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09 September

UPDATE - Contact Points

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
12/09/2025	Event: European Medicines Agency (EMA) and European Association of Urology (EAU) bilateral meeting	New
12/09/2025	PSUSA: PSUSA/00002398/202411 - periodic safety update report single assessment	New
12/09/2025	Medicine: Livmarli	Updated
12/09/2025	Event: First European Medicines Agency (EMA) and European Association for the Study of Diabetes (EASD) bilateral meeting	New
12/09/2025	News: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 9-10 September 2025	New
12/09/2025	Medicine: Portela	New
12/09/2025	Post-authorisation: Bravecto TriUNO - opinion on variation to marketing authorisation	New
12/09/2025	PSUSA: PSUSA/00001041/202501 - periodic safety update report single assessment	New
12/09/2025	Document: Product Management Service (PMS) roadmap	Updated
12/09/2025	Medicine: Velsipity	Updated

Date	Content	Status
11/09/2025	PSUSA: PSUSA/00010287/202411 - periodic safety update report single assessment	New
11/09/2025	PSUSA: PSUSA/00000427/202412 - periodic safety update report single assessment	New
11/09/2025	Medicine: Otulfi	Updated
11/09/2025	Medicine: Taltz	Updated
11/09/2025	Medicine: Axitinib Accord	Updated
11/09/2025	Medicine: Loqtorzi	Updated
11/09/2025	Medicine: Champix	Updated
11/09/2025	Medicine: Nilotinib Accord	Updated
11/09/2025	Medicine: Rukobia	Updated
11/09/2025	Page: Union Product Database	Updated
11/09/2025	Medicine: Comirnaty	Updated
11/09/2025	Medicine: Rezzayo	Updated
11/09/2025	Medicine: Menveo	Updated
11/09/2025	Medicine: Dectova	Updated
11/09/2025	Medicine: Ryjunea	Updated
10/09/2025	Event: Committee for Advanced Therapies (CAT) workshop on gene editing	Updated
10/09/2025	Medicine: Hexyon	Updated
10/09/2025	Document: PRIME eligibility requests: 2026 deadlines for submission and timetable for assessment	New
10/09/2025	Medicine: Hexacima	Updated
10/09/2025	Medicine: Tivicay	Updated
10/09/2025	Medicine: Jakavi	Updated
10/09/2025	Medicine: Imbruvica	Updated
10/09/2025	Medicine: Spravato	Updated
10/09/2025	Medicine: Arexvy	Updated
10/09/2025	Medicine: Zonisamide Viatris (previously Zonisamide Mylan)	Updated
10/09/2025	News: Management Board formally approves renewal of Executive Director’s mandate	New
10/09/2025	Medicine: Vegzelma	Updated

Date	Content	Status
10/09/2025	Document: Regulatory Procedure Management (RPM) for the Product Lifecycle Management (PLM) - Frequently asked questions	Updated
10/09/2025	Medicine: Hemlibra	Updated
10/09/2025	Medicine: Tasmar	Updated
10/09/2025	Medicine: Rekambys	Updated
10/09/2025	Medicine: Inflectra	Updated
10/09/2025	Document: Minutes of the PRAC meeting 7-10 July 2025	New
10/09/2025	PSUSA: PSUSA/00010987/202501 - periodic safety update report single assessment	New
10/09/2025	PSUSA: PSUSA/00001418/202501 - periodic safety update report single assessment	New
10/09/2025	Document: Regulatory Procedure Management (RPM) for the Product Lifecycle Management (PLM) - Frequently asked questions - tracked changes	New
10/09/2025	PSUSA: PSUSA/00001686/202411 - periodic safety update report single assessment	New
10/09/2025	Event: Workshop on the use of external controls for evidence generation in regulatory decision-making	Updated
10/09/2025	PSUSA: PSUSA/00000108/202412 - periodic safety update report single assessment	New
10/09/2025	PSUSA: PSUSA/00010266/202412 - periodic safety update report single assessment	New
10/09/2025	PSUSA: PSUSA/00003067/202412 - periodic safety update report single assessment	New
10/09/2025	PSUSA: PSUSA/00000599/202412 - periodic safety update report single assessment	New
10/09/2025	Document: List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment	Updated
10/09/2025	Event: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	Updated
09/09/2025	Medicine: Ixchiq	Updated
09/09/2025	Medicine: Vocabria	Updated
09/09/2025	Medicine: Zinforo	Updated
09/09/2025	Medicine: Revlimid	Updated
09/09/2025	Medicine: Qoyvolma	Updated

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09/09/2025	Medicine: Tenofovir disoproxil Viatris (previously Tenofovir disoproxil Mylan)	Updated
09/09/2025	Orphan: EU/3/16/1715 - orphan designation for treatment of inherited retinal dystrophies due to defects in the RPGR gene	Updated
09/09/2025	Medicine: Ecalta	Updated
09/09/2025	Medicine: Carvykti	Updated
09/09/2025	Page: Medicine evaluation figures	Updated
09/09/2025	Document: Medicinal products for human use: monthly figures - August 2025	New
09/09/2025	Document: Medicinal products for human use: monthly figures - July 2025	New
09/09/2025	PSUSA: PSUSA/00002172/202412 - periodic safety update report single assessment	New
09/09/2025	Medicine: Equisolon	Updated
09/09/2025	Medicine: Equioxx	Updated
09/09/2025	Document: Agenda of the CAT meeting 10-12 September 2025	New
09/09/2025	PSUSA: PSUSA/00010190/202412 - periodic safety update report single assessment	New
09/09/2025	Document: Agenda - PDCO agenda of the 9-12 September 2025 meeting	New
09/09/2025	Medicine: Equilis West Nile	Updated
09/09/2025	Event: Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) multistakeholder workshop on Patient Registries for Alzheimer's disease	Updated
09/09/2025	Medicine: Fungitraxx	Updated
09/09/2025	Medicine: Fortekor Plus	Updated
09/09/2025	Event: Training session on human variations web-based electronic Application Form (eAF) for non-CAPs	Updated
09/09/2025	Medicine: Felpreva	Updated
09/09/2025	Document: Agenda of the COMP meeting 9-11 September 2025	New
09/09/2025	Medicine: Fatrovax RHD	Updated
09/09/2025	Medicine: Evant	Updated
09/09/2025	Medicine: Evalon	Updated
09/09/2025	Medicine: Eurican Herpes 205	Updated
09/09/2025	Medicine: Eryseng	Updated
09/09/2025	Medicine: Eryseng Parvo	Updated

Date	Content	Status
09/09/2025	Page: Supporting innovation	Updated
09/09/2025	Document: Portfolio and technology meeting briefing document	Updated
09/09/2025	Event: Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting September 2025	Updated
09/09/2025	Event: Patients and Consumers Working Party (PCWP) plenary meeting September 2025	Updated
09/09/2025	Page: Union Product Database: release notes	Updated
09/09/2025	Event: HCPWP plenary meeting September 2025	Updated
09/09/2025	DHPC: Clozapine - direct healthcare professional communication (DHPC)	New
09/09/2025	PSUSA: PSUSA/00010402/202501 - periodic safety update report single assessment	New
09/09/2025	PSUSA: PSUSA/00001999/202501 - periodic safety update report single assessment	New
08/09/2025	Medicine: Procysbi	Updated
08/09/2025	Medicine: Lopinavir/Ritonavir Viatris (previously Ritonavir Mylan)	Updated
08/09/2025	Medicine: Nevanac	Updated
08/09/2025	Medicine: Tremfya	Updated
08/09/2025	Medicine: Eksunbi	Updated
08/09/2025	Medicine: Yaxwer	Updated
08/09/2025	Document: Start of procedure: Type II variation - Extension of indication under evaluation by the CHMP (25 July - 21 August 2025)	New
08/09/2025	Document: Start of procedure: Extension of marketing authorisation (25 July - 21 August 2025)	New
08/09/2025	Document: Agenda of the CVMP meeting 9-11 September 2025	New
08/09/2025	Document: Dossier administrative validation checklist for initial marketing authorisation applications by applicants	Updated
08/09/2025	PSUSA: PSUSA/00002359/202501 - periodic safety update report single assessment	New
08/09/2025	Page: Pre-authorisation guidance	Updated
08/09/2025	Document: Pre-submission request form for a EMA procedure prior to the submission of a marketing authorisation application or Article 58 Application	Updated
08/09/2025	Document: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure	Updated

Date	Content	Status
08/09/2025	Document: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure: document with tracked changes	Updated
08/09/2025	PSUSA: PSUSA/00002849/202411 - periodic safety update report single assessment	New
08/09/2025	Event: Global IDMP Working Group (GIDWG) Stakeholder Meeting: 1-3 October 2025	New
08/09/2025	PSUSA: PSUSA/00003162/202501 - periodic safety update report single assessment	New

NOTICE TO APPLICANTS

No updates since September 03rd, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
15.09.2025	**Rote-Hand-Brief zu Finasterid und Dutasterid: Neue Maßnahmen zur Minimierung des Risikos für Suizidgedanken** Wirkstoff: Finasterid, Dutasterid Die Zulassungsinhaber von finasterid- und dutasteridhaltigen Arzneimitteln informieren über Suizidgedanken als eine unerwünschte Arzneimittelwirkung von oral angewendeten finasteridhaltigen Produkten.
12.09.2025	**Azithromycin: Neubewertung des Nutzens und der Risiken** Wirkstoff: Azithromycin Der Durchführungsbeschluss der Europäischen Kommission zum Risikobewertungsverfahren Azithromycin wurde publiziert.
10.09.2025	**Rote-Hand-Brief zu Isozid 0,5 N Pulver zur Herstellung einer Infusionslösung: sichtbare Partikel, Verwendung eines Partikelfilters** Wirkstoff: Isoniazid Die Firma Esteve Pharmaceuticals GmbH informiert über in der Charge 286490A des Arzneimittels Isozid 0,5 N Pulver zur Herstellung einer Infusionslösung nach der Rekonstitution vorhandene sichtbare Partikel.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since August 26th, 2025.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
12.09.2025	Paul-Ehrlich-Institut gestattet Einfuhr von Atgam mit französischer Beschriftung

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.