TABLE OF CONTENTS

HEADS OF AGENCIES – CMDh

27 May

NEW - 21-22 April CMDh Minutes

NEW - Art. 46 PAR Rapibloc, Landiolol Hydrochloride Orpha-Devel (landiolol hydrochloride)

NEW - Art. 46 PAR Efluelda Tetra (quadrivalent influenza vaccine (split virion, inactivated), 60 micrograms HA/strain)

NEW - Art. 46 PAR Vaccin rabique Pasteur, Verorab (rabies virus inactivated (Wistar rabies PM/W138 1503-3M strain))

UPDATE - Non Clinical / Clinical AR for Generics - MRP & DCP

NEW - Report from the meeting held on 19-20 May 2026

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
29/05/2026	**Medicine**: Optison perflutren	Updated
29/05/2026	**Medicine**: Caprelsa vandetanib	Updated
29/05/2026	**Medicine**: Ranluspec ranibizumab	Updated
29/05/2026	**Medicine**: Eurneffy epinephrine	Updated

Date	Content	Status
29/05/2026	**Medicine**: Tysabri natalizumab	Updated
29/05/2026	**Event**: SME info day - navigating EMA support: From development to market authorisation	New
29/05/2026	**Medicine**: Teriflunomide Viatris (previously Teriflunomide Mylan) teriflunomide	Updated
29/05/2026	**Medicine**: Ozurdex dexamethasone	Updated
29/05/2026	**Medicine**: Vyepti eptinezumab	Updated
29/05/2026	**Medicine**: Comirnaty COVID-19 mRNA vaccine	Updated
29/05/2026	**Page**: Enpr-EMA priority activities	Updated
29/05/2026	**Page**: Emergency Task Force (ETF) recommendations	Updated
29/05/2026	**News**: ETF recommends updating COVID-19 vaccines to target XFG variant	New
29/05/2026	**Document**: EMA recommendation to update the antigenic composition of authorised COVID-19 vaccines for 2026-2027	New
29/05/2026	**Page**: Need for maximum residue limit (MRL) evaluation for biological substances - Scientific guideline	Updated
29/05/2026	**Document**: List of centrally authorised products with safety-related changes to the product information	Updated
29/05/2026	**Page**: Expert panel support for breakthrough medical devices: pilot programme	Updated
29/05/2026	**Page**: Scientific advice for high-risk medical devices	Updated
29/05/2026	**Event**: Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) multistakeholder workshop on real-world data collection in duchenne muscular dystrophy	New

Date	Content	Status
29/05/2026	**Document**: Concept paper on the need for revision of the guideline on the development of medicinal products for the treatment of smoking	New
29/05/2026	**Page**: Quality of medicines: questions and answers - Part 2	Updated
28/05/2026	**Medicine**: Adtralza tralokinumab	Updated
28/05/2026	**Medicine**: Pomalidomide Teva pomalidomide	Updated
28/05/2026	**Medicine**: Camcevi leuprorelin	Updated
28/05/2026	**Medicine**: Fubelv etanercept	Updated
28/05/2026	**Medicine**: Joenja leniolisib	Updated
28/05/2026	**Document**: European Medicines Agency's privacy statement for legal entity and bank account validation	Updated
28/05/2026	**Medicine**: Aquipta atogepant	Updated
28/05/2026	**Shortage**: Champix varenicline	Updated
28/05/2026	**Page**: SME Regulation and reports	Updated
28/05/2026	**Document**: 20 years supporting small and medium enterprises (SMEs) at EMA report	New
28/05/2026	**Event**: Product Management Service (PMS) information day 2026	Updated
28/05/2026	**Medicine**: Spikevax (previously COVID-19 Vaccine Moderna) COVID-19 mRNA vaccine	Updated
28/05/2026	**Document**: Product Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 3	Updated
28/05/2026	**Document**: Timetable: Marketing authorisation renewal application - ATMP	Updated
28/05/2026	**Document**: Timetable: Marketing authorisation renewal application	Updated

Date	Content	Status
28/05/2026	**Medicine**: Beromun tasonermin	Updated
28/05/2026	**PSUSA**: PSUSA/00002478/202508 - periodic safety update report single assessment poractant alfa	New
28/05/2026	**Page**: Clinical pharmacology and pharmacokinetics: questions and answers	Updated
28/05/2026	**Page**: Podcast: Inside EMA	Updated
28/05/2026	**Page**: Real-world evidence	Updated
27/05/2026	**PSUSA**: PSUSA/00001819/202509 - periodic safety update report single assessment lactitol	New
27/05/2026	**Event**: European Medicines Agency (EMA) / European Chemicals Agency (ECHA) joint meeting with industry stakeholders	New
27/05/2026	**Medicine**: Calquence acalabrutinib	Updated
27/05/2026	**Medicine**: Verzenios abemaciclib	Updated
27/05/2026	**Page**: Accelerating Clinical Trials in the EU (ACT EU)	Updated
27/05/2026	**Medicine**: Qdenga dengue tetravalent vaccine (live, attenuated)	Updated
27/05/2026	**Medicine**: Sunosi solriamfetol	Updated
27/05/2026	**Medicine**: Xenleta lefamulin	Updated
27/05/2026	**Medicine**: Opdualag relatlimab; nivolumab	Updated
27/05/2026	**Document**: Timetable: Annual renewal application of conditional marketing authorisation	Updated
27/05/2026	**Document**: Timetable: Annual reassessment - ATMP	Updated
27/05/2026	**Document**: Timetable: Annual reassessment	Updated
27/05/2026	**Document**: Timetable: Annual renewal application of conditional marketing authorisation - ATMP	Updated
27/05/2026	**Medicine**: Poherdy pertuzumab	Updated
27/05/2026	**Medicine**: Yesintek ustekinumab	Updated
27/05/2026	**Document**: List of medicinal products under additional monitoring	Updated
27/05/2026	**Document**: List of medicinal products under additional monitoring	Updated
27/05/2026	**Page**: List of medicines under additional monitoring	Updated

Date	Content	Status
27/05/2026	**Shortage**: NovoNordisk insulin (human insulin) (various short-, rapid-, intermediate-, mixed- and long-acting forms)	Updated
27/05/2026	**Medicine**: Cablivi caplacizumab	Updated
27/05/2026	**Medicine**: Tevimbra tislelizumab	Updated
27/05/2026	**Medicine**: Otulfi ustekinumab	Updated
27/05/2026	**Medicine**: Rezdiffra resmetirom	Updated
27/05/2026	**Medicine**: Trumenba meningococcal group b vaccine (recombinant, adsorbed)	Updated
27/05/2026	**Medicine**: Imcivree setmelanotide	Updated
27/05/2026	**Document**: List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs)	Updated
26/05/2026	**Page**: One Health approach	Updated
26/05/2026	**Medicine**: Avonex interferon beta-1a	Updated
26/05/2026	**Medicine**: Pomalidomide Zentiva pomalidomide	Updated
26/05/2026	**Document**: Medicinal products for human use: monthly figures - April 2026	New
26/05/2026	**Medicine**: Fycompa perampanel	Updated
26/05/2026	**News**: EU recommendations for 2026/2027 seasonal flu vaccine composition	Updated
26/05/2026	**Orphan**: EU/3/19/2146 - orphan designation for treatment of biliary tract cancer 1-[(3S)-3-{4-amino-3-[(3,5-dimethoxyphenyl)ethynyl]-1H-pyrazolo[3,4-d]pyrimidin-1-yl}pyrrolidin-1-yl]-2-propen-1-one (futibatinib)	Updated
26/05/2026	**Orphan**: EU/3/17/1914 - orphan designation for treatment of primary sclerosing cholangitis S)-3-((S)-2-(2-((2,6-difluorophenyl)amino)-2-oxoacetamido)propanamido)-4-oxo-5-(2,3,5,6-tetrafluorophenoxy)pentanoic acid	Updated
26/05/2026	**Orphan**: EU/3/12/1034 - orphan designation for treatment of sickle cell disease Humanised monoclonal antibody against P-selectin (crizanlizumab)	Updated
26/05/2026	**Orphan**: EU/3/09/622 - orphan designation for treatment of acute myeloid leukaemia N-(5-tert-Butylisoxazol-3-yl)-N'-{4-[7-(2-(morpholin-4-yl)ethoxy) imidazo[2,1-b][1,3]benzothiazol-2-yl]phenyl}urea di-hydrochloride salt	Updated
26/05/2026	**Orphan**: EU/3/03/182 - orphan designation for treatment of aneurysmal subarachnoid haemorrhage 5-Methyl-pyridine-2-sulfonic acid{6-(2-hydroxy-ethoxy)-5-(2-methoxy-phenoxy)-2-[2-(1H-tetrazol-5-yl)-pyridin-4-yl]-pyrimidin-4-yl}-amide sodium salt	Updated

Date	Content	Status
26/05/2026	**Orphan**: EU/3/02/109 - orphan designation for treatment of ovarian cancer oregovomab	Updated
26/05/2026	**Orphan**: EU/3/22/2650 - orphan designation for treatment of myasthenia gravis zilucoplan	Updated
26/05/2026	**Document**: Amended Biologics Working Party Vaccines Quality Operational Expert Group (BV-OEG) Influenza Meeting: EU recommendations for the seasonal influenza vaccine composition for the season 2026/2027	Updated
26/05/2026	**Orphan**: EU/3/09/707 - orphan designation for treatment of idiopathic pulmonary fibrosis macitentan	Updated
26/05/2026	**Orphan**: EU/3/21/2428 - orphan designation for treatment of functional single ventricle congenital heart disease macitentan	Updated
26/05/2026	**Orphan**: EU/3/21/2533 - orphan designation for treatment of chronic thromboembolic pulmonary hypertension macitentan	Updated
26/05/2026	**Orphan**: EU/3/12/1046 - orphan designation for treatment of fragile X syndrome Mavoglurant	Updated
26/05/2026	**Orphan**: EU/3/21/2471 - orphan designation for treatment of multiple myeloma humanised IgG2k Fc-modified bispecific monoclonal antibody against CD3 and BCMA	Updated
26/05/2026	**Orphan**: EU/3/22/2682 - orphan designation for treatment of Stargardt's disease vutrisiran	Updated
26/05/2026	**Orphan**: EU/3/23/2825 - orphan designation for treatment of myelodysplastic syndromes cedazuridine; decitabine	Updated
26/05/2026	**Orphan**: EU/3/10/825 - orphan designation for treatment of colchicine poisoning ovine anti-colchicine polyclonal antibody fragments	Updated
26/05/2026	**Orphan**: EU/3/13/1145 - orphan designation for treatment of soft tissue sarcoma genetically modified serotype 5/3 adenovirus coding for granulocyte-macrophage colony-stimulating factor	Updated
26/05/2026	**Orphan**: EU/3/14/1398 - orphan designation for treatment of malignant mesothelioma genetically modified serotype 5/3 adenovirus coding for granulocyte macrophage colony-stimulating factor	Updated
26/05/2026	**Orphan**: EU/3/12/1040 - orphan designation for treatment of Alagille syndrome	Updated
26/05/2026	**Orphan**: EU/3/11/909 - orphan designation for treatment of pulmonary arterial hypertension macitentan	Updated
26/05/2026	**Orphan**: EU/3/11/922 - orphan designation for prevention of fetal and neonatal alloimmune thrombocytopenia Human platelet antigen-1a immunoglobulin	Updated

Date	Content	Status
26/05/2026	**Orphan**: EU/3/20/2258 - orphan designation for treatment of immune thrombocytopenia sutimlimab	Updated
26/05/2026	**Orphan**: EU/3/18/2064 - orphan designation for treatment of marginal zone lymphoma Copanlisib	Updated
26/05/2026	**Orphan**: EU/3/20/2274 - orphan designation for treatment of haemophilia A adeno-associated virus vector serotype hu37 encoding human factor VIII	Updated
26/05/2026	**Orphan**: EU/3/14/1350 - orphan designation for treatment of tenosynovial giant cell tumour, localised and diffuse type recombinant human monoclonal antibody of the IgG1 kappa class against human macrophage colony-stimulating factor (lacnotuzumab)	Updated
26/05/2026	**Orphan**: EU/3/16/1800 - orphan designation for treatment of Wolfram syndrome Dantrolene sodium	Updated
26/05/2026	**Orphan**: EU/3/21/2446 - orphan designation for treatment of nasopharyngeal cancer tislelizumab	Updated
26/05/2026	**Orphan**: EU/3/08/555 - orphan designation for treatment of acute lymphoblastic leukaemia vincristine sulfate liposomes	Updated
26/05/2026	**Orphan**: EU/3/02/106 - orphan designation for treatment of active ulcerative colitis antisense NF-kBp65 oligonucleotide	Updated
26/05/2026	**Orphan**: EU/3/04/208 - orphan designation for treatment of polycythaemia vera acetylsalicylic acid	Updated
26/05/2026	**Orphan**: EU/3/17/1884 - orphan designation for treatment of haemophilia B recombinant human factor IX protein modified with three point mutations (dalcinonacog alfa)	Updated
26/05/2026	**Orphan**: EU/3/19/2151 - orphan designation for treatment of haemophilia B Marzeptacog alfa (activated)	Updated
26/05/2026	**Orphan**: EU/3/21/2401 - orphan designation for treatment of paroxysmal nocturnal haemoglobinuria	Updated
26/05/2026	**Orphan**: EU/3/15/1575 - orphan designation for prevention of graft-versus-host disease humanised fusion protein consisting of extracellular domain of CD24 linked to IgG1 Fc domain	Updated
26/05/2026	**Orphan**: EU/3/17/1929 - orphan designation for treatment of mastocytosis recombinant monoclonal antibody to sialic acid-binding Ig-like lectin 8	Updated
26/05/2026	**Orphan**: EU/3/21/2400 - orphan designation for treatment of eosinophilic gastroenteritis anti-SIGLEC8 IgG1 humanised monoclonal antibody	Updated
26/05/2026	**Orphan**: EU/3/19/2147 - orphan designation for treatment of primary sclerosing cholangitis 2-[3-(2-chloro-4-{[5-cyclopropyl-3-(2,6-dichlorophenyl)-1,2-oxazol-4-yl]methoxy}phenyl)-3-hydroxyazetidin-1-yl]pyridine-4-carboxylic acid-2-amino-2-(hydroxymethyl)propane-1,3-diol (1/1)	Updated

Date	Content	Status
26/05/2026	**Orphan**: EU/3/23/2803 - orphan designation for treatment of myelofibrosis Ilginatinib maleate	Updated
26/05/2026	**Orphan**: EU/3/21/2494 - orphan designation for treatment of myelodysplastic syndromes sabatolimab	Updated
26/05/2026	**Orphan**: EU/3/18/2007 - orphan designation for treatment of glycogen storage disease type II (Pompe's disease) adeno-associated viral vector serotype 8 containing the human acid alpha-glucosidase gene	Updated
26/05/2026	**Orphan**: EU/3/19/2233 - orphan designation for treatment of myelofibrosis navitoclax	Updated
26/05/2026	**Orphan**: EU/3/16/1625 - orphan designation for treatment of mantle cell lymphoma acalabrutinib	Updated
26/05/2026	**Orphan**: EU/3/20/2301 - orphan designation for treatment of acute respiratory distress syndrome (ARDS) pegylated adrenomedullin	Updated
26/05/2026	**Event**: Second HMA/EMA multi-stakeholder forum on EudraVigilance and signal detection	New
26/05/2026	**Document**: Network Portfolio Roadmap	Updated
26/05/2026	**Medicine**: Ucedane carglumic acid	Updated

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
01.06.2026	**Informationen zu Einreichung und Genehmigung von Schulungsmaterial** Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
28.05.2026	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 26.03.2026 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Epinephrin/Adrenalin (außer nasale Anwendung)** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Epinephrin/Adrenalin (außer nasale Anwendung) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

Date	Title
28.05.2026	**ACE-Hemmer-haltige Arzneimittel: Epinephrin/Adrenalin möglicherweise unwirksam bei durch ACE-Hemmer ausgelöstem Angioödem** Wirkstoff: ACE-Hemmer Während der Behandlung mit ACE-Hemmern kann es jederzeit, auch erst zu einem späteren Zeitpunkt, zum Auftreten eines Angioödems kommen. Epinephrin/Adrenalin kann bei der Behandlung eines durch ACE-Hemmer ausgelösten Angioödems möglicherweise unwirksam sein.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
28.05.2026	**28.05.2026: Erst- und Änderungsanzeige MP und IVD** Medizinprodukte und In-vitro-Diagnostika sind vor dem Inverkehrbringen ab dem 28.05.2026 in EUDAMED anzuzeigen und nicht mehr im DMIDS. Eine Ausnahme stellt die Anzeige für Aufbereitungs- und Sterilisierungsverfahren gemäß KRINKO dar, die als Anzeige unter "Medizinprodukte" erfolgt.
28.05.2026	**28.05.2026: Adressanzeigen**
28.05.2026	**Europäische Datenbank für Medizinprodukte: EUDAMED** Informationen zum Übergangszeitraum bis zur vollen Funktionsfähigkeit von EUDAMED wurden aktualisiert.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since May 12th, 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.