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08 July
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HEADS OF AGENCIES – PAEDIATRIC REGULATION

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EUROPEAN MEDICINES AGENCY (EMA)

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11/07/2025	Document: Antimicrobial Sales and Use (ASU) Platform: Release notes	Updated
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11/07/2025	Medicine: Opdualag	Updated
11/07/2025	Event: SPOR and XEVMPD status update webinar	Updated
11/07/2025	Document: Q&A extract - SPOR and XEVMPD status update webinar 9 April 2025	New

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11/07/2025	Medicine: Imfinzi	Updated
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11/07/2025	News: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 7 – 10 July 2025	New
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10/07/2025	Page: Artificial intelligence	Updated
10/07/2025	Page: Sharing data across systems: Master data on human medicines	New
10/07/2025	Document: Review of artificial intelligence and machine learning applications in medicines lifecycle 2024: Horizon Scanning Short Report	New
10/07/2025	Document: 2024 AI Observatory report	New
10/07/2025	Document: 2024 AI Observatory report: Compilation of 2024 experience	New
10/07/2025	Page: Medical device expert panels	Updated
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10/07/2025	Medicine: Revlimid	Updated
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10/07/2025	Medicine: Fymskina	Updated
10/07/2025	Medicine: Avtozma	Updated
10/07/2025	Medicine: Temozolomide Sun	Updated

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10/07/2025	Medicine: Plegridy	Updated
10/07/2025	Document: New fee regulation working arrangements	Updated
10/07/2025	Page: Fees payable to the European Medicines Agency: Fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use	Updated
10/07/2025	Page: Fees payable to the European Medicines Agency: Fees, charges and remuneration for assessment procedures and services relating to veterinary medicinal products	Updated
10/07/2025	Page: Fees payable to the European Medicines Agency: General questions and answers	Updated
10/07/2025	Page: Fees payable to the European Medicines Agency: Other fees and charges for medicinal products for human use, veterinary medicinal products and consultations on medical devices	Updated
10/07/2025	Document: New fee regulation: General questions and answers for all applicants	Updated
10/07/2025	Document: Annex I questions and answers – Fees, charges and remuneration for assessment procedures and services relating to medicinal products for human use	Updated
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09/07/2025	PIP: EMEA-003616-PIP01-24 - paediatric investigation plan	New
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09/07/2025	PIP: EMEA-003513-PIP01-23 - paediatric investigation plan	New

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09/07/2025	PIP: EMEA-003253-PIP01-22-M01 - paediatric investigation plan	New
09/07/2025	Document: Guide to CTIS training material catalogue	Updated
09/07/2025	PIP: EMEA-003607-PIP01-24 - paediatric investigation plan	New
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09/07/2025	Medicine: Toujeo (previously Optisulin)	Updated
09/07/2025	Document: Clinical Trial Information System (CTIS) structured data form - Notifications, Annual Safety Report (ASR) and results	Updated
09/07/2025	Medicine: Duvyzat	Updated
09/07/2025	Document: Minutes of the HMPC meeting 5-7 May 2025	New
09/07/2025	Medicine: Braftovi	Updated
09/07/2025	Document: Clinical Trial Information System (CTIS) structured data form - Initial application, additional Member State Concerned, (Multi trial) substantial modification, non-substantial modification, and Request for information (RFI)	Updated
09/07/2025	Medicine: Benlysta	Updated
09/07/2025	EU-M4all: Dengue Tetravalent Vaccine (Live, Attenuated) Takeda - opinion on medicine for use outside EU	Updated
09/07/2025	Event: 14th industry stakeholder platform on research and development support	Updated
09/07/2025	Document: Clinical Trial Information System (CTIS) - Sponsor handbook	Updated
09/07/2025	Event: Training session on Human variations web-based electronic Application Form (eAF) for non-CAPs	Updated
09/07/2025	Medicine: Ozempic	Updated
09/07/2025	Medicine: Exjade	Updated
09/07/2025	Medicine: Ituxredi	Updated
09/07/2025	Page: Clinical Trials Information System (CTIS): training and support	Updated

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09/07/2025	Page: Clinical Trials Information System (CTIS): online training modules for authorities	Updated
08/07/2025	PSUSA: PSUSA/00002832/202409 - periodic safety update report single assessment	New
08/07/2025	Medicine: Qdenga	Updated
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08/07/2025	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) – November 2025	Updated
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08/07/2025	Medicine: Cibinqo	Updated
08/07/2025	Document: Dates of 2026 Scientific Advice Working Party (SAWP) meetings and submission deadlines for scientific advice, protocol assistance, qualification of novel methodologies and HTACG/EMA parallel Joint Scientific Consultation (JSC) requests	New
08/07/2025	Document: Minutes of the CHMP meeting 24-27 February 2025	New
08/07/2025	Document: Annex to 24-27 February 2025 CHMP Minutes	New
08/07/2025	Shortage: Ecalta	Updated
08/07/2025	Document: Minutes of the CAT meeting 14-16 May 2025	New
08/07/2025	Document: CHMP PROM minutes for the meeting on 20 January 2025	New
08/07/2025	Event: SPOR and XEVMPD status update webinar	Updated
08/07/2025	Document: EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database - Chapter 5: Technical specifications	Updated
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07/07/2025	Medicine: Latuda	Updated
07/07/2025	Medicine: Circadin	Updated
07/07/2025	Document: Questions and answers about the clinical study data proof-of-concept pilot for industry	Updated
07/07/2025	Medicine: Nucala	Updated
07/07/2025	Event: Pharmacovigilance Risk Assessment Committee (PRAC): 7 - 10 July 2025	Updated
07/07/2025	PIP: EMEA-003241-PIP01-22-M01 - paediatric investigation plan	Updated
07/07/2025	Document: Agenda of the PRAC meeting 7-10 July 2025	New
07/07/2025	PIP: EMEA-002780-PIP02-20-M02 - paediatric investigation plan	Updated
07/07/2025	PIP: EMEA-002703-PIP01-19-M01 - paediatric investigation plan	Updated
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07/07/2025	PIP: EMEA-002033-PIP02-23 - paediatric investigation plan	New

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07/07/2025	PIP: EMEA-001739-PIP02-16-M02 - paediatric investigation plan	Updated
07/07/2025	PIP: EMEA-001613-PIP03-21-M01 - paediatric investigation plan	Updated
07/07/2025	PIP: EMEA-001373-PIP01-12-M06 - paediatric investigation plan	Updated
07/07/2025	PIP: EMEA-001290-PIP01-12-M01 - paediatric investigation plan	Updated
07/07/2025	Event: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	Updated
07/07/2025	Document: Meeting summary of the Medicine Shortages SPOC Working Party meeting on 13 May 2025	New
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07/07/2025	PIP: EMEA-000780-PIP01-09-M08 - paediatric investigation plan	Updated
07/07/2025	PIP: EMEA-000205-PIP02-11-M07 - paediatric investigation plan	Updated
07/07/2025	Page: SME Regulation and reports	Updated

NOTICE TO APPLICANTS

07. July 2025
Stakeholders' Consultation on EudraLex Volume 4 - Good Manufacturing Practice Guidelines: Chapter 4, Annex 11 and New Annex 22

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
11.07.2025	**Informationen zu Rote-Hand-Briefen und Informationsbriefen** Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht neue Hinweise zu anstehenden Rote-Hand-Briefen und Informationsbriefen.
11.07.2025	**Pharmacovigilance Risk Assessment Committee (PRAC)** Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 07.07. - 10.07.2025 behandelt wurden.
09.07.2025	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/98727/2025 vom 25.04.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Meropenem** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Meropenem infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
11.07.2025	**Europa und EUDAMED** Sicherheit und Versorgung mit Medizinprodukten weiterentwickeln, Koordination und Governance auf EU-Ebene stärken - Die europäischen Medizinproduktebehörden haben ein gemeinsames Statement zur MDR und IVDR veröffentlicht.
11.07.2025	**CAMD and HMA: European medical device competent authorities statement on reform of the EU regulatory framework for medical devices (July 2025)**

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since May 22nd, 2025.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.