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27 November

NEW - Presentations from the 19 November 2025 meeting with Interested Parties

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NEW - Art. 46 PAR Botox (botulinum toxin type A)

NEW - Art. 46 PAR Pentavac (Corynebacterium diphtheriae toxoid, Clostridium tetani toxoid, Haemophilus influenzae type B polysaccharide, Bordetella pertussis, filamentous hemagglutinin, Bordetella pertussis toxoid, poliovirus type 1, strain Mahoney, inactivated, poliovirus type 3, strain Saukett, inactivated, poliovirus type 2, strain MEF-1, inactivated)

UPDATE - Instructions for RMS when preparing the PAR based on the FAR

UPDATE - PAR template (empty) - when prepared based on FAR

UPDATE - CMDh Best Practice Guide on the compilation of the dossier for New Applications submitted in Mutual Recognition and Decentralised Procedures

UPDATE - D70 Overview AR Template (empty)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

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28/11/2025	**Orphan**: EU/3/08/548 - orphan designation for treatment of multiple myelomacarfilzomib	Updated
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24/11/2025	**Document**: PRAC recommendations on signals adopted at the 27-30 October 2025 PRAC meeting	New
24/11/2025	**Document**: New product information wording: extracts from PRAC recommendations on signals adopted at the 27-30 October 2025 PRAC	New
24/11/2025	**PSUSA**: PSUSA/00003045/202501 - periodic safety update report single assessment trimethoprim	New

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
28.11.2025	**Pharmacovigilance Risk Assessment Committee (PRAC)** Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 24.11.-27.11.2025 behandelt wurden.
27.11.2025	**92. Sitzung (20. Januar 2026 per Videokonferenz) – Tagesordnung** Sachverständigen-Ausschuss für Verschreibungspflicht nach § 53 Absatz 2 AMG
24.11.2025	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 18.09.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Buproprion** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Buproprion 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 November 20th, 2025.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
28.11.2025	Paul-Ehrlich-Institut gestattet Einfuhr von Vimkunya mit französischer Beschriftung

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.