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HEADS OF AGENCIES – CMDh

19 November

NEW - Report from the meeting held on 11-13 November 2025

17 November

NEW - 14-15 October CMDh minutes

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
21/11/2025	Page: Organisation Management Service (OMS)	Updated
21/11/2025	Page: Referentials Management Service (RMS)	Updated
21/11/2025	Page: Vaccines: concerns, questions and false claims	New
21/11/2025	Medicine: Steglujan ertugliflozin; sitagliptin	Updated
21/11/2025	Medicine: Steglatro ertugliflozin	Updated
21/11/2025	Medicine: Segluromet ertugliflozin; metformin hydrochloride	Updated
21/11/2025	Medicine: Invanz ertapenem	Updated
21/11/2025	Medicine: Obizur susoctocog alfa	Updated
21/11/2025	Page: PRIME: priority medicines	Updated
21/11/2025	Medicine: Yervoy	Updated

Date	Content	Status
	ipilimumab	
21/11/2025	Document: List of medicines currently in PRIME scheme	Updated
21/11/2025	Document: Recommendations on eligibility to PRIME scheme adopted at the CHMP meeting of 10-13 November 2025	New
21/11/2025	Medicine: Vimpat lacosamide	Updated
21/11/2025	Medicine: Opdivo nivolumab	Updated
21/11/2025	Event: Quarterly System Demo - Q4 2025	Updated
21/11/2025	Medicine: Neuraceq florbetaben (18F)	Updated
21/11/2025	Medicine: Pyzchiva ustekinumab	Updated
21/11/2025	Medicine: Eiyzey afibercept	Updated
21/11/2025	Medicine: Yselty linzagolix choline	Updated
21/11/2025	Document: Regulatory Procedure Management in IRIS roadmap	New
21/11/2025	Document: Minutes of the PRAC meeting 29 September - 2 October 2025	New
21/11/2025	Document: Minutes – Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - 20 October 2025	New
21/11/2025	Event: Joint Heads of Medicines Agencies (HMA)/European Medicines Agency (EMA) multistakeholder workshop on Patient Registries for Alzheimer's disease	Updated
21/11/2025	Document: Minutes of the HMPC meeting 22-24 September 2025	New
21/11/2025	Page: Antimicrobial resistance	Updated
21/11/2025	Document: Antimicrobial resistance – Act Now: Protect our present, secure our future	New
21/11/2025	Page: International Coalition of Medicines Regulatory Authorities (ICMRA)	Updated
21/11/2025	Medicine: Usgena ustekinumab	Updated
20/11/2025	Medicine: Afinitor everolimus	Updated
20/11/2025	Page: Download website data in JSON data format	Updated
20/11/2025	Medicine: Votubia everolimus	Updated

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20/11/2025	Medicine: Maviret glecaprevir; pibrentasvir	Updated
20/11/2025	Medicine: Izamby denosumab	Updated
20/11/2025	Medicine: Tecartus brexucabtagene autoleucel	Updated
20/11/2025	Medicine: Xydalba dalbavancin	Updated
20/11/2025	Medicine: Aectura Breezhaler indacaterol; mometasone	Updated
20/11/2025	Medicine: Enerzair Breezhaler indacaterol; glycopyrronium bromide; mometasone	Updated
20/11/2025	News: Call for expressions of interest for civil society representatives to participate in the work of EMA's Paediatric Committee	New
20/11/2025	Medicine: Gobivaz golimumab	Updated
20/11/2025	Shortage: ADHD medicines atomoxetine; methylphenidate; lisdexamfetamine	Updated
20/11/2025	Page: Classification of a product as intended for a limited market and eligibility for authorisation under Article 23 of Regulation (EU) 2019/6 (Applications for limited markets)	Updated
20/11/2025	PIP: EMA-003153-PIP01-21 - paediatric investigation plan HIV-1 Maturation Inhibitor (GSK3640254)	Updated
20/11/2025	Medicine: Teizeild teplizumab	Updated
20/11/2025	News: First-in-class treatment to delay onset of type 1 diabetes	Updated
19/11/2025	Medicine: Comirnaty COVID-19 mRNA vaccine	Updated
19/11/2025	Medicine: Erleada apalutamide	Updated
19/11/2025	Medicine: Dafiro amlodipine; valsartan	Updated
19/11/2025	Event: HMA/EMA multi-stakeholder workshop on artificial intelligence (AI)	Updated
19/11/2025	Medicine: Copalia amlodipine; valsartan	Updated
19/11/2025	Medicine: Exforge amlodipine; valsartan	Updated

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19/11/2025	Shortage: Risperidone risperidone	New
19/11/2025	Medicine: Remsima infliximab	Updated
19/11/2025	Page: Search tips	Updated
19/11/2025	Medicine: Bimervax COVID-19 Vaccine (recombinant, adjuvanted)	Updated
19/11/2025	Document: List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs)	Updated
19/11/2025	Medicine: Synjardy empagliflozin; metformin	Updated
19/11/2025	Medicine: Sogroya somapacitan	Updated
19/11/2025	Document: Notification on arrangements for requesting EMA certificates through urgent and standard procedure for December 2025	New
19/11/2025	Medicine: Shingrix herpes zoster vaccine (recombinant, adjuvanted)	Updated
19/11/2025	Medicine: Spikevax (previously COVID-19 Vaccine Moderna) COVID-19 mRNA vaccine	Updated
19/11/2025	Medicine: Descovy emtricitabine; tenofovir alafenamide	Updated
19/11/2025	Event: EMA Cancer Medicines Forum (CMF) meeting with industry stakeholders on cancer treatment optimisation	Updated
18/11/2025	Page: Medicines for human use under evaluation	Updated
18/11/2025	Document: Start of procedure: Type II variation - Extension of indication under evaluation by the CHMP (17 October - 13 November 2025)	New
18/11/2025	Document: Start of procedure: Extension of marketing authorisation (17 October - 13 November 2025)	New
18/11/2025	Medicine: Viread tenofovir disoproxil	Updated
18/11/2025	Medicine: Hirobriz Breezhaler indacaterol	Updated
18/11/2025	Medicine: Oslif Breezhaler indacaterol	Updated
18/11/2025	Medicine: Onbrez Breezhaler indacaterol	Updated
18/11/2025	Event: Workshop on the use of external controls for evidence generation in regulatory decision-making	Updated

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18/11/2025	Medicine: Efavirenz/Emtricitabine/Tenofovir disoproxil Mylan efavirenz; emtricitabine; tenofovir disoproxil	Updated
18/11/2025	Medicine: Prevenar 20 (previously Apexxnar) pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed)	Updated
18/11/2025	Event: Medicine shortages: EMA public webinar putting patients first	Updated
18/11/2025	Event: EMA workshop: Non-clinical data for regulatory decision-making on the efficacy of medical countermeasures	Updated
18/11/2025	Medicine: Inhixa enoxaparin sodium	Updated
18/11/2025	Page: Podcast: Inside EMA	New
18/11/2025	Medicine: Truvada emtricitabine; tenofovir disoproxil	Updated
18/11/2025	Medicine: Vizamyl flutemetamol (18F)	Updated
18/11/2025	Document: Scientific advice and protocol assistance adopted during the CHMP meeting 10-13 November 2025	New
18/11/2025	Document: Scientific advice and protocol assistance adopted during the CHMP meeting 13-16 October 2025	New
18/11/2025	PSUSA: PSUSA/00002735/202501 - periodic safety update report single assessment sodium citrate / sodium lauryl sulfoacetate, sodium citrate / sodium lauryl sulfoacetate / sorbitol	New
18/11/2025	Medicine: Omlyclo omalizumab	Updated
18/11/2025	Document: Scientific advice and protocol assistance adopted during the CHMP meeting 15-18 September 2025	New
18/11/2025	Medicine: Voxzogo vosoritide	Updated
18/11/2025	Medicine: Absimky ustekinumab	Updated
18/11/2025	Event: Fifth Veterinary Big Data Stakeholder Forum	Updated
18/11/2025	Page: EMA's work on public health emergencies	Updated
18/11/2025	Document: EMA health threats plan - Annex 1: Acceleration of regulatory procedures during public health emergencies	New
18/11/2025	Document: EMA health threats plan	Updated
18/11/2025	Medicine: Enwylma denosumab	Updated
18/11/2025	Medicine: Effentora	Updated

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	fentanyl	
18/11/2025	Medicine: Tecentriq atezolizumab	Updated
18/11/2025	Medicine: Ozawade pitolisant	Updated
18/11/2025	Event: EMA - European Consumer Organisation (BEUC) bilateral meeting	New
18/11/2025	Document: Dates of 2025 Scientific Advice Working Party - Human (SAWP-H) meetings and submission deadlines for scientific advice, protocol assistance, qualification of novel methodologies and HTACG/EMA parallel Joint Scientific Consultation (JSC) requests	Updated
18/11/2025	Document: Dates of 2026 Scientific Advice Working Party - Human (SAWP-H) meetings and submission deadlines for scientific advice, protocol assistance, qualification of novel methodologies and HTACG/EMA parallel Joint Scientific Consultation (JSC) requests	Updated
17/11/2025	Page: ICH E2D post-approval safety data management - scientific guideline	Updated
17/11/2025	Medicine: Ristfor sitagliptin; metformin hydrochloride	Updated
17/11/2025	PIP: EMA-001489-PIP02-19 - paediatric investigation plan Idasanutlin	Updated
17/11/2025	PIP: EMA-001489-PIP01-13-M02 - paediatric investigation plan Idasanutlin	Updated
17/11/2025	PIP: EMA-002821-PIP01-20 - paediatric investigation plan Respiratory Syncytial Virus PreF3 recombinant fusion protein (RSVPreF3)	Updated
17/11/2025	PIP: EMA-002475-PIP04-23 - paediatric investigation plan spesolimab	Updated
17/11/2025	Medicine: Awiqli insulin icodec	Updated
17/11/2025	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) – November 2025	Updated
17/11/2025	Document: Agenda of the HMPC meeting 17-19 November 2025	New
17/11/2025	Medicine: Odomzo sonidegib	Updated
17/11/2025	Document: Medicinal products for human use: monthly figures - October 2025	New
17/11/2025	Medicine: Isentress raltegravir	Updated
17/11/2025	Medicine: Loargys pegzilarginase	Updated

Date	Content	Status
17/11/2025	Medicine: Ivabradine Anpharm ivabradine	Updated
17/11/2025	News: Improved scientific advice for medicines for public health threats including antimicrobial resistance	New
17/11/2025	Page: Emergency Task Force (ETF) recommendations	Updated
17/11/2025	Page: Emergency Task Force (ETF)	Updated
17/11/2025	Page: Scientific advice and protocol assistance	Updated
17/11/2025	Page: Parallel scientific advice and special development aspects or product types	Updated
17/11/2025	Page: Clinical trials in human medicines	Updated
17/11/2025	Page: Scientific advice for public health emergencies and threats	New
17/11/2025	Document: Guidance for applicants: the ETF scientific advice that facilitates clinical trial authorisations (SA-CTA)	New
17/11/2025	Medicine: Corlantor ivabradine	Updated
17/11/2025	Medicine: Procoralan ivabradine	Updated
17/11/2025	Medicine: Rinvoq upadacitinib	Updated
17/11/2025	Medicine: Imreplys sargramostim	Updated
17/11/2025	Page: Task Forces	Updated
17/11/2025	Document: Severe cutaneous adverse reactions - standard template wording for product information	New
17/11/2025	Medicine: Ebglyss lebrikizumab	Updated

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
21.11.2025	Informationen zu Rote-Hand-Briefen und Informationsbriefen Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht neue Hinweise zu anstehenden Rote-Hand-Briefen und Informationsbriefen.
20.11.2025	Promethazin: Neue Kontraindikation für Kinder unter 6 Jahren Wirkstoff: Promethazin Das BfArM informiert darüber, dass die Anwendung promethazinhaltiger Arzneimittel aufgrund altersspezifischer Risiken unter einem Alter von 6 Jahren kontraindiziert ist.
17.11.2025	Umsetzung des Durchführungsbeschlusses der Europäischen Kommission vom 24.10.2025 zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Bosentan Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Bosentan infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
17.11.2025	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 18.09.2025 betreffend die Zulassungen für Humanarzneimittel mit den Wirkstoffen Natriummonohydrogenphosphat/Natriumdihydrogenphosphat, Natriumphosphat Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffe Natriummonohydrogenphosphat/Natriumdihydrogenphosphat, Natriumphosphat infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
20.11.2025	Bedienung des Informationssystems Bedienung des Informationssystems
20.11.2025	Systemvoraussetzungen Systemvoraussetzungen

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since November 10th, 2025.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedeuropa updates will be presented quarterly.

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