

## TABLE OF CONTENTS

HEADS OF AGENCIES – CMDH.....	1
HEADS OF AGENCIES – PAEDIATRIC REGULATION .....	1
EUROPEAN MEDICINES AGENCY (EMA) .....	1
NOTICE TO APPLICANTS.....	11
BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY).....	11
BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY) .....	12
PEI - VIGILANZ (SPECIFIC FOR GERMANY) .....	12
PHARMEUROPA TEXTS FOR COMMENT.....	12

### HEADS OF AGENCIES – CMDh

No updates since March 04<sup>th</sup>, 2026.

### HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: [click here](#)

### EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
16/03/2026	<b>Document:</b> <a href="#">Release notes - production release version 1.7.2615 March 2026 - Veterinary Medicinal Products Regulation: Union Product Database</a>	New
13/03/2026	<b>Medicine:</b> <a href="#">Carvykti</a> ciltacabtagene autoleucel	Updated
13/03/2026	<b>Medicine:</b> <a href="#">Pradaxa</a> dabigatran etexilate	Updated
13/03/2026	<b>Medicine:</b> <a href="#">Wegovy</a> semaglutide	Updated
13/03/2026	<b>Medicine:</b> <a href="#">Orphacol</a> cholic acid	Updated
13/03/2026	<b>Page:</b> <a href="#">Qualification of non-mutagenic impurities - Scientific guideline</a>	Updated
13/03/2026	<b>Medicine:</b> <a href="#">Vazkepa</a> icosapent ethyl	Updated
13/03/2026	<b>Medicine:</b> <a href="#">Arsenic trioxide Accord</a> arsenic trioxide	Updated

<b>Date</b>	<b>Content</b>	<b>Status</b>
13/03/2026	<b>Document:</b> <a href="#">Joint Controllership Arrangement with regard to the Clinical Trials Information System (CTIS)</a>	Updated
13/03/2026	<b>Document:</b> <a href="#">European Medicines Agency's data protection notice regarding personal data processing in the Clinical Trials Information System (CTIS)</a>	Updated
13/03/2026	<b>Document:</b> <a href="#">Questions and Answers on the Joint Controllership Arrangement and data protection matters related to the use of the Clinical Trials Information System</a>	Updated
13/03/2026	<b>Document:</b> <a href="#">QRD veterinary Appendix I - Adverse event (PhV) MSs reporting details</a>	Updated
13/03/2026	<b>Medicine:</b> <a href="#">Xerava</a> eravacycline	Updated
13/03/2026	<b>Medicine:</b> <a href="#">Skyclarys</a> omaveloxolone	Updated
13/03/2026	<b>Medicine:</b> <a href="#">Vizamyl</a> flutemetamol (18F)	Updated
13/03/2026	<b>Document:</b> <a href="#">Darwin EU: Making health data count</a>	Updated
13/03/2026	<b>Medicine:</b> <a href="#">Anktiva</a> nogapendekin alfa inbakicept	Updated
13/03/2026	<b>Page:</b> <a href="#">Availability of medicines before and during crises</a>	Updated
13/03/2026	<b>Page:</b> <a href="#">Union list of critical medicines</a>	Updated
13/03/2026	<b>News:</b> <a href="#">EMA Management Board: highlights of March 2026 meeting</a>	New
13/03/2026	<b>Page:</b> <a href="#">Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG)</a>	Updated
13/03/2026	<b>Medicine:</b> <a href="#">AviGate S. Infantis</a> Salmonella Infantis vaccine (live)	New
13/03/2026	<b>Medicine:</b> <a href="#">VeroBlue-3</a> bluetongue virus vaccine (inactivated)	New
13/03/2026	<b>News:</b> <a href="#">Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 10-12 March 2026</a>	New

Date	Content	Status
13/03/2026	<b>Medicine:</b> <a href="#">Ebymect</a> dapagliflozin; metformin	Updated
13/03/2026	<b>Medicine:</b> <a href="#">Edistride</a> dapagliflozin	Updated
13/03/2026	<b>Medicine:</b> <a href="#">Qtern</a> saxagliptin; dapagliflozin	Updated
13/03/2026	<b>Medicine:</b> <a href="#">Xigduo</a> dapagliflozin; metformin	Updated
13/03/2026	<b>Page:</b> <a href="#">Data protection and privacy at EMA</a>	Updated
13/03/2026	<b>News:</b> <a href="#">Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 9 - 12 March 2026</a>	New
13/03/2026	<b>Document:</b> <a href="#">Appendix 1: Acceptable intakes established for N-nitrosamines</a>	Updated
13/03/2026	<b>Page:</b> <a href="#">Union Product Database</a>	Updated
13/03/2026	<b>Document:</b> <a href="#">EU Implementation Guide (IG) on veterinary medicines product data in the Union Product Database - Example payloads for API</a>	New
13/03/2026	<b>Document:</b> <a href="#">Records of data processing activity relating to temporary agency workers (interims)</a>	New
13/03/2026	<b>Document:</b> <a href="#">European Medicines Agency's data protection notice for women leadership development and mentoring activities</a>	New
13/03/2026	<b>Event:</b> <a href="#">Management Board meeting: 12 March 2026</a>	Updated
13/03/2026	<b>Document:</b> <a href="#">Minutes - HMA-EMA joint Network Data Steering Group meeting - 11 February 2026</a>	New
13/03/2026	<b>Event:</b> <a href="#">EMA Veterinary Medicines Info Day 2026</a>	Updated
13/03/2026	<b>Page:</b> <a href="#">Development of anti-cancer medicinal products in paediatric patients - Scientific guideline</a>	New
13/03/2026	<b>Document:</b> <a href="#">Concept paper on the development of a reflection paper on proof-of-concept data to support the development of anti-cancer medicinal products in paediatric patients</a>	New

<b>Date</b>	<b>Content</b>	<b>Status</b>
12/03/2026	<b>Medicine:</b> <a href="#">Elucirem</a> gadopiclenol	Updated
12/03/2026	<b>Medicine:</b> <a href="#">Vueway</a> gadopiclenol	Updated
12/03/2026	<b>Medicine:</b> <a href="#">Tecartus</a> brexucabtagene autoleucl	Updated
12/03/2026	<b>Medicine:</b> <a href="#">Yescarta</a> axicabtagene ciloleucl	Updated
12/03/2026	<b>Medicine:</b> <a href="#">Forxiga</a> dapagliflozin	Updated
12/03/2026	<b>Medicine:</b> <a href="#">Lenalidomide Krka (previously Lenalidomide Krka d.d. Novomesto)</a> lenalidomide	Updated
12/03/2026	<b>Medicine:</b> <a href="#">Quviviq</a> daridorexant	Updated
12/03/2026	<b>Herbal:</b> <a href="#">Zingiberis rhizoma - herbal medicinal product</a> Ginger	Updated
12/03/2026	<b>Herbal:</b> <a href="#">Trigonellae foenugraeci semen - herbal medicinal product</a> Fenugreek seed	Updated
12/03/2026	<b>Medicine:</b> <a href="#">Eliquis</a> apixaban	Updated
12/03/2026	<b>Herbal:</b> <a href="#">Rosmarini folium - herbal medicinal product</a> Rosemary leaf	Updated
12/03/2026	<b>Medicine:</b> <a href="#">Exdensur</a> depemokimab	Updated
12/03/2026	<b>Herbal:</b> <a href="#">Rosmarini aetheroleum - herbal medicinal product</a> Rosemary oil	Updated
12/03/2026	<b>Herbal:</b> <a href="#">Pilosellae herba cum radice - herbal medicinal product</a> Mouse-ear hawkweed	Updated
12/03/2026	<b>Herbal:</b> <a href="#">Ginseng radix - herbal medicinal product</a> Ginseng	Updated
12/03/2026	<b>Herbal:</b> <a href="#">Cnici benedicti herba - herbal medicinal product</a> St. Benedict's thistle (also blessed thistle, holy thistle or spotted thistle)	Updated
12/03/2026	<b>Document:</b> <a href="#">List of medicines currently in PRIME scheme</a>	Updated
12/03/2026	<b>Event:</b> <a href="#">Clinical Trials Information System (CTIS): Walk-in clinic April 2026</a>	New

<b>Date</b>	<b>Content</b>	<b>Status</b>
12/03/2026	<b>Page:</b> <a href="#">Article 141(1) opinions on any scientific matter: veterinary medicines</a>	Updated
12/03/2026	<b>Page:</b> <a href="#">Veterinary antibiotics: Dosage review and adjustment (ADRA) project</a>	New
12/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000226246 - paediatric investigation plan marstacimab</a>	Updated
12/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000226217 - paediatric investigation plan bictegravir; emtricitabine; tenofovir alafenamide</a>	Updated
12/03/2026	<b>Medicine:</b> <a href="#">Rxulti brexpiprazole</a>	Updated
12/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000225746 - paediatric investigation plan atogepant</a>	Updated
12/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000226088 - paediatric investigation plan relacorilant</a>	Updated
12/03/2026	<b>Document:</b> <a href="#">CAT quarterly highlights and approved ATMPs - March 2026</a>	New
12/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000225073 - paediatric investigation plan recombinant parathyroid hormone</a>	New
12/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000225023 - paediatric investigation plan efgartigimod alfa</a>	New
12/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000224955 - paediatric investigation plan ribitol</a>	Updated
12/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000224883 - paediatric investigation plan rinatabart sesutecan</a>	New
12/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000225241 - paediatric investigation plan calcium chloride dihydrate; magnesium chloride hexahydrate; sodium chloride; sodium lactate; xylitol; d-glucose; levocarnitine</a>	New
12/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000224912 - paediatric investigation plan cannabidiol</a>	Updated
11/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000224768 - paediatric investigation plan vosoritide</a>	Updated
11/03/2026	<b>PIP:</b> <a href="#">EMEA-001652-PIP01-14-M06 - paediatric investigation plan cariprazine hydrochloride</a>	Updated
11/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000224283 - paediatric investigation plan pegcetacoplan</a>	Updated

Date	Content	Status
11/03/2026	<b>Document:</b> <a href="#">Applications for new human medicines under evaluation: March 2026</a>	New
11/03/2026	<b>Herbal:</b> <a href="#">Valerianae radix - herbal medicinal product</a> Valerian Root	Updated
11/03/2026	<b>Document:</b> <a href="#">Minutes of the COMP meeting 20-22 January 2026</a>	New
11/03/2026	<b>PSUSA:</b> <a href="#">PSUSA/00002004/202505 - periodic safety update report single assessment</a> methadone	New
11/03/2026	<b>PSUSA:</b> <a href="#">PSUSA/00001102/202507 - periodic safety update report single assessment</a> dimetindene / phenylephrine	New
11/03/2026	<b>PSUSA:</b> <a href="#">PSUSA/00000061/202508 - periodic safety update report single assessment</a> ademetonine	New
11/03/2026	<b>Document:</b> <a href="#">DARWIN EU Advisory Board: Membership</a>	Updated
11/03/2026	<b>Document:</b> <a href="#">Agenda of the CVMP meeting 10-12 March 2026</a>	Updated
11/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000224175 - paediatric investigation plan</a> azamidugene autotemcel (OTL-203)	Updated
11/03/2026	<b>PIP:</b> <a href="#">EMEA-003026-PIP02-21 - paediatric investigation plan</a> whole-cell heat-inactivated bacterial strains of Escherichia coli, Klebsiella pneumoniae, Proteus vulgaris and Enterococcus faecalis	Updated
11/03/2026	<b>PIP:</b> <a href="#">EMEA-003639-PIP01-24 - paediatric investigation plan</a> adeno-associated virus serotype 9 vector containing the human LAMP2 isoform B transgene (RP-A501)	New
11/03/2026	<b>PIP:</b> <a href="#">EMEA-003636-PIP01-24 - paediatric investigation plan</a> respiratory syncytial virus, prefusion F protein, virus-like particle / human metapneumovirus, prefusion F protein, virus-like particle (IVX-A12)	New
11/03/2026	<b>PIP:</b> <a href="#">EMEA-003635-PIP01-24 - paediatric investigation plan</a> heterologous intestinal microbiota from healthy donors (MBK-01)	New
11/03/2026	<b>Document:</b> <a href="#">Minutes of the PRAC meeting 12 - 15 January 2026</a>	New
11/03/2026	<b>Medicine:</b> <a href="#">Winrevair</a> sotatercept	Updated
11/03/2026	<b>PIP:</b> <a href="#">EMEA-001161-PIP02-11-M03 - paediatric investigation plan</a> Modified Vaccinia Ankara - Bavarian Nordic virus (smallpox)	Updated

<b>Date</b>	<b>Content</b>	<b>Status</b>
11/03/2026	<b>PIP:</b> <a href="#">EMEA-003119-PIP01-21-M01 - paediatric investigation plan zuranolone</a>	Updated
11/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000224110 - paediatric investigation plan esketamine hydrochloride</a>	Updated
11/03/2026	<b>PIP:</b> <a href="#">EMEA-003604-PIP01-24 - paediatric investigation plan luliconazole</a>	New
11/03/2026	<b>Medicine:</b> <a href="#">Vitrakvi</a> larotrectinib	Updated
11/03/2026	<b>Medicine:</b> <a href="#">Vimpat</a> lacosamide	Updated
11/03/2026	<b>PIP:</b> <a href="#">EMEA-003161-PIP02-24 - paediatric investigation plan golcadomide hydrochloride</a>	New
11/03/2026	<b>PIP:</b> <a href="#">EMEA-003533-PIP01-23 - paediatric investigation plan livmoniplimab</a>	New
11/03/2026	<b>PIP:</b> <a href="#">EMEA-003532-PIP01-23 - paediatric investigation plan budigalimab</a>	New
11/03/2026	<b>PIP:</b> <a href="#">EMEA-002476-PIP03-24 - paediatric investigation plan letetresgene autoleucel</a>	New
11/03/2026	<b>Medicine:</b> <a href="#">Spinraza</a> nusinersen	Updated
11/03/2026	<b>Medicine:</b> <a href="#">Kirsty (previously Kixelle)</a> insulin aspart	Updated
11/03/2026	<b>Medicine:</b> <a href="#">Lysodren</a> mitotane	Updated
11/03/2026	<b>Document:</b> <a href="#">Vaxchora: avoiding errors when making up and using the vaccine</a>	Updated
11/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000223656 - paediatric investigation plan givinostat</a>	Updated
11/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000223608 - paediatric investigation plan molnupiravir</a>	Updated
10/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000230373 - paediatric investigation plan rinatabart sesutecan</a>	New
10/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000230375 - paediatric investigation plan rinatabart sesutecan</a>	New
10/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000223523 - paediatric investigation plan paltusotine</a>	New

<b>Date</b>	<b>Content</b>	<b>Status</b>
10/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000223677</a> - paediatric investigation plan coramitug	New
10/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000228821</a> - paediatric investigation plan zeleneptide pevedotin	New
10/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000228365</a> - paediatric investigation plan botensilimab	New
10/03/2026	<b>Medicine:</b> <a href="#">Iloperidone Vanda Pharmaceuticals</a> iloperidone	Updated
10/03/2026	<b>PSUSA:</b> <a href="#">PSUSA/00002828/202504</a> - periodic safety update report single assessment sulprostone	New
10/03/2026	<b>Medicine:</b> <a href="#">Ponvory</a> ponesimod	Updated
10/03/2026	<b>Medicine:</b> <a href="#">Kengrexal</a> cangrelor	Updated
10/03/2026	<b>Medicine:</b> <a href="#">Lydisilka</a> estetrol; drospirenone	Updated
10/03/2026	<b>Medicine:</b> <a href="#">Drovelis</a> estetrol; drospirenone	Updated
10/03/2026	<b>Document:</b> <a href="#">Record of data processing activity for EudraVigilance</a>	Updated
10/03/2026	<b>Page:</b> <a href="#">Class III implantable devices and Class IIb medical devices intended to administer or remove medicinal products: expert panel opinions</a>	Updated
10/03/2026	<b>Page:</b> <a href="#">High-risk medical devices: consultation procedures</a>	Updated
10/03/2026	<b>Document:</b> <a href="#">List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment</a>	Updated
10/03/2026	<b>Medicine:</b> <a href="#">Amversio</a> betaine anhydrous	Updated
10/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000228360</a> - paediatric investigation plan ezetimibe; rosuvastatin	New
10/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000228114</a> - paediatric investigation plan mesdopetam	New
10/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000228097</a> - paediatric investigation plan sacituzumab govitecan	New

<b>Date</b>	<b>Content</b>	<b>Status</b>
10/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000227674 - paediatric investigation plan zampilimab</a>	New
10/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000228776 - paediatric investigation plan abemaciclib</a>	Updated
10/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000228333 - paediatric investigation plan sufentanil citrate; ketamine (hydrochloride)</a>	Updated
10/03/2026	<b>PSUSA:</b> <a href="#">PSUSA/00000383/202506 - periodic safety update report single assessment</a> benzylpenicillin, benzathine benzylpenicillin, benzathine benzylpenicillin / lidocaine, procaine benzylpenicillin, benzathine benzylpenicillin / procaine benzylpenicillin	New
10/03/2026	<b>PSUSA:</b> <a href="#">PSUSA/00001126/202507 - periodic safety update report single assessment</a> diphtheria / tetanus / pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed), diphtheria / tetanus / pertussis (acellular, component) and poliomyelitis (inactivated) vaccine (adsorbed, reduced antigen(s) content)	New
10/03/2026	<b>PSUSA:</b> <a href="#">PSUSA/00002453/202505 - periodic safety update report single assessment</a> pneumococcal polysaccharide vaccine	New
10/03/2026	<b>PSUSA:</b> <a href="#">PSUSA/00002312/202506 - periodic safety update report single assessment</a> caffeine / codeine / paracetamol / propyphenazone, acetylsalicylic acid / caffeine / codeine / paracetamol	New
10/03/2026	<b>Medicine:</b> <a href="#">Teduglutide Viatriis</a> teduglutide	Updated
10/03/2026	<b>Medicine:</b> <a href="#">Alkindi</a> hydrocortisone	Updated
10/03/2026	<b>Document:</b> <a href="#">European Medicines Agency's data protection notice for the EudraVigilance Signal and Safety Analytics (EV SSA) platform</a>	Updated
10/03/2026	<b>Medicine:</b> <a href="#">Veoza</a> fezolinetant	Updated
10/03/2026	<b>Page:</b> <a href="#">Supporting innovation</a>	Updated
10/03/2026	<b>Page:</b> <a href="#">Portfolio and technology meetings</a>	Updated
10/03/2026	<b>Document:</b> <a href="#">Portfolio and technology meeting briefing document</a>	Updated

<b>Date</b>	<b>Content</b>	<b>Status</b>
10/03/2026	<b>Event:</b> <a href="#">PCWP/HCPWP joint meeting</a>	Updated
10/03/2026	<b>Document:</b> <a href="#">Procedural guidance to scientific committees' members and experts on completing the European Medicines Agency's declaration of interests in the Experts Management Tool</a>	Updated
10/03/2026	<b>Document:</b> <a href="#">Methodology to identify vulnerabilities in supply chains of critical medicines</a>	New
10/03/2026	<b>Document:</b> <a href="#">SMS guidance for external users</a>	Updated
10/03/2026	<b>Event:</b> <a href="#">Committee for Medicinal Products for Veterinary Use (CVMP): 10-12 March 2026</a>	Updated
09/03/2026	<b>Page:</b> <a href="#">Eligible healthcare professionals' organisations</a>	Updated
09/03/2026	<b>Document:</b> <a href="#">Network Data Steering Group workplan 2026-2028: Data and artificial intelligence in medicines regulation</a>	New
09/03/2026	<b>Page:</b> <a href="#">Network Data Steering Group (NDSG)</a>	Updated
09/03/2026	<b>PIP:</b> <a href="#">EMEA-001502-PIP01-13 - paediatric investigation plan adeno-associated viral vector serotype 9 containing human sulfamidase gene</a>	Updated
09/03/2026	<b>PIP:</b> <a href="#">EMEA-001722-PIP01-14-M02 - paediatric investigation plan eteplirsen</a>	Updated
09/03/2026	<b>Document:</b> <a href="#">Record of data processing activity relating to Security Access Control System</a>	Updated
09/03/2026	<b>PSUSA:</b> <a href="#">PSUSA/00001499/202502 - periodic safety update report single assessment gabapentin</a>	Updated
09/03/2026	<b>Medicine:</b> <a href="#">Nucala mepolizumab</a>	Updated
09/03/2026	<b>Medicine:</b> <a href="#">Cayston aztreonam</a>	Updated
09/03/2026	<b>PIP:</b> <a href="#">EMEA-003550-PIP01-23 - paediatric investigation plan humanized IgG4 Monoclonal Antibody against FIXa and FX (NXT007)</a>	New
09/03/2026	<b>Document:</b> <a href="#">Agenda of the PRAC meeting 9-12 March 2026</a>	New

Date	Content	Status
09/03/2026	<b>PIP:</b> <a href="#">EMA/003502-PIP02-24 - paediatric investigation plan mezagitamab</a>	New
09/03/2026	<b>Page:</b> <a href="#">PRAC recommendations on safety signals</a>	Updated
09/03/2026	<b>Document:</b> <a href="#">PRAC recommendations on signals adopted at the 9-12 February 2026 PRAC meeting</a>	New
09/03/2026	<b>Document:</b> <a href="#">List of signals discussed at PRAC since September 2012</a>	Updated
09/03/2026	<b>Event:</b> <a href="#">Webinar on the use of platform approaches in the non-clinical and clinical domains</a>	Updated
09/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000243095 - paediatric investigation plan teplizumab</a>	Updated
09/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000232930 - paediatric investigation plan mirikizumab</a>	Updated
09/03/2026	<b>PIP:</b> <a href="#">EMA/PE/0000232848 - paediatric investigation plan mirikizumab</a>	Updated
09/03/2026	<b>Document:</b> <a href="#">National Innovation Offices Contacts</a>	Updated
09/03/2026	<b>Page:</b> <a href="#">Organisation Management Service (OMS)</a>	Updated

## NOTICE TO APPLICANTS

No updates since October 30<sup>th</sup>, 2025.

## BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
13.03.2026	<b>Pharmacovigilance Risk Assessment Committee (PRAC)</b> Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 09.03.-12.03.2026 behandelt wurden.
10.03.2026	<b>Umsetzung der zwei einstimmigen Beschlüsse der Koordinierungsgruppe vom 11.12.2025 und vom 13.12.2017 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Simvastatin</b> Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Simvastatin 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 March 05<sup>th</sup>, 2026.

## **PEI - VIGILANZ (SPECIFIC FOR GERMANY)**

<b>Date</b>	<b>Title</b>
12.03.2026	<a href="#">Informationsschreiben von Biotest Pharma GmbH: Yimmugo</a>

## **PHARMEUROPA TEXTS FOR COMMENT**

Information on Pharmeuropa updates will be presented quarterly.

Trotz regelmäßiger Aktualisierung und sorgfältiger Überwachung der Veröffentlichungen können wir keine Haftung oder Garantie für die Aktualität, Richtigkeit und Vollständigkeit der hier bereitgestellten Informationen übernehmen. Dieser Newsletter enthält Links zu anderen Websites. Trotz sorgfältiger inhaltlicher Kontrolle übernehmen wir keine Haftung für die Inhalte externer Links. Für den Inhalt der verlinkten Seiten sind ausschließlich deren Betreiber verantwortlich.

Despite regular updating and careful monitoring of the publications, we cannot take any responsibility or guarantee for the topicality, correctness and completeness of the information provided here. This Newsletter contains links to other websites. Despite careful control of the content we would like to point out that we are not liable for the contents of external web links. The editors of the respective websites are fully responsible for their contents.