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30 April

UPDATE - Contact Points

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
04/05/2026	**Page**: PRAC recommendations on safety signals	Updated
04/05/2026	**Document**: List of signals discussed at PRAC since September 2012	Updated
04/05/2026	**Document**: New product information wording: extracts from PRAC recommendations on signals adopted at the 7-10 April 2026 PRAC	New
04/05/2026	**Document**: PRAC recommendations on signals adopted at the 7-10 April 2026 PRAC meeting	New
30/04/2026	**Medicine**: Scemblix asciminib	Updated
30/04/2026	**Medicine**: mCombriax influenza mRNA vaccine; COVID-19 mRNA vaccine	Updated

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30/04/2026	**Event**: European Medicines Agency meeting with senior representatives of pharmaceutical companies	Updated
30/04/2026	**Medicine**: mResvia Single-stranded 5' capped mRNA encoding the respiratory syncytial virus glycoprotein F stabilised in the prefusion conformation; Respiratory syncytial virus mRNA vaccine (nucleoside modified)	Updated
30/04/2026	**Page**: Liraglutide 6 mg/mL solution for injection in a prefilled pen product-specific bioequivalence guidance	New
30/04/2026	**Page**: Tafamidis soft gelatin capsules 20 mg and 61 mg product-specific bioequivalence guidance	New
30/04/2026	**Event**: EMA and European Association of Nuclear Medicine (EANM) bilateral meeting	Updated
30/04/2026	**Document**: List of centrally authorised products with safety-related changes to the product information	Updated
29/04/2026	**Document**: New product information wording: extracts from PRAC recommendations on signals adopted at the 12-15 January 2026 PRAC	Updated
29/04/2026	**Page**: Class III implantable devices and Class IIb medical devices intended to administer or remove medicinal products: expert panel opinions	Updated
29/04/2026	**Document**: European Shortages Monitoring Platform (ESMP) User guide for national competent authorities	Updated
29/04/2026	**Page**: VICH GL18(R2) impurities: residual solvents in new veterinary medicinal products, active substances and excipients - Scientific guideline	Updated
29/04/2026	**Page**: ICH Q3C (R9) Residual solvents - Scientific guideline	Updated
29/04/2026	**Document**: Annexes to ICH Q3C guideline on impurities: guideline for residual solvents (EMA/CHMP/ICH/82260/2006) and VICH GL18 Impurities: residual solvents in new veterinary medicinal products, active substances and excipients (EMA/CVMP/VICH/502/1999) - Revision 2	New
29/04/2026	**News**: EMA launches new advisory group on vaccine confidence	New

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29/04/2026	**Page**: Advisory group on vaccine confidence	New
29/04/2026	**Document**: Vaccine confidence advisory group: Terms of reference	New
29/04/2026	**Page**: Website outages and upgrades	Updated
29/04/2026	**Medicine**: Spikevax (previously COVID-19 Vaccine Moderna) COVID-19 mRNA vaccine	Updated
29/04/2026	**Medicine**: Comirnaty COVID-19 mRNA vaccine	Updated
29/04/2026	**Document**: Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2026	Updated
29/04/2026	**Document**: List of medicinal products under additional monitoring	Updated
29/04/2026	**Document**: List of medicinal products under additional monitoring	Updated
29/04/2026	**Document**: List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs)	Updated
28/04/2026	**Medicine**: Neuraceq florbetaben (18F)	Updated
28/04/2026	**Page**: Plasma master file certificates	Updated
28/04/2026	**Document**: Agenda - European Platform for Regulatory Science Research meeting	Updated
28/04/2026	**Medicine**: Xromi hydroxycarbamide	Updated
28/04/2026	**Medicine**: Siklos hydroxycarbamide	Updated
28/04/2026	**Medicine**: Darzalex daratumumab	Updated
28/04/2026	**Document**: List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment	Updated
28/04/2026	**Medicine**: Micardis telmisartan	Updated

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28/04/2026	**Medicine**: MicardisPlus telmisartan; hydrochlorothiazide	Updated
28/04/2026	**MRL**: Lidocaine - maximum residue limit lidocaine	Updated
28/04/2026	**Document**: Records of data processing activity for the use of Microsoft Applications: OneDrive, Outlook 365, Teams and SharePoint	Updated
28/04/2026	**Document**: European Medicines Agency's Data Protection Notice for the use of Microsoft Applications: OneDrive, Outlook 365, Teams and SharePoint	Updated
28/04/2026	**Medicine**: Lopinavir/Ritonavir Viatris (previously Ritonavir Mylan) lopinavir; ritonavir	Updated
28/04/2026	**Medicine**: Tecentriq atezolizumab	Updated
28/04/2026	**Medicine**: Perjeta pertuzumab	Updated
28/04/2026	**Medicine**: Dazublys trastuzumab	Updated
28/04/2026	**Document**: Agenda - European Medicines Regulatory Network workshop on Geographic Atrophy endpoints	Updated
28/04/2026	**Document**: Guidance on the details of the classification of variations requiring assessment according to Article 62 of Regulation (EU) 2019/6 for veterinary medicinal products and on the documentation to be submitted pursuant to those variations	Updated
28/04/2026	**Medicine**: Vfend voriconazole	Updated
28/04/2026	**Medicine**: Balversa erdafitinib	Updated
28/04/2026	**News**: New pilot to support development of 'breakthrough' medical devices	New
28/04/2026	**Page**: Expert panel support for breakthrough medical devices: pilot programme	Updated
28/04/2026	**Document**: Advice request: Template for applicants for breakthrough medical devices pilot	Updated
28/04/2026	**Document**: Breakthrough status request: Template for applicants for breakthrough medical devices pilot	Updated
28/04/2026	**Document**: Highlights - 16th Industry Standing Group meeting	New
28/04/2026	**Document**: European Shortages Monitoring Platform (ESMP): Implementation guide for national competent authorities	Updated
28/04/2026	**Document**: European Shortages Monitoring Platform (ESMP): Implementation guide for marketing authorisation holders	Updated

Date	Content	Status
28/04/2026	**Document**: European Shortages Monitoring Platform (ESMP) User guide for marketing authorisation holders	Updated

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
04.05.2026	**Informationen zu Einreichung und Genehmigung von Schulungsmaterial** Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien.
04.05.2026	**Rote-Hand-Brief zu Fosphenytoin Desitin 75 mg/ml Infusions-/ Injektionslösung (Fosphenytoin-Dinatrium): Risiko von Medikationsfehlern und Off-Label-Anwendung bei Kindern unter 5 Jahren** Wirkstoff: Fosphenytoin-Dinatrium Die Firma Desitin Arzneimittel GmbH informiert darüber, dass Fosphenytoin Desitin 75 mg/ml Infusions-/ Injektionslösung (Fosphenytoin-Dinatrium) nicht zur Anwendung bei Kindern unter 5 Jahren indiziert ist.
04.05.2026	**Informationen zu Rote-Hand-Briefen und Informationsbriefen** Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht neue Hinweise zu anstehenden Rote-Hand-Briefen und Informationsbriefen.
28.04.2026	**Rote-Hand-Brief zu Bendamustin Accord (Bendamustin): Risiko von Medikationsfehlern** Wirkstoff: Bendamustin Die Firma Accord Healthcare B.V. informiert über ein mögliches Risiko für das Auftreten von Medikationsfehlern bei der Zubereitung von Bendamustin Accord Konzentrat zur Herstellung einer Infusionslösung.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since April 17th, 2026.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since April 22nd, 2026.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.