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No updates since August 27th, 2025.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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EUROPEAN MEDICINES AGENCY (EMA)

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08/09/2025	Event: GIDWG Stakeholder Meeting: 1-3 October 2025	New
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05/09/2025	Document: Medicine shortage communication (MSC): Victoza 6 mg/mL solution for injection in pre-filled pen (liraglutide)	New

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05/09/2025	News: PRAC starts safety review of levamisole, a medicine used to treat parasitic worm infections	New
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04/09/2025	Medicine: Contacera	Updated
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04/09/2025	Medicine: Topotecan Hospira	Updated
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04/09/2025	Orphan: EU/3/16/1715 - orphan designation for treatment of inherited retinal dystrophies due to defects in the RPGR gene	Updated
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02/09/2025	Document: EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database - Chapter 6: Examples for submission of legacy data (obsolete)	Updated
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02/09/2025	Medicine: Nobilis Multriva Gm+REOm	Updated
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01/09/2025	Document: Agenda of the PRAC meeting 1-4 September 2025	New
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01/09/2025	Medicine: Zenrelia	Updated
01/09/2025	Medicine: Numelvi	Updated
01/09/2025	Medicine: Jcovden (previously COVID-19 Vaccine Janssen)	Updated
01/09/2025	Event: Clinical Trials Information System (CTIS): Walk-in clinic September 2025	New
01/09/2025	Event: Committee for Advanced Therapies (CAT) workshop on gene editing	Updated
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01/09/2025	Page: World Health Organization (WHO)	Updated
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01/09/2025	Page: Transfer of data on suspected adverse reactions to WHO	New
01/09/2025	Document: Applications for new human medicines under evaluation: September 2025	New
01/09/2025	Document: Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) dataload friendly file including deprecated terms	Updated
01/09/2025	Page: Industry Standing Group meetings	Updated
01/09/2025	Event: 14th Industry Standing Group (ISG) meeting	New
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01/09/2025	Event: European Platform for Regulatory Science Research meeting September 2025	New
01/09/2025	Referral: Finasteride- and dutasteride-containing medicinal products - referral	Updated
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NOTICE TO APPLICANTS

3 September 2025

Stakeholders' Consultation on EudraLex Volume 4 - Good Manufacturing Practice Guidelines: Chapter 1

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
08.09.2025	**Rote-Hand-Brief zu Clozapin: Überarbeitete Empfehlungen zur routinemäßigen Blutbildkontrolle im Hinblick auf das Risiko einer Agranulozytose** Wirkstoff: Clozapin Die Zulassungsinhaber von clozapinhaltigen Arzneimitteln informieren über die überarbeiteten Empfehlungen zur routinemäßigen Blutbildkontrolle.
08.09.2025	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 24.07.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Domperidon** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Domperidon infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
08.09.2025	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 24.07.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Nicotin** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Nicotin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
05.09.2025	**Informationen zu Rote-Hand-Briefen und Informationsbriefen** Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht neue Hinweise zu anstehenden Rote-Hand-Briefen und Informationsbriefen.

Date	Title
05.09.2025	**Levamisol: Überprüfung des Risikos für eine Leukoenzephalopathie** Wirkstoff: Levamisol Die Europäische Arzneimittel-Agentur (EMA) beginnt mit der Sicherheitsüberprüfung von levamisolhaltigen Arzneimitteln zur Behandlung von parasitären Wurminfektionen.
05.09.2025	**Pharmacovigilance Risk Assessment Committee (PRAC)** Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 01.09.-04.09.2025 behandelt wurden.
02.09.2025	**Umsetzung des Durchführungsbeschlusses der Europäischen Kommission vom 21.08.2025 zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff (E)-Stiripentol** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff (E)-Stiripentol infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
01.09.2025	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppevom 19.06.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Isoniazid** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Isoniazid infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since August 26th, 2025.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since May 22nd, 2025.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.