
TABLE OF CONTENTS

HEADS OF AGENCIES – CMDH.....	1
HEADS OF AGENCIES – PAEDIATRIC REGULATION	2
EUROPEAN MEDICINES AGENCY (EMA)	2
NOTICE TO APPLICANTS.....	11
BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)	11
BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)	13
PEI - VIGILANZ (SPECIFIC FOR GERMANY)	13
PHARMEUROPA TEXTS FOR COMMENT.....	13

HEADS OF AGENCIES – CMDh

18 December

[UPDATE - List of active substances for which data has been submitted in accordance with Article 45 of the Paediatric Regulation](#)

[UPDATE - EMA/CMDh Explanatory notes on Variation Application Form - Human medicinal products only](#)

[CORRECTION - Q&A Submission of variations for human medicinal products](#)

[UPDATE - Hormone Replacement Therapy - Core SmPC](#)

[UPDATE - Hormone Replacement Therapy - Core Package Leaflet](#)

17 December

[NEW - PSUFU Levonorgestrel intra-uterine devices \(LNG-IUDs\)](#)

[NEW - PSUR WS summary AR nebivolol hydrochloride/amlodipine besilate](#)

[NEW - Art. 45 PAR Mycobutin \(rifabutin\)](#)

[NEW - Art. 45 PAR Prothyrid 100 microgram/10 microgram \(levothyroxine sodium/liothyronine hydrochloride\)](#)

[NEW - Art. 45 PAR Cynomel 0,025 mg, Thyrotardin inject \(liothyronine sodium\) / Thybon 20 Henning, Thybon 100 Henning \(liothyronine hydrochloride\)](#)

[UPDATE - National recommendations for requests to act as RMS](#)

[UPDATE - CMDh Best Practice Guide on Variation Worksharing, Chapter 7](#)

[NEW - Report from the meeting held on 9-11 December 2025](#)

[NEW - 11-13 November CMDh minutes](#)

[NEW - Minutes of the 19 November 2025 meeting with Interested Parties](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
19/12/2025	Page: Plasma master file certificates	Updated
19/12/2025	PSUSA: PSUSA/00010473/202503 - periodic safety update report single assessment varicella vaccine (live)	New
19/12/2025	PSUSA: PSUSA/00010473/202503 - periodic safety update report single assessment varicella vaccine (live)	New
19/12/2025	Medicine: Avastin bevacizumab	Updated
19/12/2025	Medicine: Fabhalta iptacopan	Updated
19/12/2025	Medicine: Attrogy diflunisal	Updated
19/12/2025	Medicine: Tremfya guselkumab	Updated
19/12/2025	Medicine: Rotarix rotavirus vaccine, live	Updated
19/12/2025	Medicine: Olumiant baricitinib	Updated
19/12/2025	Medicine: Minjuvi tafasitamab	Updated
19/12/2025	Medicine: Shingrix herpes zoster vaccine (recombinant, adjuvanted)	Updated
19/12/2025	Medicine: Replagal agalsidase alfa	Updated
19/12/2025	Medicine: Pregabalin Viatris (previously Pregabalin Mylan) pregabalin	Updated
19/12/2025	Medicine: Tuzulby methylphenidate hydrochloride	Updated
19/12/2025	Medicine: Leflunomide medac leflunomide	Updated
19/12/2025	PSUSA: PSUSA/00002688/202503 - periodic safety update report single assessment selegiline	New

Date	Content	Status
19/12/2025	PSUSA: PSUSA/00002656/202502 - periodic safety update report single assessment Rocuronium	New
19/12/2025	News: Emer Cooke, EMA's Executive Director: 2025 achievements in medicine regulation	New
19/12/2025	News: EMA Management Board: highlights of December 2025 meeting	New
19/12/2025	News: EMA business hours over holiday period	New
19/12/2025	Medicine: Yargesa miglustat	Updated
19/12/2025	Medicine: Simulect basiliximab	Updated
19/12/2025	Medicine: Macitentan AccordPharma macitentan	Updated
19/12/2025	PSUSA: PSUSA/00002640/202503 - periodic safety update report single assessment rifampicin	New
19/12/2025	Medicine: Methylthioninium chloride Proveblue methylthioninium chloride	Updated
19/12/2025	Medicine: Ruconest conestat alfa	Updated
19/12/2025	Medicine: Altuvect efanesoctocog alfa	Updated
19/12/2025	PSUSA: PSUSA/00002039/202503 - periodic safety update report single assessment metoprolol	New
19/12/2025	Medicine: Pirfenidone Viatris pirfenidone	Updated
19/12/2025	Post-authorisation: HetlioZ - opinion on variation to marketing authorisation tasimelteon	Updated
19/12/2025	Medicine: Macitentan Accord macitentan	Updated
19/12/2025	Medicine: Comirnaty COVID-19 mRNA vaccine	Updated
19/12/2025	Page: Information management	Updated
19/12/2025	Document: Technology Capability Investment Plan to 2028 - Becoming a digital hub for the European medicines regulator network	New
18/12/2025	Medicine: Afqlir afibercept	Updated

Date	Content	Status
18/12/2025	PSUSA: PSUSA/00002502/202503 - periodic safety update report single assessment prazepam	New
18/12/2025	Medicine: Puregon follitropin beta	Updated
18/12/2025	Medicine: Fetcroja cefiderocol	Updated
18/12/2025	Medicine: RotaTeq rotavirus vaccine, live	Updated
18/12/2025	Medicine: Orgalutran ganirelix	Updated
18/12/2025	Event: EMA - European Consumer Organisation (BEUC) bilateral meeting	Updated
18/12/2025	Medicine: Jentaduo linagliptin; metformin hydrochloride	Updated
18/12/2025	Medicine: Cetrotide cetorelix	Updated
18/12/2025	Page: PRIME: priority medicines	Updated
18/12/2025	Document: List of medicines currently in PRIME scheme	Updated
18/12/2025	Medicine: Absimky ustekinumab	Updated
18/12/2025	Medicine: Saphnelo anifrolumab	Updated
18/12/2025	Medicine: Blarcamesine Anavex blarcamesine	Updated
18/12/2025	Medicine: Strimvelis autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human ADA cDNA sequence	Updated
18/12/2025	Medicine: Qtern saxagliptin; dapagliflozin	Updated
18/12/2025	Medicine: Xigduo dapagliflozin; metformin	Updated
18/12/2025	Medicine: Ebymeet dapagliflozin; metformin	Updated
18/12/2025	Medicine: Cosentyx secukinumab	Updated
18/12/2025	Medicine: Leflunomide ratiopharm leflunomide	Updated
18/12/2025	Document: Agenda - Management Board meeting: 17-18 December 2025	Updated

Date	Content	Status
18/12/2025	Medicine: Mepact mifamurtide	Updated
18/12/2025	Document: Minutes of the PRAC meeting 27 - 30 October 2025	New
18/12/2025	Medicine: Caelyx pegylated liposomal doxorubicin	Updated
18/12/2025	Medicine: Azacitidine Kabi azacitidine	Updated
18/12/2025	Shortage: Fiasp PumpCart (insulin aspart) insulin aspart	Updated
18/12/2025	Document: Name Review Group form - questions and answers	Updated
18/12/2025	Shortage: NovoRapid PumpCart (insulin aspart) insulin aspart	Updated
18/12/2025	Medicine: Breyanzi lisocabtagene maraleucel	Updated
18/12/2025	Page: Allergen products development for immunotherapy and allergy diagnosis in moderate to low-sized study populations - Scientific guideline	Updated
18/12/2025	Medicine: Alyftrek deutivacaftor / tezacaftor / vanzacaftor	Updated
18/12/2025	Medicine: Invokana canagliflozin	Updated
18/12/2025	PIP: EMA/PE/0000232894 - paediatric investigation plan adeno-associated viral vector serotype 9 containing the human MECP2 gene (TSHA-102)	New
18/12/2025	PIP: EMA/PE/0000232896 - paediatric investigation plan antisense oligonucleotide against patatin like phospholipase domain containing protein 3 gene (PNPLA3), conjugated to N-acetylgalactosamine (AZD2693), sodium salt	New
18/12/2025	Document: Minutes - Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - 20 November 2025	New
18/12/2025	Event: EMA Cancer Medicines Forum (CMF) meeting with industry stakeholders on cancer treatment optimisation	Updated
17/12/2025	Medicine: Ziihera zanidatamab	Updated
17/12/2025	Medicine: Trumenba meningococcal group b vaccine (recombinant, adsorbed)	Updated
17/12/2025	Medicine: Lucentis ranibizumab	Updated
17/12/2025	Medicine: Entyvio vedolizumab	Updated

Date	Content	Status
17/12/2025	Document: List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs)	Updated
17/12/2025	Page: Medicine shortages and availability issues: guidance for companies	Updated
17/12/2025	Document: Call for user acceptance testers for the read functionality in the Public Product Management Service (PMS) Application Programming Interface (API)	Updated
17/12/2025	Document: Shortage Prevention Plan (SPP) and Shortage Mitigation Plan (SMP) pilot report	New
17/12/2025	Document: Concept Paper on the revision of Annex 3 of the guidelines on Good Manufacturing Practice for Radiopharmaceuticals	Updated
17/12/2025	Medicine: Ocrevus ocrelizumab	Updated
17/12/2025	Event: Quarterly System Demo - Q4 2025	Updated
17/12/2025	Document: Overview of (invented) names reviewed in November 2025 by the Name Review Group (NRG) adopted at the CHMP meeting of 11 December 2025	New
17/12/2025	Medicine: Adjupanrix (previously Pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) GlaxoSmithKline Biologicals) pandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted)	Updated
17/12/2025	PIP: EMA/PE/0000182345 - paediatric investigation plan inbakicept, nogapendekin alfa	New
17/12/2025	PIP: EMA/PE/0000182333 - paediatric investigation plan precentabart tocentecan	New
17/12/2025	PIP: EMA/PE/0000182297 - paediatric investigation plan oxybutynin	New
17/12/2025	PIP: EMA/PE/0000182239 - paediatric investigation plan setmelanotide	Updated
17/12/2025	PIP: EMA/PE/0000182217 - paediatric investigation plan cedazuridine; decitabine	Updated
17/12/2025	PIP: EMA/PE/0000182170 - paediatric investigation plan regorafenib	Updated
17/12/2025	Medicine: Tasigna nilotinib	Updated
17/12/2025	PIP: EMA/PE/0000181778 - paediatric investigation plan rilvegostomig	New
17/12/2025	Medicine: Rapiscan regadenoson	Updated
17/12/2025	PIP: EMA/PE/0000181518 - paediatric investigation plan Lerodalcibep	Updated

Date	Content	Status
17/12/2025	PIP: EMA/PE/0000181441 - paediatric investigation plan telisotuzumab conjugated to (2S)-2-(2-bromoacetamido)-N-[(2S)-1-({3-[(7S)-7-ethyl-7-hydroxy-8,11-dioxo-7,8,11,13-tetrahydro-2H,10H-[1,3]dioxolo[4,5-g]pyrano[3',4':6,7]indolizino[1,2-b]quinolin-14-yl]bicyclo[1.1.1]pentan-1-yl}amino)-1-oxopropan-2-yl]-3-methylbutanamide	New
17/12/2025	PIP: EMA/PE/0000221101 - paediatric investigation plan esepapogene zalarnarepvec	New
17/12/2025	PIP: EMA/PE/0000181335 - paediatric investigation plan Budesonide; Formoterol (fumarate); glycopyrronium bromide	Updated
17/12/2025	PIP: EMA/PE/0000220986 - paediatric investigation plan tenapanor	New
17/12/2025	Referral: Oxbryta - referral voxelotor	Updated
17/12/2025	Medicine: Datroway datopotamab deruxtecán	Updated
17/12/2025	Event: Meeting on the impact of chemical and environmental policies on the healthcare sector and availability of medicines	New
17/12/2025	Document: Table of decisions of labelling exemption requests falling under article 63 of Directive 2001/83/EC examined by the Quality Review of Documents (QRD) Group	Updated
17/12/2025	Document: QRD Appendix V - Adverse-drug-reaction reporting details	Updated
17/12/2025	Medicine: Rivaroxaban Koanaa rivaroxaban	Updated
17/12/2025	PIP: EMA/PE/0000221175 - paediatric investigation plan vibegron	Updated
17/12/2025	PIP: EMA/PE/0000181300 - paediatric investigation plan avalglucosidase alfa	Updated
17/12/2025	PIP: EMA/PE/0000181294 - paediatric investigation plan Tolebrutinib	Updated
17/12/2025	PIP: EMA/PE/0000181238 - paediatric investigation plan resiquimod	New
17/12/2025	PIP: EMA/PE/0000181236 - paediatric investigation plan telisotuzumab conjugated to (2S)-2-(2-bromoacetamido)-N-[(2S)-1-({3-[(7S)-7-ethyl-7-hydroxy-8,11-dioxo-7,8,11,13-tetrahydro-2H,10H-[1,3]dioxolo[4,5-g]pyrano[3',4':6,7]indolizino[1,2-b]quinolin-14-yl]bicyclo[1.1.1]pentan-1-yl}amino)-1-oxopropan-2-yl]-3-methylbutanamide	New
17/12/2025	PIP: EMA/PE/0000221419 - paediatric investigation plan pneumococcal polysaccharide serotype 3 - diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 8 – diphtheria CRM197 conjugate;	Updated

Date	Content	Status
	pneumococcal polysaccharide serotype 15C – diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 6A – diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 15A – diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 16F – diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 19A – diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 23A – diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 24F – diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 17F – diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 33F – diphtheria CRM197 conjugate (15-valent pneumococcal polysaccharide conjugate vaccine [V114]); pneumococcal polysaccharide serotype 10A – diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 12F – diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 20A – diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 31 – diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 35B – diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 7F – diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 22F – diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 9N – diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 11A – diphtheria CRM197 conjugate; pneumococcal polysaccharide serotype 23B – diphtheria CRM197 conjugate (V116)	
17/12/2025	PIP: EMA/PE/0000181219 - paediatric investigation plan bedaquiline fumarate	Updated
17/12/2025	Page: Extended EudraVigilance medicinal product dictionary (XEVMPD) training	Updated
17/12/2025	Event: eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course - June 2026	New
17/12/2025	Event: eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course - March 2026	New
17/12/2025	Event: eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course - April 2026	New
17/12/2025	Event: eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course for sponsors - March 2026	New
17/12/2025	Event: eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course for sponsors - April 2026	New
16/12/2025	Document: Factsheet - Industry reporting via the European Shortages Monitoring Platform (ESMP) during a crisis or MSSG-led preparedness action	New
16/12/2025	Document: Frequently asked questions on the European Shortages Monitoring Platform (ESMP)	Updated
16/12/2025	Medicine: Pradaxa dabigatran etexilate	Updated

Date	Content	Status
16/12/2025	Medicine: Ngenla somatrogon	Updated
16/12/2025	Medicine: Matever levetiracetam	Updated
16/12/2025	Medicine: Seffalair Spiromax salmeterol; fluticasone propionate	Updated
16/12/2025	Medicine: Omforro midazolam	Updated
16/12/2025	Page: European Shortages Monitoring Platform (ESMP): Interoperability with national and pharmaceutical industry systems	New
16/12/2025	Page: European Shortages Monitoring Platform (ESMP)	Updated
16/12/2025	Medicine: Erelzi etanercept	Updated
16/12/2025	Document: Quality Review of Documents (QRD) working group plenary meeting dates	Updated
16/12/2025	Page: European Shortages Monitoring Platform (ESMP): Guidance, training materials and events	New
16/12/2025	Document: European Shortages Monitoring Platform (ESMP) Informational brief	Updated
16/12/2025	Document: Factsheet - Network reporting via the European Shortages Monitoring Platform (ESMP) during a crisis	New
16/12/2025	Document: Factsheet - Network reporting via the European Shortages Monitoring Platform (ESMP) during an MSSG-led preparedness action	New
16/12/2025	Document: Factsheet - Industry reporting via the European Shortages Monitoring Platform (ESMP) in normal circumstances	New
16/12/2025	Medicine: Kesimpta ofatumumab	Updated
16/12/2025	Medicine: Sunlenca lenacapavir	Updated
16/12/2025	Medicine: Ventavis iloprost	Updated
16/12/2025	Event: Q&A Clinic - New Variation Classification in eAF	New
16/12/2025	Medicine: Cyanokit hydroxocobalamin	Updated
16/12/2025	Medicine: Opsumit macitentan	Updated
16/12/2025	Medicine: Trisenox arsenic trioxide	Updated

Date	Content	Status
16/12/2025	Medicine: Ambrisentan Viatris (previously Ambrisentan Mylan) ambrisentan	Updated
16/12/2025	Medicine: Cholib fenofibrate; simvastatin	Updated
16/12/2025	PIP: EMA/PE/0000221199 - paediatric investigation plan bemcentinib	New
16/12/2025	PIP: EMA/PE/0000221500 - paediatric investigation plan phleum pratense pollen extract	New
16/12/2025	PIP: EMA/PE/0000221511 - paediatric investigation plan recombinant human apolipoprotein A-I	New
16/12/2025	PIP: EMA/PE/0000221664 - paediatric investigation plan parietaria judaica pollen extract	New
16/12/2025	PIP: EMA/PE/0000221674 - paediatric investigation plan xaluritamig	New
16/12/2025	PIP: EMA/PE/0000221695 - paediatric investigation plan cupressus arizonica pollen extract	New
16/12/2025	PIP: EMA/PE/0000221772 - paediatric investigation plan olea europaea pollen extract	New
16/12/2025	PIP: EMA/PE/0000221424 - paediatric investigation plan dermatophagoides pteronyssinus extract	New
16/12/2025	Medicine: Libmeldy autologous CD34+ cells encoding ARSA gene	Updated
16/12/2025	Document: Start of procedure: Type II variation - Extension of indication under evaluation by the CHMP (14 November - 11 December 2025)	New
16/12/2025	Document: Start of procedure: Extension of marketing authorisation (14 November - 11 December 2025)	New
16/12/2025	Medicine: Agamree vamorolone	Updated
16/12/2025	Document: Pharmacovigilance-related regulatory recommendations for centrally authorised veterinary medicinal products during 2025	Updated
16/12/2025	Document: New product information wording – Extracts from PRAC recommendations on signals adopted at the 8-11 January 2024 PRAC	Updated
16/12/2025	Document: New product information wording – Extracts from PRAC recommendations on signals adopted at the 27-30 November 2023 PRAC	Updated
15/12/2025	Medicine: Retsevmo selpercatinib	Updated
15/12/2025	Medicine: Coagadex human coagulation factor X	Updated

Date	Content	Status
15/12/2025	Medicine: Remicade infliximab	Updated
15/12/2025	Page: Worksharing: questions and answers	Updated
15/12/2025	Page: Type-II variations: questions and answers	Updated
15/12/2025	Page: Extensions of marketing authorisations: questions and answers	Updated
15/12/2025	Medicine: Repatha evolocumab	Updated
15/12/2025	Medicine: Levetiracetam Hospira levetiracetam	Updated
15/12/2025	Document: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure: document with tracked changes	Updated
15/12/2025	Document: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure	Updated
15/12/2025	Page: Good Manufacturing Practice (GMP) / Good Distribution Practice (GDP) Inspectors Working Group	Updated
15/12/2025	Page: Podcast: Inside EMA	Updated
15/12/2025	Document: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure: document with tracked changes	Updated
15/12/2025	Document: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure	Updated
15/12/2025	Page: Pre-authorisation guidance	Updated

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
16.12.2025	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 15.10.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Codein Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Codein infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

Date	Title
16.12.2025	Sotatercept: Perikarderguss - Aktualisierung der Fach- und Gebrauchsinformation Wirkstoff: Sotatercept Im Rahmen des europäischen Verfahrens zur Bewertung der periodischen Sicherheitsberichte (PSUR Single Assessment) wurde für den Wirkstoff Sotatercept Perikarderguss als neue Nebenwirkung in die Fach- und Gebrauchsinformation aufgenommen.
16.12.2025	Trimethoprim: Kontraindikation im 1. Trimenon, neue Nebenwirkungen Halluzinationen und DRESS Wirkstoff: Trimethoprim Aktualisierung der Fach- und Gebrauchsinformation von Trimethoprim infolge der Bewertung periodischer Sicherheitsberichte.
16.12.2025	Rote-Hand-Brief zu Melphalanhydrochlorid, Melphalan AqVida 90 mg/ml Konzentrat zur Herstellung einer Infusionslösung: Potenzielles Risiko einer Überdosierung aufgrund einer höheren Konzentration Wirkstoff: Melphalanhydrochlorid Die Firma AqVida GmbH informiert darüber, dass Melphalan AqVida 90 mg/ml eine Melphalan-Formulierung ist, die in nur einer Durchstechflasche geliefert wird.
15.12.2025	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 15.10.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Dorzolamid Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Dorzolamid infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
15.12.2025	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 15.10.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Prednison Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Prednison infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

Date	Title
15.12.2025	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 15.10.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Atenolol Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Atenolol infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
16.12.2025	Möglicher Zusammenhang zwischen Brustimplantaten und der Entstehung eines anaplastischen großzelligen Lymphoms (ALCL) Aktuelle Informationen zu texturierten Brustimplantaten
16.12.2025	Brustimplantate aus Silikon: Allgemeine Hinweise und Risiken Aus zahlreichen Quellen ist dem BfArM bekannt geworden, dass sich viele Brustimplantateträgerinnen bei der Entscheidung zu diesem Eingriff der damit verbundenen möglichen Risiken und möglichen Folgen nicht ausreichend bewusst waren. Das BfArM möchte daher einen Beitrag dazu leisten, dass Frauen die mit der Implantation verbundenen Konsequenzen und möglichen Risiken besser kennenlernen.
16.12.2025	SAE- und DD-Meldung im Rahmen einer klinischen Prüfung SAE- und DD-Meldung im Rahmen einer klinischen Prüfung

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
19.12.2025	Informationsschreiben von CSL Behring GmbH: Beriglobin (Humanes normales Immunglobulin)

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeducation updates will be presented quarterly.

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