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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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14/08/2026	**Medicine**: Fulphila pegfilgrastim	Updated
14/08/2026	**Medicine**: Lutathera lutetium (177Lu) oxodotreotide	Updated
14/08/2026	**Page**: Scientific publications	Updated
14/08/2026	**Page**: Artificial intelligence	Updated
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14/08/2026	**Document**: European Medicines Agency's data protection notice on 360 assessment	New
14/08/2026	**Event**: EMA multi-stakeholder workshop on supporting innovation in cardiovascular medicines and medical devices in the EU	Updated
14/08/2026	**Document**: Presentation - AI and digital technologies transforming cardiovascular device in novation (S. Zenker)	New

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14/08/2026	**Document**: Presentation - AI in cardiovascular care (F. Asselbergs)	New
14/08/2026	**Document**: Presentation - Fostering innovation in cardiovascular diseases with digitalisationand AI (K. Azer)	New
14/08/2026	**Medicine**: Tuzulby methylphenidate hydrochloride	Updated
14/08/2026	**Document**: Presentation - Experience gained and lessons learned from recent and ongoing initiatives (A. Segec)	New
14/08/2026	**Document**: Presentation - Emerging and innovative devices - state of play and key questions (J. Russo)	New
14/08/2026	**Document**: Presentation - Emerging and innovative therapies - state of play and key questions (O. Vedin)	New
14/08/2026	**Document**: Presentation - Challenges and opportunities in medicines development (A. Baczynska)	New
14/08/2026	**PIP**: EMA/PE/0000232482 - paediatric investigation plan tegoprubart	New
13/08/2026	**Event**: Digitalisation and artificial Intelligence in pharmaceutical manufacturing: Quality Innovation Group (QIG) - Follow-up roundtable meeting	Updated
13/08/2026	**Medicine**: KemSu sufentanil; ketamine	Updated
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13/08/2026	**Document**: Presentation - Adiposity: The gateway to cardiometabolic diseases (L. Fábryová)	New
13/08/2026	**Document**: Presentation - Cardiometabolic diseases: Tackling the unmet need in CV risk reduction (F. Giorgino)	New

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13/08/2026	**Document**: Presentation - Cardiometabolic diseases: tackling the unmet need in cardiovascular risk reduction (J. Nabais)	New
13/08/2026	**Document**: Presentation - Global collaboration in cardiovascular medicine development (M. Inoue)	New
13/08/2026	**Document**: Presentation - Clinical imperatives for implementing regulatory science for medical devices (A. Fraser)	New
13/08/2026	**Document**: Presentation - Recent (regulatory) developments in medicines for cardiovascular indications (A. Irs)	New
13/08/2026	**Document**: Presentation - Clinical research: opportunties and challenges (T. Lüscher)	New
13/08/2026	**Document**: Presentation - The safe hearts plan (Y. Azzopardi)	New
13/08/2026	**Document**: Presentation - Lived experience in unmet need (M. Holler)	New
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13/08/2026	**Medicine**: Ezmekly mirdametinib	Updated
13/08/2026	**Medicine**: Exdensur depemokimab	Updated
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13/08/2026	**PSUSA**: PSUSA/00002420/202510 - periodic safety update report single assessment pipamperone	New
13/08/2026	**Page**: Reliance for post-authorisation changes pilots	Updated
13/08/2026	**Document**: Meeting report: Regulators-only workshop on reliance for post-approval changes (PACs) 18–19 May 2026	New
13/08/2026	**Document**: Reliance for postauthorisation changes (PACs): Mid-pilot review	New
13/08/2026	**Event**: Industry webinar on new electronic application form (eAF) version	Updated

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12/08/2026	**Document**: Product Management Service (PMS) – Frequently Asked Questions (FAQs)	Updated
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12/08/2026	**Document**: Annex 1 - Qualification opinion briefing book for the Big MS Data network registries on Post Authorization Safety Studies	New
12/08/2026	**Document**: Annex 2 - Observational long-term safety surveillance registry studies in the Big MS Data (BMSD) network	New
12/08/2026	**Document**: Draft qualification opinion for the Big Multiple Sclerosis Data (BMSD) network	New
12/08/2026	**Document**: Annex 5 - Initial Qualification Procedure - List of Issues - Big MS Data Network (BMSD) and incorporated multiple sclerosis (MS)	New
12/08/2026	**Document**: Process for the electronic submission of medicinal product information - Chapter 3	Updated
12/08/2026	**Document**: Product Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 2 - tracked changes	Updated
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11/08/2026	**Medicine**: Kanjinti trastuzumab	Updated
11/08/2026	**Event**: Clinical Trials Information System (CTIS): Walk-in clinic October 2026	New

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11/08/2026	**Medicine**: Yesintek ustekinumab	Updated
10/08/2026	**Page**: Vaccine Monitoring Platform	Updated
10/08/2026	**Medicine**: Boey trenibotulinumtoxinE	Updated
10/08/2026	**PIP**: EMA/PE/0000273488 - paediatric investigation plan rocatinlimab	Updated
10/08/2026	**Post-authorisation**: Jivi - opinion on variation to marketing authorisation damoctocog alfa pegol	New
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10/08/2026	**Document**: Vaccine Monitoring Platform (VMP) research agenda - Update 2026	Updated
10/08/2026	**Document**: Vaccine Monitoring Platform (VMP) research agenda	Updated
10/08/2026	**Medicine**: Oncept IL-2 feline interleukin-2 recombinant canarypox virus (vCP1338 virus)	Updated
10/08/2026	**Medicine**: Nuvaxovid COVID-19 Vaccine (recombinant, adjuvanted)	Updated
10/08/2026	**DHPC**: Litfulo - direct healthcare professional communication (DHPC) ritlecitinib tosilate	New

NOTICE TO APPLICANTS

No updates since June 24th, 2026.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
13.08.2026	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 25.06.2026 betreffend die Zulassungen für Humanarzneimittel mit den Wirkstoffen all-rac-α-Tocopherol, RRR-α-Tocopherol, Vitamin E** Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffe all-rac-α-Tocopherol, RRR-α-Tocopherol, Vitamin E infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

Date	Title
11.08.2026	**Ausschreibung eines Pharmakovigilanzforschungsprojektes zur Untersuchung von misoprostolhaltigen Arzneimitteln zur Geburtseinleitung** vom 11.08.2026
10.08.2026	**Tavneos (Avacopan): Überprüfung der Wirksamkeit aufgrund von Fragen zur Datenintegrität der Hauptstudie** Wirkstoff: Avacopan Die Europäische Kommission empfiehlt den Widerruf der Genehmigung für das Inverkehrbringen von Tavneos.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since August 3rd, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since August 3rd, 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.

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