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HEADS OF AGENCIES – CMDh

03 April 2026

[UPDATE - Position paper common grounds seen for invalidation/delaying day 0 for variations](#)

[UPDATE - Questions and Answers on Variations](#)

[UPDATE - Examples for acceptable and not acceptable groupings for MRP/DCP products](#)

[UPDATE - Type II variation Preliminary Variation Assessment Report](#)

[UPDATE - Chapter 1 - CMDh Best Practice Guide for the allocation of the Mutual Recognition variation number for Type I notifications, Type II variations, grouping and worksharing](#)

[UPDATE - Chapter 6 - CMDh BPG for the Processing of \(Super-\)Grouped Applications in the Mutual Recognition Procedure](#)

[UPDATE - Questions and answers on the Paediatric Regulation](#)

[UPDATE - Best Practice Guide for Article 45 and 46 – Paediatric Regulation - EU Worksharing Procedure](#)

[UPDATE - D70 Overview AR Template \(empty\)](#)

[UPDATE - Overview AR Template \(incl. instructions\)](#)

[UPDATE - PAR template \(empty\) - when prepared based on FAR](#)

[UPDATE - Instructions for RMS when preparing the PAR based on the FAR](#)

[UPDATE - CMDh position paper on the use of Mobile scanning and other technologies to be included in the labelling and/or package leaflet in order to provide information about the medicinal product](#)

[UPDATE - Annex 2 - Applicant's declaration template](#)

[NEW - CMDh Multi-annual Workplan to 2028](#)

[NEW - CMDh Summary of activities 2025](#)

01 April 2026

[NEW - Report from the meeting held on 24-25 March 2026](#)

[UPDATE - Contact Points](#)

31 March 2026

[NEW - 24-25 February CMDh Minutes](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

| Date | Content | Status |
|------------|--|---------|
| 01/04/2026 | Medicine: Keppra levetiracetam | Updated |
| 01/04/2026 | Medicine: Ryzneuta efbemalenograstim alfa | Updated |
| 01/04/2026 | Medicine: Ilumira lutetium (177Lu) chloride | Updated |
| 01/04/2026 | Medicine: Beyfortus nirsevimab | Updated |
| 01/04/2026 | Medicine: Fycompa perampanel | Updated |
| 01/04/2026 | Event: Breakthrough medical devices: information session | New |
| 01/04/2026 | Medicine: RoActemra tocilizumab | Updated |
| 01/04/2026 | Page: Core summary of product characteristics for human normal immunoglobulin for subcutaneous and intramuscular use - Scientific guideline | Updated |
| 01/04/2026 | Medicine: Firazyr icatibant | Updated |
| 01/04/2026 | Page: Clinical investigation of human normal immunoglobulin for subcutaneous and/or intramuscular administration (SCIg/IMIg) - Scientific guideline | Updated |
| 01/04/2026 | Document: Minutes of the COMP meeting 17-19 February 2026 | New |

| Date | Content | Status |
|------------|---|---------|
| 01/04/2026 | Event: ACT EU webinar on draft guidance on the conduct of clinical trials during public health emergencies | Updated |
| 01/04/2026 | Document: Policy 82: Union Product Database (UPD) Access Policy - Veterinary Medicinal Products | Updated |
| 01/04/2026 | Document: Joint Controllership Arrangement with regard to the Union product database (UPD) | Updated |
| 01/04/2026 | Document: Records of data processing activity for the Union Product Database | Updated |
| 01/04/2026 | Document: European Medicines Agency's data protection notice for the exchange of information during the Critical Medicines Vulnerability Assessment exercise | New |
| 01/04/2026 | Document: Scientific advice and protocol assistance adopted during the CHMP meeting 23-26 March 2026 | New |
| 01/04/2026 | Event: Management Board meeting: 12 March 2026 | Updated |
| 01/04/2026 | Page: Medicines for human use under evaluation | Updated |
| 01/04/2026 | Document: Orphan medical devices regular process: Guide for applicants | New |
| 01/04/2026 | Document: Orphan medical devices regular process: 2026 timetable | New |
| 01/04/2026 | Document: Clinical advice request: Template for applicants | New |
| 01/04/2026 | Document: Orphan status request: Template for applicants | New |
| 01/04/2026 | Medicine: Eliquis apixaban | Updated |
| 01/04/2026 | Medicine: Winrevair sotatercept | Updated |
| 01/04/2026 | Event: Workshop on the use of external controls for evidence generation in regulatory decision-making | Updated |
| 01/04/2026 | Medicine: Remsima infliximab | Updated |

| Date | Content | Status |
|------------|--|---------|
| 01/04/2026 | Medicine: LysaKare arginine; lysine | Updated |
| 01/04/2026 | Event: Workshop on Vulnerability Assessment | Updated |
| 01/04/2026 | Page: Scientific Advisory Group on Immune and Inflammatory Diseases | Updated |
| 01/04/2026 | Document: List of European Union reference dates (EURD) and frequency of submission of periodic safety update reports (PSURs) | Updated |
| 01/04/2026 | Document: Implantable cardiac devices (various) - Notified body 2797 - 15/07/2025 - Expert decision and opinion in the context of the clinical evaluation consultation procedure (CECP) | New |
| 01/04/2026 | Document: List of clinical evaluation consultation procedure (CECP) opinions issued for medical devices awaiting finalisation of conformity assessment | Updated |
| 01/04/2026 | Event: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party | Updated |
| 01/04/2026 | Document: List of centrally authorised products with safety-related changes to the product information | Updated |
| 31/03/2026 | Page: Paediatric addendum to the guideline on clinical investigation of medicinal products for the treatment of pulmonary arterial hypertension - Scientific guideline | Updated |
| 31/03/2026 | Document: Paediatric addendum to CHMP guideline on the clinical investigations of medicinal products for the treatment of pulmonary arterial hypertension | New |
| 31/03/2026 | Document: Concept paper on the need for revision of the guideline on clinical investigation of medicinal products for the treatment of amyotrophic lateral sclerosis | New |
| 31/03/2026 | Page: Clinical investigation of medicinal products for the treatment of amyotrophic lateral sclerosis - Scientific guideline | Updated |
| 31/03/2026 | Medicine: Elfabrio pegunigalsidase alfa | Updated |
| 31/03/2026 | Medicine: Topotecan Hospira topotecan | Updated |
| 31/03/2026 | Medicine: Vaxelis diphtheria, tetanus, pertussis (acellular, component), hepatitis B (rDNA), poliomyelitis (inactivated) and Haemophilus type b conjugate vaccine (adsorbed) | Updated |

| Date | Content | Status |
|------------|--|---------|
| 31/03/2026 | Medicine: Zoledronic acid Mylan zoledronic acid | Updated |
| 31/03/2026 | Medicine: Hepcludex bulevirtide | Updated |
| 31/03/2026 | Medicine: Alecensa alectinib | Updated |
| 31/03/2026 | Medicine: Erleada apalutamide | Updated |
| 31/03/2026 | Medicine: Cinacalcet Accordpharma cinacalcet | Updated |
| 31/03/2026 | Medicine: Jemperli dostarlimab | Updated |
| 31/03/2026 | Referral: Tavneos - referral avacopan | Updated |
| 31/03/2026 | Medicine: Brilique ticagrelor | Updated |
| 31/03/2026 | News: EMA consults on virtual control groups to help reduce animal use in medicines development | New |
| 31/03/2026 | Page: Opinions and letters of support on the qualification of novel methodologies for medicine development | Updated |
| 31/03/2026 | Document: Draft Qualification opinion for Virtual Control Groups (VCG) to replace Concurrent Control Groups (CCG) in rat non-GLP Dose-Range Finding (DRF) studies | New |
| 31/03/2026 | Document: Annex 4 - Initial Qualification Procedure List of Issues and Replies - Virtual Control Groups | New |
| 31/03/2026 | Document: Annex 3 - CHMP Scientific Advice - Summary Qualification Document | New |
| 31/03/2026 | Page: Scientific publications | Updated |
| 31/03/2026 | Medicine: Spikevax (previously COVID-19 Vaccine Moderna) COVID-19 mRNA vaccine | Updated |
| 31/03/2026 | Medicine: Comirnaty COVID-19 mRNA vaccine | Updated |
| 31/03/2026 | News: EMA business hours over Easter holiday period | New |
| 31/03/2026 | Document: Annex 1 - Standard Operating Procedure for the Implementation of Virtual Control Groups in Preclinical Studies | New |
| 31/03/2026 | Page: European medicines agencies network strategy (EMANS) | Updated |
| 31/03/2026 | Document: European medicines agencies network strategy (EMANS) to 2025: Final report | New |
| 31/03/2026 | Medicine: Ogsiveo nirogacestat | Updated |
| 31/03/2026 | Page: Pharmaceutical industry | Updated |

| Date | Content | Status |
|------------|---|---------|
| 31/03/2026 | Page: Newsletters | Updated |
| 30/03/2026 | Referral: Ipidacrine-containing medicinal products - referral ipidacrine | Updated |
| 30/03/2026 | Medicine: Finlee dabrafenib | Updated |
| 30/03/2026 | Medicine: Uzpruvo ustekinumab | Updated |
| 30/03/2026 | Medicine: Alyftrek deutivacaftor / tezacaftor / vanzacaftor | Updated |
| 30/03/2026 | Medicine: Glyxambi empagliflozin; linagliptin | Updated |
| 30/03/2026 | Medicine: Tecentriq atezolizumab | Updated |
| 30/03/2026 | Medicine: Imuldosa ustekinumab | Updated |
| 30/03/2026 | Medicine: Increlex mecasermin | Updated |
| 30/03/2026 | Medicine: Flucelvax influenza vaccine (surface antigen, inactivated, prepared in cell cultures) | Updated |
| 30/03/2026 | Medicine: Wegovy semaglutide | Updated |
| 30/03/2026 | News: EU recommendations for 2026/2027 seasonal flu vaccine composition | New |

NOTICE TO APPLICANTS

No updates since October 30th, 2025.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

| Date | Title |
|------------|---|
| 31.03.2026 | Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe vom 11.12.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Captopril Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Captopril infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG. |
| 30.03.2026 | Rote-Hand-Brief zu verschiedenen Arzneimitteln der Dr. Friedrich Eberth Arzneimittel GmbH: Risiko durch nicht aktualisierte Gebrauchsinformationen Wirkstoff: Cefazolin, Cefotaxim, Ceftazidim, Ceftriaxon, Levofloxacin, Moxifloxacin, Voriconazol Die Firma Dr. Friedrich Eberth Arzneimittel GmbH GmbH informiert über ein mögliches Risiko für die Patientensicherheit durch nicht aktualisierte Gebrauchsinformationen. |

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

| Date | Title |
|------------|--|
| 02.04.2026 | Registrierung von Medizinprodukten: Übergang vom DMIDS zu EUDAMED Es wurden neue FAQ zur Registrierung in EUDAMED und zum Übergang vom DMIDS zu EUDAMED veröffentlicht. |
| 31.03.2026 | Hinweis zur Anwendung der Celox PPH Tamponade Die Tamponaden werden als Uterustamponade zur Behandlung bei postpartaler Blutung (PPH) eingesetzt, wenn andere Maßnahmen keine ausreichende blutungsstillende Wirkung erzielen. Vor dem Hintergrund der aktuellen Empfehlung der Weltgesundheitsorganisation (WHO) zur Behandlung der postpartalen Blutung hat sich der Hersteller entschieden, die Celox PPH Tamponade nicht weiter auf dem Markt bereitzustellen. |

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

| Date | Title |
|------------|---|
| 01.04.2026 | Chikungunya-Impfstoff Vimkungya mit französischer Beschriftung erneut in Deutschland verfügbar |

PHARMEUROPA TEXTS FOR COMMENT

| | Group | Issue | Deadline |
|---|-------|-------|------------|
| 2.1.4. Sieves This chapter has undergone pharmacopoeial harmonisation. See chapter 5.8. Pharmacopoeial harmonisation. Reference number: PA/PH/Exp. POW/T (25) 26 ANP Text number: 20104 Direct link | POW | 38.2 | 2026-06-30 |
| 2.7.13. Assay of human anti-D immunoglobulin Reference number: PA/PH/Exp. 6B/T (25) 10 ANP Text number: 20713 Direct link | 6B | 38.2 | 2026-06-30 |
| 2.9.38. Particle-size distribution analysis by analytical sieving Reference number: PA/PH/Exp. POW/T (22) 6 ANP Text number: 20938 Direct link | POW | 38.2 | 2026-06-30 |
| 5.1.10. Guidelines for using the test for bacterial endotoxins Reference number: PA/PH/Exp. BET/T (25) 12 ANP Text number: 50110 Direct link | BET | 38.2 | 2026-06-30 |
| Bitter fennel, cut Reference number: PA/PH/Exp. 13A/T (25) 33 ANP Text number: 3254 | 13A | 38.2 | 2026-06-30 |

| | | | |
|--|-----|------|------------|
| Direct link | | | |
| Chlorobutanol Reference number: PA/PH/Exp. 10A/T (25) 59 ANP Text number: 0382 Direct link | 10A | 38.2 | 2026-06-30 |
| Chlorobutanol hemihydrate Reference number: PA/PH/Exp. 10A/T (25) 60 ANP Text number: 0383 Direct link | 10A | 38.2 | 2026-06-30 |
| Cholecalciferol concentrate (oily form) Reference number: PA/PH/Exp. VIT/T (25) 15 ANP Text number: 0575 Direct link | VIT | 38.2 | 2026-06-30 |
| Cholecalciferol concentrate (powder form) Reference number: PA/PH/Exp. VIT/T (25) 45 ANP Text number: 0574 Direct link | VIT | 38.2 | 2026-06-30 |
| Eltrombopag olamine Reference number: PA/PH/Exp. P4/T (21) 11 ANP Text number: 3178 Direct link | P4 | 38.2 | 2026-06-30 |
| Empagliflozin Reference number: PA/PH/Exp. P4/T (23) 43 ANP Text number: 3234 Direct link | P4 | 38.2 | 2026-06-30 |
| Fennel, bitter Reference number: PA/PH/Exp. 13A/T (25) 32 ANP Text number: 0824 Direct link | 13A | 38.2 | 2026-06-30 |
| Ferrous gluconate hydrate Reference number: PA/PH/Exp. 9/T (26) 1 ANP Text number: 0493 Direct link | 9 | 38.2 | 2026-06-30 |
| Fish oil, rich in omega-3 acids Reference number: PA/PH/Exp. 13H/T (26) 7 ANP Text number: 1912 Direct link | 13H | 38.2 | 2026-06-30 |
| Fludrocortisone acetate Reference number: PA/PH/Exp. SIT/T (25) 61 ANP Text number: 0767 Direct link | 10B | 38.2 | 2026-06-30 |
| Flumetasone pivalate Reference number: PA/PH/Exp. SIT/T (25) 62 ANP Text number: 1327 | 10B | 38.2 | 2026-06-30 |

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|--|-----|------|------------|
| Direct link | | | |
| Flurazepam monohydrochloride Reference number: PA/PH/Exp. 10B/T (26) 4 ANP Text number: 0905 Direct link | 10B | 38.2 | 2026-06-30 |
| Fluvastatin sodium Reference number: PA/PH/Exp. 10A/T (26) 11 ANP Text number: 2333 Direct link | 10A | 38.2 | 2026-06-30 |
| Glycerol distearate Reference number: PA/PH/Exp. 13H/T (26) 4 ANP Text number: 1428 Direct link | 13H | 38.2 | 2026-06-30 |
| Glycerol monostearate 40-55 Reference number: PA/PH/Exp. 13H/T (26) 2 ANP Text number: 0495 Direct link | 13H | 38.2 | 2026-06-30 |
| Hydroxocobalamin acetate Reference number: PA/PH/Exp. VIT/T (26) 2 ANP Text number: 0913 Direct link | VIT | 38.2 | 2026-06-30 |
| Liothyronine sodium Reference number: PA/PH/Exp. 11/T (26) 2 ANP Text number: 0728 Direct link | 11 | 38.2 | 2026-06-30 |
| Meldonium dihydrate Reference number: PA/PH/Exp. 10A/T (26) 10 ANP Text number: 2624 Direct link | 10A | 38.2 | 2026-06-30 |
| Melissa leaf Reference number: PA/PH/Exp. 13A/T (24) 91 ANP Text number: 1447 Direct link | 13A | 38.2 | 2026-06-30 |
| Metformin hydrochloride and dapagliflozin propylene glycol tablets Reference number: PA/PH/Exp. P4/T (22) 43 ANP Text number: 3207 Direct link | P4 | 38.2 | 2026-06-30 |
| Mycophenolate mofetil Reference number: PA/PH/Exp. 10A/T (25) 82 ANP Text number: 1700 Direct link | 10A | 38.2 | 2026-06-30 |
| Nabilone Reference number: PA/PH/Exp. 11/T (23) 56 ANP R1 | 11 | 38.2 | 2026-06-30 |

| | | | |
|--|-----|------|------------|
| Text number: 3102 Direct link | | | |
| Nicotine Reference number: PA/PH/Exp. 11/T (25) 112 ANP Text number: 1452 Direct link | 11 | 38.2 | 2026-06-30 |
| Nicotine ditartrate dihydrate Reference number: PA/PH/Exp. 11/T (25) 113 ANP Text number: 2599 Direct link | 11 | 38.2 | 2026-06-30 |
| Nicotine resinate Reference number: PA/PH/Exp. 11/T (25) 10 ANP Text number: 1792 Direct link | 11 | 38.2 | 2026-06-30 |
| Nicotine resinate with glycerol Reference number: PA/PH/Exp. 11/T (25) 114 ANP Text number: 3292 Direct link | 11 | 38.2 | 2026-06-30 |
| Oleyl alcohol Reference number: PA/PH/Exp. 13H/T (26) 3 ANP Text number: 2073 Direct link | 13H | 38.2 | 2026-06-30 |
| Omega-3-acid ethyl esters 60 Reference number: PA/PH/Exp. 13H/T (26) 8 ANP Text number: 2063 Direct link | 13H | 38.2 | 2026-06-30 |
| Omega-3-acid ethyl esters 90 Reference number: PA/PH/Exp. 13H/T (26) 5 ANP Text number: 1250 Direct link | 13H | 38.2 | 2026-06-30 |
| Omega-3-acid triglycerides Reference number: PA/PH/Exp. 13H/T (26) 6 ANP Text number: 1352 Direct link | 13H | 38.2 | 2026-06-30 |
| Oseltamivir phosphate Reference number: PA/PH/Exp. P4/T (25) 45 ANP Text number: 2422 Direct link | P4 | 38.2 | 2026-06-30 |
| Porcine influenza vaccine (inactivated) Reference number: PA/PH/Exp. 15V/T (25) 27 ANP Text number: 0963 Direct link | 15V | 38.2 | 2026-06-30 |
| Porcine parvovirus vaccine (inactivated) Reference number: PA/PH/Exp. 15V/T (25) 28 ANP | 15V | 38.2 | 2026-06-30 |

| | | | |
|---|-----|------|------------|
| Text number: 0965 Direct link | | | |
| Prednisolone acetate Reference number: PA/PH/Exp. 10B/T (25) 84 ANP Text number: 0734 Direct link | 10B | 38.2 | 2026-06-30 |
| Squalane Reference number: PA/PH/Exp. 13H/T (26) 1 ANP Text number: 1630 Direct link | 13H | 38.2 | 2026-06-30 |
| Suppression of Belladonna, prepared Reference number: PA/PH/Exp. 13B/T (26) 7 ANP Text number: 0222 Direct link | 13B | 38.2 | 2026-06-30 |
| Swine erysipelas vaccine (inactivated) Reference number: PA/PH/Exp. 15V/T (25) 26 ANP Text number: 0064 Direct link | 15V | 38.2 | 2026-06-30 |
| Triamcinolone Reference number: PA/PH/Exp. 10B/T (25) 85 ANP Text number: 1376 Direct link | 10B | 38.2 | 2026-06-30 |
| Ustekinumab concentrated solution Reference number: PA/PH/Exp. MAB/T (25) 8 ANP R2 Text number: 3165 Direct link | MAB | 38.2 | 2026-06-30 |
| Ustekinumab injection Reference number: PA/PH/Exp. MAB/T (26) 3 ANP R2 Text number: 3188 Direct link | MAB | 38.2 | 2026-06-30 |
| Vitamin A concentrate (oily form), synthetic Reference number: PA/PH/Exp. VIT/T (25) 16 ANP Text number: 0219 Direct link | VIT | 38.2 | 2026-06-30 |

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