**Azithromycin: Neubewertung des Nutzens und der Risiken** Wirkstoff: Azithromycin Mit Bescheid vom 17.09.2025 wird der Durchführungsbeschluss der EU-Kommission national umgesetzt.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
24.09.2025	**09.09.2025: Klinische Prüfung gemäß MDR/IVDR/MPDG** Anleitung zu Klinischen Prüfungen bzw. Leistungsstudien im DMIDS aktualisiert

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
26.09.2025	Rote-Hand-Brief: Leqembi (Lecanemab)

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.