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No updates since November 27th, 2025.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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EUROPEAN MEDICINES AGENCY (EMA)

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08/12/2025	**Page**: Scientific publications	Updated
08/12/2025	**Event**: EMA/HMA annual data forum	Updated
08/12/2025	**Page**: Good pharmacogenomic practice - Scientific guideline	Updated
08/12/2025	**Document**: Concept paper on the guideline revision on good pharmacogenomic practice	New
08/12/2025	**Page**: Substance and product data management services	Updated
08/12/2025	**Document**: Call for user acceptance testers for the read functionality in the Public Product Management Service (PMS) Application Programming Interface (API)	New
08/12/2025	**DHPC**: Remsima - direct healthcare professional communication (DHPC) infliximab	New
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05/12/2025	**Medicine**: Enzalutamide Viatris enzalutamide	Updated
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05/12/2025	**Medicine**: Zomarist vildagliptin; metformin	Updated
05/12/2025	**Event**: European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties meeting with all eligible organisations - 2025	Updated
05/12/2025	**Medicine**: Voraxaze glucarpidase	Updated
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05/12/2025	**News**: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 2-4 December 2025	New
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05/12/2025	**Medicine**: Firocoxib CP-Pharma firocoxib	New
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05/12/2025	**Post-authorisation**: Dexdomitor - opinion on variation to marketing authorisation dexmedetomidine	New
05/12/2025	**Medicine**: Imnovid (previously Pomalidomide Celgene) pomalidomide	Updated
05/12/2025	**Page**: Medicines for human use under evaluation	Updated
05/12/2025	**Document**: Applications for new human medicines under evaluation: December 2025	New
05/12/2025	**Page**: Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use'	Updated
05/12/2025	**Document**: All languages - Annex to the European Commission guideline on ‘Excipients in the labelling and package leaflet of medicinal products for human use’ (SANTE-2017-11668) - Revision 5	New
05/12/2025	**PIP**: EMA/PE/0000183059 - paediatric investigation plan abrocitinib	Updated
05/12/2025	**PIP**: EMA/PE/0000221076 - paediatric investigation plan adrenaline (epinephrine)	Updated
05/12/2025	**PIP**: EMA/PE/0000183220 - paediatric investigation plan iclepertin	Updated

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05/12/2025	**PIP**: EMA/PE/0000221589 - paediatric investigation plan split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain; split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain; split influenza virus, inactivated containing antigens equivalent to the B-like strain (Victoria lineage); split influenza virus, inactivated containing antigens equivalent to the B-like strain (Yamagata lineage)	Updated
05/12/2025	**PIP**: EMA/PE/0000238005 - paediatric investigation plan Inebilizumab	Updated
05/12/2025	**PIP**: EMA/PE/0000238074 - paediatric investigation plan Mitapivat	Updated
05/12/2025	**PIP**: EMA/PE/0000182362 - paediatric investigation plan tildrakizumab	Updated
05/12/2025	**PIP**: EMA/PE/0000221709 - paediatric investigation plan apitegromab	Updated
05/12/2025	**PIP**: EMA/PE/0000254020 - paediatric investigation plan risankizumab	Updated
05/12/2025	**PIP**: EMA/PE/0000274326 - paediatric investigation plan risankizumab	Updated
04/12/2025	**Page**: Interim guidance on enhanced safety surveillance for seasonal influenza vaccines in the EU - Scientific guideline	Updated
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04/12/2025	**Page**: CHMP opinions on consultation procedures	Updated
04/12/2025	**Document**: Consultation on an ancillary medicinal substance incorporated in a medical device - Gynemed GmbH & Co. KG HSA-containing ART media	New
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04/12/2025	**Medicine**: Sogroya somapacitan	Updated
04/12/2025	**Medicine**: Opdivo nivolumab	Updated
04/12/2025	**Page**: Availability of medicines before and during crises	Updated
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04/12/2025	**Medicine**: Dengvaxia dengue tetravalent vaccine (live, attenuated)	Updated
04/12/2025	**Shortage**: Dynastat parecoxib	Updated
04/12/2025	**Medicine**: Paxlovid nirmatrelvir; ritonavir	Updated
04/12/2025	**Page**: Antiviral medicines for pandemic influenza	Updated
04/12/2025	**Page**: Signal management (veterinary medicines)	Updated
04/12/2025	**Page**: Veterinary good pharmacovigilance practices (VGVP)	Updated
04/12/2025	**Document**: Veterinary Union Pharmacovigilance Database - Best Practice Guide	Updated
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04/12/2025	**Medicine**: Brinsupri Brensocatib	Updated
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04/12/2025	**Medicine**: Hetlioz tasimelteon	Updated
04/12/2025	**Medicine**: Adcetris brentuximab vedotin	Updated
04/12/2025	**Document**: Veterinary Scientific Advice procedure – timelines 2026 - information for applicants	Updated
04/12/2025	**Medicine**: Lynparza olaparib	Updated
04/12/2025	**Medicine**: Sunitinib Accord sunitinib	Updated
04/12/2025	**Document**: Dengvaxia : EPAR - All authorised presentations	Updated
04/12/2025	**Medicine**: Tagrisso osimertinib	Updated
04/12/2025	**Page**: Website outages and upgrades	Updated
03/12/2025	**Event**: First EMA/HMA multi-stakeholder forum on EudraVigilance and signal detection	Updated
03/12/2025	**Event**: Questions and answers clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API) - November 2025	Updated

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03/12/2025	**Medicine**: Tryngolza olezarsen	Updated
03/12/2025	**Page**: Eligible healthcare professionals' organisations	Updated
03/12/2025	**Document**: Abbreviations used in EMA scientific committees and Coordination Group for Mutual Recognition and Decentralised Procedures (CMD) documents, and in relation to EMA's regulatory activities	Updated
03/12/2025	**Medicine**: Baraclude entecavir	Updated
03/12/2025	**PSUSA**: PSUSA/00000576/202412 - periodic safety update report single assessment caspofungin	New
03/12/2025	**Document**: Classification of changes	Updated
03/12/2025	**Document**: Classification of changes (tracked changes)	Updated
03/12/2025	**Document**: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure: document with tracked changes	Updated
03/12/2025	**Document**: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure	Updated
03/12/2025	**PSUSA**: PSUSA/00002947/202412 - periodic safety update report single assessment tibolone	New
03/12/2025	**Medicine**: Delstrigo doravirine; lamivudine; tenofovir disoproxil	Updated
03/12/2025	**Medicine**: Cancidas (previously Caspofungin MSD) caspofungin	Updated
03/12/2025	**Medicine**: Incellipan pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted, prepared in cell cultures)	Updated
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03/12/2025	**Page**: EudraVigilance: electronic reporting	Updated
03/12/2025	**Document**: Compliance notifications explanation and Q&A	New
03/12/2025	**Medicine**: Keytruda pembrolizumab	Updated
03/12/2025	**Document**: HMPC: overview of assessment work - priority list	Updated

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03/12/2025	**Medicine**: Protopic tacrolimus	Updated
03/12/2025	**Medicine**: Oczyesa octreotide	Updated
03/12/2025	**Page**: Safety of medicines	Updated
03/12/2025	**Document**: Keeping medicines safe: Reporting side effects can make medicines safer for everyone	New
03/12/2025	**Document**: Keeping medicines safe: What actions can EMA take?	New
03/12/2025	**Event**: Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service - April 2026	New
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03/12/2025	**Event**: Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service - March 2026	New
03/12/2025	**Event**: Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service - May 2026	New
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03/12/2025	**Event**: Q&A clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API) - May 2026	New
03/12/2025	**Page**: Network Data Steering Group (NDSG)	Updated
03/12/2025	**Document**: HMA-EMA joint Network Data Steering Group meeting - 6 October 2025	New
03/12/2025	**Medicine**: Ontozry cenobamate	Updated
03/12/2025	**Medicine**: Aybintio	Updated

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	bevacizumab	
03/12/2025	**Document**: Agenda of the CAT meeting 3-5 December 2025	New
02/12/2025	**PSUSA**: PSUSA/00002558/202501 - periodic safety update report single assessment propylthiouracil	New
02/12/2025	**Event**: Q&A clinic on eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) service	Updated
02/12/2025	**Document**: CAT quarterly highlights and approved ATMPs - December 2025	New
02/12/2025	**EU-M4all**: Aluvia - opinion on medicine for use outside EU lopinavir; ritonavir	Updated
02/12/2025	**Page**: Outcomes of imposed non-interventional post-authorisation safety studies	Updated
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02/12/2025	**Medicine**: Izamby denosumab	Updated
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02/12/2025	**Medicine**: Gilenya fingolimod	Updated
02/12/2025	**Medicine**: Tevimbra tislelizumab	Updated
02/12/2025	**Medicine**: Krazati adagrasib	Updated
02/12/2025	**Medicine**: Upstaza eladocagene exuparvovec	Updated
02/12/2025	**PIP**: EMEA-001451-PIP02-24 - paediatric investigation plan tildrakizumab	New
02/12/2025	**PIP**: EMEA-001943-PIP07-24 - paediatric investigation plan ravulizumab	New
02/12/2025	**PIP**: EMA/PE/0000232315 - paediatric investigation plan spesolimab	Updated
02/12/2025	**Event**: Committee for Medicinal Products for Veterinary Use (CVMP): 2-4 December 2025	Updated
02/12/2025	**Document**: Agenda of the CVMP meeting 2-4 December 2025	New

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02/12/2025	**Document**: Questions and answers on implementation of the medical devices and in vitro diagnostic medical devices Regulations ((EU) 2017/745 and (EU) 2017/746) - tracked changes	Updated
02/12/2025	**Document**: Questions and answers on implementation of the medical devices and in vitro diagnostic medical devices Regulations ((EU) 2017/745 and (EU) 2017/746)	Updated
02/12/2025	**Document**: IRIS guide for applicants - How to create, submit and manage IRIS applications, for industry and individual applicants	Updated
02/12/2025	**Document**: Union Product Database (UPD) - Questions & answers: Network use	New
02/12/2025	**Document**: Union Product Database (UPD) registration guide for UI and API users	Updated
02/12/2025	**Event**: Q&A clinic on Substance, Organisation, Referentials Management Services - February 2026	New
02/12/2025	**Event**: Q&A clinic on Substance, Organisation, Referentials Management Services - January 2026	New
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02/12/2025	**Event**: Q&A clinic on Substance, Organisation, Referentials Management Services - March 2026	New
02/12/2025	**Event**: Q&A clinic on Substance, Organisation, Referentials Management Services - May 2026	New
02/12/2025	**Event**: SPOR and XEVMPD status update webinar - Q2 2026	New
02/12/2025	**Event**: SPOR and XEVMPD status update webinar - Q3 2026	New
02/12/2025	**Event**: SPOR and XEVMPD status update webinar - Q4 2026	New
02/12/2025	**Document**: Agenda of the COMP meeting 2-3 December 2025	New
01/12/2025	**Event**: 20th industry stakeholder platform - operation of European Union (EU) pharmacovigilance	Updated
01/12/2025	**PSUSA**: PSUSA/00010883/202504 - periodic safety update report single assessment carvedilol / ivabradine	New
01/12/2025	**PSUSA**: PSUSA/00003097/202501 - periodic safety update report single assessment vancomycin	New
01/12/2025	**Medicine**: Xofluza baloxavir marboxil	Updated
01/12/2025	**Medicine**: Rasagiline Viatris (previously Rasagiline Mylan) rasagiline	Updated

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01/12/2025	**Medicine**: Benepali etanercept	Updated
01/12/2025	**Medicine**: Xelevia sitagliptin	Updated
01/12/2025	**Medicine**: Cerezyme imiglucerase	Updated
01/12/2025	**EU-M4all**: Dengue Tetravalent Vaccine (Live, Attenuated) Takeda - opinion on medicine for use outside EU dengue tetravalent vaccine (live, attenuated)	Updated
01/12/2025	**Event**: Third workshop between notified bodies and expert panels	New
01/12/2025	**Medicine**: Erleada apalutamide	Updated
01/12/2025	**Medicine**: Velmetia sitagliptin; metformin	Updated
01/12/2025	**Medicine**: Rivastigmine Sandoz rivastigmine	Updated
01/12/2025	**Medicine**: Rivastigmine Hexal rivastigmine	Updated
01/12/2025	**Medicine**: Rivastigmine 1 A Pharma rivastigmine	Updated
01/12/2025	**Medicine**: Zinplava bezlotoxumab	Updated
01/12/2025	**Medicine**: Efficib sitagliptin; metformin	Updated
01/12/2025	**Medicine**: Aimovig erenumab	Updated
01/12/2025	**Medicine**: Akynzeo netupitant; palonosetron	Updated
01/12/2025	**Medicine**: Briviact (in Italy: Nubriveo) brivaracetam	Updated
01/12/2025	**Medicine**: Tesavel sitagliptin	Updated
01/12/2025	**Medicine**: Dupixent dupilumab	Updated
01/12/2025	**Page**: Clinical investigation of medicinal products in the treatment of Parkinson's disease - Scientific guideline	Updated
01/12/2025	**Document**: Concept paper on the need for revision of the guideline on clinical investigation of medicinal products in the treatment of Parkinson’s disease	New

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01/12/2025	**Document**: Minutes - Management Board meeting: 2 October 2025	New
01/12/2025	**Document**: Appendix 1: Acceptable intakes established for N-nitrosamines	Updated
01/12/2025	**Page**: Stakeholders and Communication	Updated

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
03.12.2025	**Umsetzung des Durchführungsbeschlusses der Europäischen Kommission vom 21.11.2025 zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Caspofungin** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Caspofungin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
03.12.2025	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 18.09.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Botulinum-Toxin Typ A zur Injektion (Ph.Eur.), frei von Komplexproteinen** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Botulinum-Toxin Typ A zur Injektion (Ph.Eur.), frei von Komplexproteinen, infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
02.12.2025	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 15.10.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Natriumcitrat/Dodecyl(sulfoacetat)-Natriumsalz, Natriumcitrat/Dodecyl(sulfoacetat)-Natriumsalz/Sorbitol** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Natriumcitrat/Dodecyl(sulfoacetat)-Natriumsalz, Natriumcitrat/Dodecyl(sulfoacetat)-Natriumsalz/Sorbitol infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

Date	Title
02.12.2025	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 18.09.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Botulinum-Toxin Typ A zur Injektion (Ph.Eur.) (außer zentral zugelassene Arzneimittel)** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Botulinum-Toxin Typ A zur Injektion (Ph.Eur.) (außer zentral zugelassene Arzneimittel 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)

No updates since November 28th, 2025.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.