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HEADS OF AGENCIES – CMDh

01 July

UPDATE - SOP on the processing of PSUR single assessment for nationally authorised products

UPDATE - Data requested for New Applications in the MRP/DCP

UPDATE - Data requested for Variations and/or Renewal Applications in the MRP/DCP

UPDATE - Requirements on Submissions for New Marketing Authorisation Applications within MRP, DCP and National Procedures

UPDATE - Requirements on submissions for Variations and Renewals within MRP and National Procedures

NEW - Agenda of the 19 June 2025 meeting with Interested Parties

NEW - Presentations from the 19 June 2025 meeting with Interested Parties

30 June

UPDATE: Guidance on the application of the revised variations framework

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
04/07/2025	Medicine: Hyftor	Updated
04/07/2025	Medicine: MenQuadfi	Updated
04/07/2025	Medicine: Strimvelis	Updated
04/07/2025	Medicine: ProQuad	Updated
04/07/2025	Medicine: Jivi	Updated

Date	Content	Status
04/07/2025	Medicine: Palforzia	Updated
04/07/2025	Medicine: Oczyesa	Updated
04/07/2025	Medicine: Rilonacept FGK Representative Service GmbH	Updated
04/07/2025	Document: Procedural guidance to scientific committees' members and experts on completing the European Medicines Agency's declaration of interests in the Experts Management Tool	Updated
04/07/2025	Document: Minutes of the PRAC meeting 5-8 May 2025	New
04/07/2025	Medicine: Orfadin	Updated
04/07/2025	News: Strengthening supply chain of anti-D immunoglobulins	New
04/07/2025	Document: Recommendations of the Executive Steering Group on Shortages and Safety of Medicinal Products to address anti-D immunoglobulin supply chain vulnerabilities	New
04/07/2025	Page: Availability of medicines before and during crises	Updated
04/07/2025	Medicine: Neoatrimon	Updated
04/07/2025	Medicine: Leflunomide medac	Updated
04/07/2025	Medicine: Tivdak	Updated
04/07/2025	Document: Agenda of the HMPC meeting 7-9 July 2025	New
04/07/2025	Medicine: Austedo	Updated
03/07/2025	Medicine: Pregabalin Viatris Pharma (previously Pregabalin Pfizer)	Updated
03/07/2025	Event: 13th Industry Standing Group (ISG) meeting	Updated
03/07/2025	Event: First EMA-ACRO bilateral meeting	New
03/07/2025	Medicine: Lyvdelzi (previously Seladelpar Gilead)	Updated
03/07/2025	Medicine: Ziihera	Updated
03/07/2025	Page: EudraVigilance Veterinary	Updated
03/07/2025	Document: Combined Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) list of clinical terms for reporting suspected adverse events in animals and humans to veterinary medicinal products - Rev.16	Updated
02/07/2025	Medicine: Kalydeco	Updated
02/07/2025	Medicine: Cufence	Updated
02/07/2025	Medicine: Kafrio	Updated
02/07/2025	Medicine: Pemetrexed Pfizer (previously Pemetrexed Hospira)	Updated
02/07/2025	Event: Questions and answers clinic on Product Management Service (PMS) Product User Interface (PUI) and Application Programming Interface (API) - May 2025	Updated

Date	Content	Status
02/07/2025	Document: Network Data Steering Group workplan 2025-2028	Updated
02/07/2025	Page: CHMP opinions on consultation procedures	Updated
02/07/2025	Medicine: Idefirix	Updated
02/07/2025	Page: Healthcare professionals: Key documents	Updated
02/07/2025	Event: EMA/FVE info session for veterinary practitioners: Understanding the first report of sales and use of antimicrobials in animals	Updated
02/07/2025	Medicine: Xalkori	Updated
01/07/2025	Medicine: Busulfan Fresenius Kabi	Updated
01/07/2025	Medicine: Amvuttra	Updated
01/07/2025	Document: Minutes of the COMP meeting 13-15 May 2025	New
01/07/2025	Page: QRD guidance on the use of adopted abbreviations and pictograms on the packaging of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP), decentralised (DCP), subsequent recognition (SRP) and national procedures	Updated
01/07/2025	Document: QRD guidance on the use of adopted abbreviations and pictograms on the packaging of veterinary medicinal products authorised via the centralised (CP), mutual recognition (MRP), decentralised (DCP), subsequent recognition (SRP) and national procedures	Updated
01/07/2025	Medicine: Constella	Updated
01/07/2025	Medicine: Cimzia	Updated
01/07/2025	Medicine: Livmarli	Updated
01/07/2025	Medicine: Xydalba	Updated
01/07/2025	Page: Ibuprofen product-specific bioequivalence guidance	Updated
01/07/2025	Page: Dolutegravir product-specific bioequivalence guidance	Updated
01/07/2025	Page: Levothyroxine product-specific bioequivalence guidance	Updated
01/07/2025	Medicine: Synjardy	Updated
01/07/2025	Medicine: Breyanzi	Updated
01/07/2025	Document: Medicinal Product master data for better regulation and better health - Network Data Steering Group (NDSG) recommendations for human Product Master Data implementation and data management	New
01/07/2025	Medicine: Naveruclif	Updated
01/07/2025	Document: Annual accounts: Financial year 2024	New
01/07/2025	Document: Declaration on the qualification of an enterprise as a micro, small or medium-sized enterprise (SME)	Updated

Date	Content	Status
01/07/2025	Medicine: Sorafenib Accord	Updated
01/07/2025	Medicine: Columvi	Updated
01/07/2025	Page: Ethical use of animals in medicine testing	Updated
30/06/2025	Medicine: Comirnaty	Updated
30/06/2025	Medicine: Spikevax (previously COVID-19 Vaccine Moderna)	Updated
30/06/2025	Page: Transparency: exceptional measures for COVID-19 medicines	Updated
30/06/2025	Medicine: Jardiance	Updated
30/06/2025	Orphan: EU/3/25/3060 - orphan designation for treatment of gastric cancer	New
30/06/2025	Medicine: BroPair Spiromax	Updated
30/06/2025	Medicine: Levetiracetam Actavis	Updated
30/06/2025	Orphan: EU/3/25/3054 - orphan designation for treatment of idiopathic pulmonary fibrosis	New
30/06/2025	Medicine: Glyxambi	Updated
30/06/2025	Medicine: Keppra	Updated
30/06/2025	Orphan: EU/3/25/3059 - orphan designation for treatment of acute myeloid leukaemia	New
30/06/2025	Page: Guidance on the application of the revised variations framework	Updated
30/06/2025	Page: Ursodeoxycholic acid product-specific bioequivalence guidance	Updated
30/06/2025	Page: Prasugrel product-specific bioequivalence guidance	Updated
30/06/2025	Page: About this website	Updated
30/06/2025	Page: Paracetamol product-specific bioequivalence guidance	Updated
30/06/2025	Page: Oseltamivir product-specific bioequivalence guidance	Updated
30/06/2025	Page: Metformin product-specific bioequivalence guidance	Updated
30/06/2025	Page: Accessibility	New
30/06/2025	Page: Dabigatran etexilate product-specific bioequivalence guidance	Updated
30/06/2025	Medicine: Levetiracetam ratiopharm	Updated
30/06/2025	Document: Annual activity report 2024	New
30/06/2025	Page: Real-world evidence	Updated
30/06/2025	Page: Memantine product-specific bioequivalence guidance	Updated
30/06/2025	Orphan: EU/3/25/3063 - orphan designation for treatment of Becker muscular dystrophy	New
30/06/2025	Page: Posaconazole product-specific bioequivalence guidance	Updated

Date	Content	Status
30/06/2025	Document: Infosheet: EMA review of real-world data studies from September 2021 to February 2025	New
30/06/2025	Document: Real-world evidence framework to support EU regulatory decision-making: 3rd report on the experience gained with regulator-led studies from February 2024 to February 2025	New
30/06/2025	Medicine: Levetiracetam Teva	Updated
30/06/2025	Event: eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) training course for sponsors - September 2025	New
30/06/2025	Page: Reflection paper on lessons learned from the COVID-19 pandemic: Scientific considerations on non-clinical aspects	New
30/06/2025	Page: ICH E20 adaptive designs for clinical trials - Scientific guideline	New
30/06/2025	Document: ICH E20 guideline on adaptive designs for clinical trials - Step 2b	New
30/06/2025	Orphan: EU/3/13/1117 - orphan designation for treatment of Stargardt's disease	Updated
30/06/2025	Orphan: EU/3/22/2607 - orphan designation for treatment of Fabry disease	Updated
30/06/2025	Orphan: EU/3/19/2203 - orphan designation for treatment of Netherton syndrome	Updated
30/06/2025	Orphan: EU/3/09/645 - orphan designation for treatment of acromegaly	Updated
30/06/2025	Page: Lurasidone product-specific bioequivalence guidance	Updated
30/06/2025	Document: List of centrally authorised products with safety-related changes to the product information	Updated
30/06/2025	Page: Apixaban product-specific bioequivalence guidance	Updated
30/06/2025	Page: Acenocoumarol product-specific bioequivalence guidance	Updated
30/06/2025	Page: Voriconazole product-specific bioequivalence guidance	Updated
30/06/2025	Page: Periodic safety update reports (PSURs)	Updated
30/06/2025	Page: Tadalafil product-specific bioequivalence guidance	Updated
30/06/2025	Page: Repaglinide product-specific bioequivalence guidance	Updated
30/06/2025	Document: Process for submitting existing data on medicinal products authorised for human use – SIAMED II & XEVMPD to PMS deltas - Chapter 9	Updated
30/06/2025	Medicine: Emtricitabine/Tenofovir disoproxil Mylan	Updated
30/06/2025	Event: Quarterly System Demo - Q2 2025	Updated
30/06/2025	Page: PRAC recommendations on safety signals	Updated
30/06/2025	Document: List of signals discussed at PRAC since September 2012	Updated

Date	Content	Status
30/06/2025	Document: New product information wording: extracts from PRAC recommendations on signals adopted at the 2-5 June 2025 PRAC	New
30/06/2025	Document: PRAC recommendations on signals adopted at the 2-5 June 2025 PRAC meeting	New
30/06/2025	Page: Requesting scientific advice or protocol assistance from EMA	Updated
30/06/2025	Medicine: Levetiracetam Actavis Group	Updated
30/06/2025	Medicine: Vyjuvek	Updated
30/06/2025	Medicine: Xenpozyme	Updated

NOTICE TO APPLICANTS

No updates since January 30th 2023.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

Date	Title
02.07.2025	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/132418/2025 vom 25.04.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Etonogestrel Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Etonogestrel infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

Date	Title
01.07.2025	Leistungsstudien mit CDx - Zuständige Ethik-Kommissionen Kurzinformation zu den Zuständigkeiten der Ethik-Kommissionen bei Leistungsstudien mit therapiebegleitenden Diagnostika
01.07.2025	Klinische Prüfung gemäß MDR/IVDR/MPDG Anleitung zu Klinischen Prüfungen bzw. Leistungsstudien im DMIDS aktualisiert
01.07.2025	Kompakter Überblick Erstantrag gemäß MDR/IVDR/MPDG
01.07.2025	Überblick Verfahren und Workflows gemäß MDR/IVDR/MPDG
01.07.2025	DiGA und DiPA Datensicherheitskriterien Hinweis: Gemäß § 139e Absatz 10 Fünftes Buch Sozialgesetzbuch (SGB V) und § 78a Absatz 7 Elftes Buch Sozialgesetzbuch (SGB XI) müssen Hersteller von digitalen Gesundheits- und Pflegeanwendungen die Erfüllung der Anforderungen an die Datensicherheit anhand der Technischen Richtlinien spätestens ab dem 01.01.2025 unter Vorlage eines entsprechenden Zertifikats nachweisen.

Date	Title
30.06.2025	Hinweise zu Anlagen Hinweise zu Anlagen bei der Erfassung von klinischen Prüfungen im DMIDS aktualisiert.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since May 22nd, 2025.

PHARMEUROPA TEXTS FOR COMMENT

	Group	Issue	Deadline
2.5.46. Phenolic antioxidants in plastic materials Reference number: PA/PH/Exp. 16/T (23) 3 ANP Text number: 20546 Direct link	16	37.3	2025-09-30
2.6.42. Test for procoagulant activity in immunoglobulin preparations Reference number: PA/PH/Exp. 6B/T (24) 1 ANP Text number: 20642 Direct link	6B	37.3	2025-09-30
2.8.27. Determination of estragole Reference number: PA/PH/Exp. 13A/T (25) 23 ANP Text number: 20827 Direct link	13A	37.3	2025-09-30
3.1.3. Polyolefins Reference number: PA/PH/Exp. 16/T (24) 27 ANP Text number: 30103 Direct link	16	37.3	2025-09-30
3.1.5. Polyethylene with additives for containers for parenteral preparations and for ophthalmic preparations Reference number: PA/PH/Exp. 16/T (24) 28 ANP Text number: 30105 Direct link	16	37.3	2025-09-30
3.1.6. Polypropylene for containers and closures for parenteral preparations and ophthalmic preparations Reference number: PA/PH/Exp. 16/T (24) 29 ANP Text number: 30106 Direct link	16	37.3	2025-09-30
3.1.7. Poly(ethylene - vinyl acetate) for containers and tubing for total parenteral nutrition preparations Reference number: PA/PH/Exp. 16/T (24) 30 ANP Text number: 30107 Direct link	16	37.3	2025-09-30

	Group	Issue	Deadline
3.2.1. Glass containers for pharmaceutical use Reference number: PA/PH/Exp. GLS/T (20) 12 ANP Text number: 30201 Direct link	GLS	37.3	2025-09-30
5.2.14. Substitution of in vivo method(s) by in vitro method(s) for the quality control of vaccines Reference number: PA/PH/Exp. 15/T (25) 2 ANP Text number: 50214 Direct link	15	37.3	2025-09-30
5.34. Additional information on gene therapy medicinal products for human use Reference number: PA/PH/Exp. GTP/T (24) 8 ANP Text number: 53400 Direct link	GTP	37.3	2025-09-30
Adalimumab concentrated solution Reference number: PA/PH/Exp. MAB/T (24) 4 ANP Text number: 3147 Direct link	MAB	37.3	2025-09-30
Alectinib hydrochloride Reference number: PA/PH/Exp. P4/T (23) 38 ANP Text number: 3219 Direct link	P4	37.3	2025-09-30
Alectinib hydrochloride capsules Reference number: PA/PH/Exp. P4/T (23) 39 ANP Text number: 3220 Direct link	P4	37.3	2025-09-30
Belladonna for homoeopathic preparations Reference number: PA/PH/Exp. HOM/T (23) 12 ANP Text number: 2489 Direct link	HOM	37.3	2025-09-30
Bluetongue vaccine (inactivated) Reference number: PA/PH/Exp. 15V/T (19) 46 ANP Text number: 2899 Direct link	15V	37.3	2025-09-30
Bosentan monohydrate Reference number: PA/PH/Exp. 10D/T (25) 13 ANP Text number: 3250 Direct link	10D	37.3	2025-09-30
Calcium hydroxide Reference number: PA/PH/Exp. 9/T (25) 12 ANP Text number: 1078 Direct link	9	37.3	2025-09-30

	Group	Issue	Deadline
Carmellose calcium Reference number: PA/PH/Exp. EXP/T (25) 9 ANP Text number: 0886 Direct link	CEL	37.3	2025-09-30
Daptomycin Reference number: PA/PH/Exp. 7/T (22) 2 ANP Text number: 3034 Direct link	7	37.3	2025-09-30
Fluorescein sodium Reference number: PA/PH/Exp. 10D/T (23) 45 ANP Text number: 1213 Direct link	10D	37.3	2025-09-30
Fritillaria cirrhosa bulb Reference number: PA/PH/Exp. TCM/T (19) 36 ANP Text number: 2586 Direct link	TCM	37.3	2025-09-30
Glutamic acid Reference number: PA/PH/Exp. 10D/T (23) 31 ANP Text number: 0750 Direct link	10D	37.3	2025-09-30
Glycerol dibehenate Reference number: PA/PH/Exp. EXP/T (25) 7 ANP Text number: 1427 Direct link	13H	37.3	2025-09-30
Glycerol distearate Reference number: PA/PH/Exp. EXP/T (25) 8 ANP Text number: 1428 Direct link	13H	37.3	2025-09-30
Human normal immunoglobulin for intravenous administration Reference number: PA/PH/Exp. 6B/T (24) 11 ANP Text number: 0918 Direct link	6B	37.3	2025-09-30
Human normal immunoglobulin for subcutaneous administration Reference number: PA/PH/Exp. 6B/T (24) 12 ANP Text number: 2788 Direct link	6B	37.3	2025-09-30
Influenza vaccine (split virion, inactivated) Reference number: PA/PH/Exp. 15/T (25) 14 ANP Text number: 0158 Direct link	15	37.3	2025-09-30

	Group	Issue	Deadline
Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) Reference number: PA/PH/Exp. 15/T (25) 18 ANP Text number: 2149 Direct link	15	37.3	2025-09-30
Influenza vaccine (surface antigen, inactivated, virosome) Reference number: PA/PH/Exp. 15/T (25) 17 ANP Text number: 2053 Direct link	15	37.3	2025-09-30
Influenza vaccine (surface antigen, inactivated) Reference number: PA/PH/Exp. 15/T (25) 16 ANP Text number: 0869 Direct link	15	37.3	2025-09-30
Influenza vaccine (whole virion, inactivated) Reference number: PA/PH/Exp. 15/T (25) 15 ANP Text number: 0159 Direct link	15	37.3	2025-09-30
Iopamidol Reference number: PA/PH/Exp. 11/T (25) 34 ANP Text number: 1115 Direct link	11	37.3	2025-09-30
Iron sucrose concentrated solution Reference number: PA/PH/Exp. NBC/T (14) 11 ANP Text number: 2753 Direct link	NANO	37.3	2025-09-30
Lauromacrogol 400 Reference number: PA/PH/Exp. 13H/T (22) 9 ANP R2 Text number: 2046 Direct link	13H	37.3	2025-09-30
Lemon verbena leaf Reference number: PA/PH/Exp. 13A/T (20) 35 ANP Text number: 1834 Direct link	13A	37.3	2025-09-30
Neotame Reference number: PA/PH/Exp. 10D/T (23) 25 ANP Text number: 3218 Direct link	10D	37.3	2025-09-30
Octyldodecanol Reference number: PA/PH/Exp. 13H/T (24) 112 ANP Text number: 1136 Direct link	13H	37.3	2025-09-30

	Group	Issue	Deadline
Polyoxypropylene stearyl ether Reference number: PA/PH/Exp. 13H/T (24) 57 ANP Text number: 2602 Direct link	13H	37.3	2025-09-30
Primula flower Reference number: PA/PH/Exp. 13A/T (22) 8 ANP Text number: 2540 Direct link	13A	37.3	2025-09-30
Ropivacaine hydrochloride Reference number: PA/PH/Exp. 10A/T (16) 64 ANP Text number: 2800 Direct link	10A	37.3	2025-09-30
Sage leaf (Salvia officinalis) Reference number: PA/PH/Exp. 13A/T (24) 93 ANP Text number: 1370 Direct link	13A	37.3	2025-09-30
Sage leaf (salvia officinalis), cut Reference number: PA/PH/Exp. 13A/T (25) 28 ANP Text number: 3201 Direct link	13A	37.3	2025-09-30
Saw palmetto fruit Reference number: PA/PH/Exp. 13A/T (24) 92 ANP Text number: 1848 Direct link	13A	37.3	2025-09-30
Sorbic acid Reference number: PA/PH/Exp. SIT/T (25) 22 ANP Text number: 0592 Direct link	10D	37.3	2025-09-30
Spine date seed Reference number: PA/PH/Exp. TCM/T (09) 67 ANP Text number: 2613 Direct link	TCM	37.3	2025-09-30
Sulfadiazine Reference number: PA/PH/Exp. SIT/T (25) 20 ANP Text number: 0294 Direct link	7	37.3	2025-09-30
Sulfamethoxazole Reference number: PA/PH/Exp. SIT/T (25) 21 ANP Text number: 0108 Direct link	7	37.3	2025-09-30

	Group	Issue	Deadline
Sulfanilamide Reference number: PA/PH/Exp. SIT/T (25) 18 ANP Text number: 1571 Direct link	7	37.3	2025-09-30
Suppression of Ephedrine Reference number: PA/PH/Exp. 10A/T (25) 26 ANP Text number: 0488 Direct link	10A	37.3	2025-09-30
Suppression of Ephedrine hemihydrate Reference number: PA/PH/Exp. 10A/T (25) 27 ANP Text number: 0489 Direct link	10A	37.3	2025-09-30
Suppression of Ephedrine hydrochloride, racemic Reference number: PA/PH/Exp. 10A/T (25) 28 ANP Text number: 0715 Direct link	10A	37.3	2025-09-30
Suppression of Ouabain Reference number: PA/PH/Exp. 11/T (25) 15 ANP Text number: 0048 Direct link	11	37.3	2025-09-30
Testosterone isocaproate Reference number: PA/PH/Exp. 10B/T (25) 6 ANP Text number: 1737 Direct link	10B	37.3	2025-09-30
Verbena herb Reference number: PA/PH/Exp. 13A/T (20) 34 ANP Text number: 1854 Direct link	13A	37.3	2025-09-30

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