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EUROPEAN MEDICINES AGENCY (EMA)

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07/11/2025	**Page**: CVMP recommendations on limited market classification and eligibility for authorisation under Article 23	Updated
07/11/2025	**Page**: Union Product Database: release notes	Updated
07/11/2025	**Document**: Release notes - production release version 1.7.2541 - 7 November 2025 - Veterinary Medicinal Products Regulation: Union Product Database	New
07/11/2025	**Document**: Clinical Trial Information System (CTIS) - Sponsor handbook	Updated
07/11/2025	**Medicine**: Cubicin daptomycin	Updated
07/11/2025	**Medicine**: Zepatier elbasvir; grazoprevir	Updated
07/11/2025	**Medicine**: Yesintek ustekinumab	Updated
07/11/2025	**Medicine**: Fingolimod Mylan fingolimod	Updated
07/11/2025	**Medicine**: Zoledronic acid Mylan zoledronic acid	Updated
07/11/2025	**Event**: HMA/EMA multi-stakeholder workshop on artificial intelligence	Updated

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06/11/2025	**Medicine**: Bridion sugammadex	Updated
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06/11/2025	**Referral**: Veterinary medicinal products containing amoxicillin - referral amoxicillin	New
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06/11/2025	**Medicine**: Entecavir Viatris (previously Entecavir Mylan) entecavir	Updated
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06/11/2025	**PIP**: EMEA-003288-PIP01-22 - paediatric investigation plan bexicaserin	New
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05/11/2025	**Event**: Fifth Veterinary Big Data Stakeholder Forum	Updated
05/11/2025	**Medicine**: Mektovi binimetinib	Updated
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05/11/2025	**Document**: On-boarding of users to Substance, Product, Organisation and Referentials (SPOR) data services	Updated
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05/11/2025	**Page**: Substance and product data management services	Updated
05/11/2025	**Document**: European Medicines Agency Write PMS API implementation Guide	Updated
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05/11/2025	**Document**: Applications for new human medicines under evaluation: November 2025	New
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04/11/2025	**Document**: Timetable: Post-authorisation measures (PAMs) assessed by PRAC - ATMP	Updated
04/11/2025	**Document**: Minutes of the PRAC meeting 2-5 June 2025	Updated
04/11/2025	**Event**: Committee for Advanced Therapies (CAT): 5-7 November 2025	Updated
04/11/2025	**Document**: Minutes of the PRAC meeting 7-10 July 2025	Updated
04/11/2025	**Page**: Good pharmacovigilance practices (GVP)	Updated

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04/11/2025	**Document**: Standard operating procedure for processing of requests for fee reduction falling under paragraph 5 of Article 6 of Regulation (EU) 2024/568	Updated
04/11/2025	**Event**: EMA Cancer Medicines Forum (CMF) meeting with industry stakeholders on cancer treatment optimisation	Updated
04/11/2025	**Document**: Adzynma : EPAR - Public assessment report	Updated
04/11/2025	**Page**: Combination Products Operational Group	New
04/11/2025	**Page**: Medical devices	Updated
04/11/2025	**Page**: Combination Products Operational Group: agendas and minutes	New
04/11/2025	**Medicine**: Tuzulby methylphenidate hydrochloride	Updated
04/11/2025	**Document**: QRD Form 2 and checklist for the submission of day +25 files - human	Updated
04/11/2025	**Document**: QRD Form 2 and checklist for the submission of day +25 files - veterinary	Updated
04/11/2025	**Document**: Member states contact points for translations review	Updated
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04/11/2025	**Document**: Contact details of national competent authorities for requests to use a sticker to place the Unique Identifier on the outer/immediate packaging of centrally approved products	Updated
04/11/2025	**Document**: Contact details of national competent authorities for requests of translation exemptions falling under Art. 63.3 of Directive 2001/83/EC and cases of shortages	Updated
04/11/2025	**Document**: Abbreviation of names of days on calendarised blisters	Updated
04/11/2025	**Medicine**: Truqap capivasertib	Updated
04/11/2025	**PSUSA**: PSUSA/00001029/202503 - periodic safety update report single assessment diazepam	New
10/11/2025	**Event**: Medicine shortages: EMA public webinar putting patients first	Updated
04/11/2025	**PSUSA**: PSUSA/00010808/202503 - periodic safety update report single assessment erythromycin (systemic use)	New
04/11/2025	**Event**: Fourth European Medicines Agency - Medtech Europe bilateral meeting	New
04/11/2025	**Medicine**: Tremfya guselkumab	Updated

Date	Content	Status
04/11/2025	**Document**: Agenda - 1st EMA and European Respiratory Society (ERS) bilateral meeting	New
04/11/2025	**Medicine**: Piqray alpelisib	Updated
04/11/2025	**Medicine**: Tafinlar dabrafenib	Updated
04/11/2025	**Medicine**: Vgenfli aflibercept	Updated
04/11/2025	**Page**: Fighting medicine shortages: It takes a team	New
04/11/2025	**Page**: Medicine shortages and availability issues	Updated
04/11/2025	**News**: EMA partners with healthcare professionals and consumers for #ItTakesATeam medicine shortages campaign	New
04/11/2025	**Medicine**: Bravecto TriUNO fluralaner; moxidectin; pyrantel	Updated
03/11/2025	**Document**: Advice to medical device manufacturers - 2026 Timetable	New
03/11/2025	**PSUSA**: PSUSA/00001597/202502 - periodic safety update report single assessment hepatitis B vaccine (rDNA)	New
03/11/2025	**PSUSA**: PSUSA/00000461/202412 - periodic safety update report single assessment bupropion	New
03/11/2025	**Medicine**: Mekinist trametinib	Updated
03/11/2025	**Medicine**: Spexotras trametinib	Updated
03/11/2025	**Document**: Agenda of the CVMP meeting 4-6 November 2025	New
03/11/2025	**Medicine**: Atectura Breezhaler indacaterol; mometasone	Updated
03/11/2025	**Document**: Meeting Summary - Medicine Shortages (SPOC) Working Party 10 September 2025	New
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03/11/2025	**Document**: Agenda of the COMP meeting 4-6 November 2025	New

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03/11/2025	**Document**: Policy 46: European Medicines Agency policy on video surveillance	Updated
03/11/2025	**Page**: CHMP opinions on consultation procedures	Updated
03/11/2025	**Document**: Consultation on an ancillary medicinal substance incorporated in a medical device - XVIVO Heart Solution	New
03/11/2025	**Shortage**: Eldisine vindesine	Updated
03/11/2025	**Document**: Records of data processing activity for Early Notification System (ENS)	New
03/11/2025	**Document**: European Medicine Agency's data protection notice for the Interactive Regulatory Information System (IRIS)	Updated
03/11/2025	**Page**: One Health approach	Updated

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
07.11.2025	**Rote-Hand-Brief zu Phenhydan Injektionslösung: Risiko sichtbarer Partikel, Verwendung eines Partikelfilters** Wirkstoff: Phenytoin-Natrium Die Firma Desitin Arzneimittel GmbH informiert über einen möglichen Qualitätsmangel des Arzneimittels Phenhydan Injektionslösung.
06.11.2025	**Informationen zu Einreichung und Genehmigung von Schulungsmaterial** Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien
03.11.2025	**Informationen zu Rote-Hand-Briefen und Informationsbriefen** Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht neue Hinweise zu anstehenden Rote-Hand-Briefen und Informationsbriefen.

Date	Title
03.11.2025	**Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 18.09.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Ciclosporin (systemische Anwendung)** Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Ciclosporin (systemische Anwendung) 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 October 15th, 2025.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
10.11.2025	Informationsbrief von Regeneron GmbH: Libtayo (Cemiplimab)

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.