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No updates since August 4th, 2026.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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EUROPEAN MEDICINES AGENCY (EMA)

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04/09/2026	**Page**: Union Product Database: release notes	Updated
04/09/2026	**Medicine**: Miglustat Dipharma miglustat	Updated
04/09/2026	**Document**: Guidance for applicants on how to submit ePI in centralised procedures	New
04/09/2026	**Page**: Electronic product information (ePI)	Updated
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04/09/2026	**Page**: Pharmaceutical industry: Getting involved in EMA activities	New
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04/09/2026	**News**: New EU supply chain to end Visudyne shortage	New
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02/09/2026	**Document**: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure	Updated

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02/09/2026	**Document**: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure: document with tracked changes	Updated
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01/09/2026	**Medicine**: Seffalair Spiromax salmeterol; fluticasone propionate	Updated
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01/09/2026	**News**: Voluntary data submission pilot to advance innovative alternatives to animal testing	New
01/09/2026	**Page**: New approach methodologies to replace and reduce animal testing: Voluntary data submission pilot	New
01/09/2026	**Document**: Voluntary data submission (VDS) pilot information document	New
01/09/2026	**Document**: Voluntary data submission (VDS) pilot application form	New
01/09/2026	**Medicine**: Aujemflu Influenza vaccine (surface antigen, inactivated, adjuvanted, prepared in cell culture)	Updated
01/09/2026	**Medicine**: Zadenvi denosumab	Updated
01/09/2026	**Document**: Regulatory Procedure Management (RPM) for the Product Lifecycle Management (PLM) in IRIS - Frequently asked questions	Updated
01/09/2026	**Document**: IRIS guide for applicants - How to create, submit and manage IRIS applications, for industry and individual applicants	Updated

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01/09/2026	**Page**: Veterinary Medicines	Updated
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31/08/2026	**Document**: Quick guide for EMA experts: registration, declaration of interests and contracts	New
31/08/2026	**Medicine**: Orladeyo berotralstat	Updated
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31/08/2026	**Document**: Agenda of the PRAC meeting 31 August - 3 September 2026	New
31/08/2026	**Document**: Record of processing activity on 360 assessment (public)	New
31/08/2026	**Medicine**: Usrenty ustekinumab	Updated
31/08/2026	**Medicine**: Enurev Breezhaler glycopyrronium bromide	Updated
31/08/2026	**Medicine**: Daybu trofinetide	Updated
31/08/2026	**Document**: Shortage Prevention Plans (SPP) template	New

Date	Content	Status
31/08/2026	**Document**: Guidance for industry on implementing Shortage Prevention Plans (SPP)	Updated
31/08/2026	**Document**: List of centrally authorised products with safety-related changes to the product information	Updated

NOTICE TO APPLICANTS

No updates since June 24th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
04.09.2026	**Injizierbare eisenhaltige Arzneimittel: Überprüfung des Risikos für niedrige Phosphatspiegel im Blut und damit zusammenhängende Knochenerkrankungen** Wirkstoff: Eisen in injizierbaren Darreichungsformen Die Europäische Arzneimittel-Agentur (EMA) beginnt mit der Überprüfung von injizierbaren eisenhaltigen Arzneimitteln.
04.09.2026	**Pharmacovigilance Risk Assessment Committee (PRAC)** Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 31.08.-03.09.2026 behandelt wurden.
03.09.2026	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 25.06.2026 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Pipamperon** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Pipamperon infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
02.09.2026	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 25.06.2026 betreffend die Zulassungen für Humanarzneimittel mit der Wirkstoffkombination Carbidopa/Levidopa** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff die Wirkstoffkombination Carbidopa/Levidopa infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
31.08.2026	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 25.06.2026 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Terbinafin** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Terbinafin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

Date	Title
31.08.2026	**Aktuelle Hinweise zu Einreichung und Genehmigung von Schulungsmaterial** Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
31.08.2026	**93. Sitzung (21. Juli 2026 per Videokonferenz) – Ergebnisprotokoll** Sachverständigen-Ausschuss für Verschreibungspflicht nach § 53 Absatz 2 AMG

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since August 12th, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since August 3rd, 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.