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HEADS OF AGENCIES – CMDh

No updates since December 20th 2023.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

12/01/2024	Medicine: Inrebic	Updated
12/01/2024	Medicine: Pregabalin Pfizer	Updated
12/01/2024	Page: Big data	Updated
12/01/2024	Document: Guidance on paediatric submissions	Updated
12/01/2024	Document: Annex to interim measures regarding notification of pharmacovigilance alerts by marketing authorisation holders under Regulation (EU) 2019/6: contact points	Updated
12/01/2024	Medicine: Jemperli	Updated
12/01/2024	Medicine: Scemblix	Updated
12/01/2024	Medicine: Yescarta	Updated
12/01/2024	Medicine: Paxlovid	Updated
12/01/2024	Medicine: Lyrica	Updated
12/01/2024	News: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 8-11 January 2024	New
12/01/2024	News: Potential risk of neurodevelopmental disorders in children born to men treated with valproate medicines: PRAC recommends precautionary measures	New
12/01/2024	PSUSA: PSUSA/00002190/202306 - periodic safety update report single assessment	New
12/01/2024	PSUSA: PSUSA/00001191/202305 - periodic safety update report single assessment	New
12/01/2024	Medicine: Lorviqua	Updated
12/01/2024	Referral: Hydroxyprogesterone-containing medicinal products - referral	Updated
12/01/2024	Medicine: Libtayo	Updated
12/01/2024	Page: Q&A: Good clinical practice (GCP)	Updated
11/01/2024	Document: Policy on the determination of the condition(s) for a paediatric investigation plan (PIP) / waiver (scope of the PIP / waiver)	Updated

11/01/2024	PSUSA: PSUSA/00002329/202306 - periodic safety update report single assessment	New
11/01/2024	Medicine: Benepali	Updated
11/01/2024	PSUSA: PSUSA/00000048/202306 - periodic safety update report single assessment	New
11/01/2024	Medicine: Pazenir	Updated
11/01/2024	PSUSA: PSUSA/00002925/202305 - periodic safety update report single assessment	New
11/01/2024	PSUSA: PSUSA/00001783/202305 - periodic safety update report single assessment	New
11/01/2024	Medicine: Flebogamma DIF (previously Flebogammadif)	Updated
11/01/2024	Medicine: Lokelma	Updated
11/01/2024	Medicine: Enbrel	Updated
11/01/2024	Page: Opinions and letters of support on the qualification of novel methodologies for medicine development	Updated
11/01/2024	Document: Human medicines highlights - January 2024	New
11/01/2024	Medicine: Yuflyma	Updated
11/01/2024	Medicine: Keytruda	Updated
11/01/2024	Medicine: Cosentyx	Updated
11/01/2024	PIP: EMA-003339-PIP01-22 - paediatric investigation plan	New
11/01/2024	PIP: EMA-003084-PIP03-22 - paediatric investigation plan	New
11/01/2024	Medicine: Roclanda	Updated
11/01/2024	PSUSA: PSUSA/00010492/202304 - periodic safety update report single assessment	New
11/01/2024	PSUSA: PSUSA/00010491/202304 - periodic safety update report single assessment	New
11/01/2024	PIP: EMA-003380-PIP01-22 - paediatric investigation plan	New
11/01/2024	PIP: EMA-003309-PIP01-22 - paediatric investigation plan	New
11/01/2024	PIP: EMA-002840-PIP02-22 - paediatric investigation plan	New
11/01/2024	Medicine: Vixelis	Updated
11/01/2024	PIP: EMA-002798-PIP03-22 - paediatric investigation plan	New
11/01/2024	Medicine: Byooviz	Updated
11/01/2024	PIP: EMA-002698-PIP03-22 - paediatric investigation plan	New
11/01/2024	PIP: EMA-002698-PIP02-22 - paediatric investigation plan	New
11/01/2024	Document: Scientific guidelines with summary-of-product-characteristics recommendations	Updated
11/01/2024	Document: IRIS guide to registration and RPIs	Updated
11/01/2024	Document: Recommended submission dates for veterinary medicinal products	Updated
11/01/2024	Medicine: Skyrizi	Updated
11/01/2024	PIP: EMA-003119-PIP01-21-M01 - paediatric investigation plan	Updated
11/01/2024	PIP: EMA-001860-PIP03-16-M08 - paediatric investigation plan	Updated
11/01/2024	PIP: EMA-001825-PIP01-15-M04 - paediatric investigation plan	Updated
11/01/2024	PIP: EMA-001465-PIP01-13-M05 - paediatric investigation plan	Updated
11/01/2024	PIP: EMA-001280-PIP01-12-M05 - paediatric investigation plan	Updated
11/01/2024	PIP: EMA-001219-PIP01-11-M06 - paediatric investigation plan	Updated
11/01/2024	Document: EudraVigilance veterinary - Registration manual	Updated
10/01/2024	Page: Pharmacovigilance Inspectors Working Group	Updated
10/01/2024	Page: Website outages and upgrades	Updated
10/01/2024	Medicine: Latuda	Updated
10/01/2024	Event: Pharmacovigilance Risk Assessment Committee (PRAC): 23-26 October 2023	Updated
10/01/2024	Medicine: Azacitidine Mylan	Updated

10/01/2024	Medicine: Bavencio	Updated
10/01/2024	Medicine: Remsima	Updated
10/01/2024	Medicine: Pheburane	Updated
10/01/2024	Medicine: Takhzyro	Updated
10/01/2024	Medicine: Remicade	Updated
10/01/2024	Medicine: Azacitidine betapharm	Updated
10/01/2024	Medicine: Briviact (in Italy: Nubriveo)	Updated
10/01/2024	Medicine: Nimvastid	Updated
10/01/2024	Medicine: Roteas	Updated
10/01/2024	Medicine: Evkeeza	Updated
10/01/2024	Medicine: NexoBrid	Updated
10/01/2024	Medicine: Ritonavir Mylan	Updated
10/01/2024	Medicine: Dectova	Updated
10/01/2024	Medicine: Renvela	Updated
10/01/2024	Medicine: Humalog	Updated
10/01/2024	Medicine: Prolia	Updated
09/01/2024	Medicine: Eylea	Updated
09/01/2024	Medicine: Lenvima	Updated
09/01/2024	Medicine: Tevimbra	Updated
09/01/2024	Medicine: Erleada	Updated
09/01/2024	Medicine: Talvey	Updated
09/01/2024	Document: Workplan 2023-2025: HMA-EMA joint Big Data Steering Group	Updated
09/01/2024	Medicine: GHRYVELIN (previously Macimorelin Aeterna Zentaris)	Updated
09/01/2024	Medicine: Ziagen	Updated
09/01/2024	Medicine: Vazkepa	Updated
09/01/2024	Event: Clinical Trials Information System (CTIS) bitesize talk: Training materials, CTIS pre-requisites, and updates on transparency rules	Updated
09/01/2024	Document: European Medicines Agency's privacy statement for the operation of the Security Access Control System	Updated
09/01/2024	Document: European Medicines Agency's privacy statement for the operation of video-surveillance (CCTV) system	Updated
09/01/2024	Medicine: Myozyme	Updated
09/01/2024	Document: Record of data processing activity relating to Security Access Control System (public)	Updated
09/01/2024	Document: Record of data processing activity relating to the filmmaker security database for staff vehicles/bicycles and lost/found property (public)	Updated
09/01/2024	Medicine: Koselugo	Updated
09/01/2024	Medicine: Vocabria	Updated
08/01/2024	Document: List of substances and products subject to worksharing for signal management	Updated
08/01/2024	Medicine: Zejula	Updated
08/01/2024	Medicine: Mysimba	Updated
08/01/2024	Referral: Mysimba - referral	Updated
08/01/2024	Medicine: Neupro	Updated
08/01/2024	Medicine: Mycamine	Updated
08/01/2024	Medicine: Mayzent	Updated
08/01/2024	Medicine: Zomarist	Updated
08/01/2024	Page: Funding	Updated
08/01/2024	Medicine: Eucreas	Updated
08/01/2024	Medicine: Revlimid	Updated
08/01/2024	Medicine: Icandra (previously Vildagliptin / metformin hydrochloride Novartis)	Updated

08/01/2024	Medicine: Vimpat	Updated
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NOTICE TO APPLICANTS

No updates since January 30th 2023.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

12.01.2024	Valproat: Potenzielles Risiko für neurologische Entwicklungsstörungen bei Kindern, die von Vätern gezeugt wurden, die valproathaltige Arzneimittel eingenommen haben Wirkstoff: Valproat Der Ausschuss für Risikobewertung im Bereich der Pharmakovigilanz (PRAC) der Europäischen Arzneimittel-Agentur (EMA) empfiehlt Vorsichtsmaßnahmen für die Behandlung von männlichen Patienten mit valproathaltigen Arzneimitteln.
12.01.2024	Valproat: Risiko angeborener Missbildungen und Entwicklungsstörungen bei Anwendung in der Schwangerschaft Wirkstoff: ValproatP RAC empfiehlt Vorsichtsmaßnahmen aufgrund des potenziellen Risikos von neurologischen Entwicklungsstörungen bei Kindern.
12.01.2024	Pirfenidon – Arzneimittelwirkung mit Eosinophilie und systemischen Symptomen (DRESS) Pirfenidon – Arzneimittelwirkung mit Eosinophilie und systemischen Symptomen (DRESS)
12.01.2024	Pharmacovigilance Risk Assessment Committee (PRAC) Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht die neuen Signale, die im Rahmen der PRAC-Sitzung vom 08.01-11.01.2023 behandelt wurden.
11.01.2024	Hinweis des BfArM über das Ergebnis zum PSUSA/00002472/202210 zu Polystyrolsulfonat Zu Arzneimitteln mit dem Wirkstoff Polystyrolsulfonat wurde ein europäisches, die periodischen Sicherheitsberichte bewertendes Verfahren durchgeführt. Basierend auf der Empfehlung des PRAC hat die CMDh im Mai 2023 einen einstimmigen Beschluss gefasst.
11.01.2024	Umsetzung des Durchführungsbeschlusses der Europäischen Kommission zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit der Wirkstoffkombination Abacavir/Lamivudin vom 29.11.2023 Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffkombination Abacavir/Lamivudin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
11.01.2024	Umsetzung des Durchführungsbeschlusses der Europäischen Kommission zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Abacavir vom 29.11.2023 Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Abacavir 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 December 28th 2023.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since November 16th 2023.

PHARMEUROPA TEXTS FOR COMMENT

Text	Group	Issue	Deadline
2.5.42. N-Nitrosamines in active substances and medicinal products <i>Reference number: PA/PH/SG (20) 68 ANP</i> <i>Text number: 20542</i>	MG	36.1	31.03.2024
2.6.7. Mycoplasmas <i>Reference number: PA/PH/Exp. MYC/T (21) 1 ANP R1</i> <i>Text number: 20607</i>	MYC	36.1	31.03.2024
Haemodialysis, solutions for <i>Reference number: PA/PH/Exp. DIA/T (22) 12 ANP</i> <i>Text number: 0128</i>	DIA	36.1	31.03.2024
Haemofiltration and haemodiafiltration, concentrated solutions for <i>Reference number: PA/PH/Exp. DIA/T (22) 3 ANP</i> <i>Text number: 2770</i>	DIA	36.1	31.03.2024
Haemofiltration and haemodiafiltration, solutions for <i>Reference number: PA/PH/Exp. DIA/T (22) 13 ANP</i> <i>Text number: 0861</i>	DIA	36.1	31.03.2024
Haemodialysis, concentrated solutions for <i>Reference number: PA/PH/Exp. DIA/T (22) 11 ANP</i> <i>Text number: 3206</i>	DIA	36.1	31.03.2024
5.1.9. Guidelines for using the test for sterility <i>Reference number: PA/PH/Exp. 1/T (23) 17 ANP</i> <i>Text number: 50109</i>	1	36.1	31.03.2024
Influenza vaccine (whole virion, inactivated) <i>Reference number: PA/PH/Exp. 15/T (23) 42 ANP</i> <i>Text number: 0159</i>	15	36.1	31.03.2024
Smallpox vaccine (live) <i>Reference number: PA/PH/Exp. 15/T (23) 50 ANP</i> <i>Text number: 0164</i>	15	36.1	31.03.2024
Haemodialysis solutions, concentrated, water for diluting <i>Reference number: PA/PH/Exp. DIA/T (22) 4 ANP</i> <i>Text number: 1167</i>	DIA	36.1	31.03.2024
Hepatitis A vaccine (inactivated, adsorbed) <i>Reference number: PA/PH/Exp. 15/T (23) 46 ANP</i> <i>Text number: 1107</i>	15	36.1	31.03.2024
Influenza vaccine (surface antigen, inactivated, virosome)	15	36.1	31.03.2024

Text	Group	Issue	Deadline
<i>Reference number: PA/PH/Exp. 15/T (23) 44 ANP</i> <i>Text number: 2053</i>			
Peritoneal dialysis, solutions for <i>Reference number: PA/PH/Exp. DIA/T (22) 14 ANP</i> <i>Text number: 0862</i>	DIA	36.1	31.03.2024
Poliomyelitis vaccine (inactivated) <i>Reference number: PA/PH/Exp. 15/T (23) 47 ANP</i> <i>Text number: 0214</i>	15	36.1	31.03.2024
Ropivacaine hydrochloride monohydrate <i>Reference number: PA/PH/Exp. P4/T (23) 26 ANP</i> <i>Text number: 2335</i>	P4	36.1	31.03.2024
Sitagliptin phosphate monohydrate <i>Reference number: PA/PH/Exp. P4/T (23) 28 ANP</i> <i>Text number: 2778</i>	P4	36.1	31.03.2024
Yellow fever vaccine (live) <i>Reference number: PA/PH/Exp. 15/T (23) 49 ANP</i> <i>Text number: 0537</i>	15	36.1	31.03.2024
Cedarwood oil, Atlas or Himalaya type <i>Reference number: PA/PH/Exp. 13A/T (18) 40 ANP</i> <i>Text number: 3002</i>	13A	36.1	31.03.2024
Influenza vaccine (split virion, inactivated) <i>Reference number: PA/PH/Exp. 15/T (23) 41 ANP</i> <i>Text number: 0158</i>	15	36.1	31.03.2024
Influenza vaccine (surface antigen, inactivated) <i>Reference number: PA/PH/Exp. 15/T (23) 43 ANP</i> <i>Text number: 0869</i>	15	36.1	31.03.2024
JK-PSMA-7 (18F) injection <i>Reference number: PA/PH/Exp. 14/T (22) 15 ANP</i> <i>Text number: 3205</i>	14	36.1	31.03.2024
Tick-borne encephalitis vaccine (inactivated) <i>Reference number: PA/PH/Exp. 15/T (23) 48 ANP</i> <i>Text number: 1375</i>	15	36.1	31.03.2024
Clary sage oil <i>Reference number: PA/PH/Exp. 13A/T (20) 27 ANP</i> <i>Text number: 1850</i>	13A	36.1	31.03.2024
Influenza vaccine (surface antigen, inactivated, prepared in cell cultures) <i>Reference number: PA/PH/Exp. 15/T (23) 45 ANP</i> <i>Text number: 2149</i>	15	36.1	31.03.2024
Levetiracetam <i>Reference number: PA/PH/Exp. 10B/T (23) 74 ANP</i> <i>Text number: 2535</i>	10B	36.1	31.03.2024
Rivaroxaban <i>Reference number: PA/PH/Exp. 10B/T (23) 76 ANP</i> <i>Text number: 2932</i>	10B	36.1	31.03.2024
Clopidogrel hydrogen sulfate <i>Reference number: PA/PH/Exp. 10C/T (23) 33 ANP</i> <i>Text number: 2531</i>	10c	36.1	31.03.2024
Lamivudine <i>Reference number: PA/PH/Exp. P4/T (23) 25 ANP</i> <i>Text number: 2217</i>	P4	36.1	31.03.2024
Vaccines for veterinary use	115v	36.1	31.03.2024

Text	Group	Issue	Deadline
<i>Reference number: PA/PH/Exp. 15V/T (23) 30 ANP</i> <i>Text number: 0062</i>			
Esomeprazole magnesium dihydrate <i>Reference number: PA/PH/Exp. 10C/T (23) 29 ANP</i> <i>Text number: 2787</i>	10C	36.1	31.03.2024
Esomeprazole sodium <i>Reference number: PA/PH/Exp. 10C/T (23) 31 ANP</i> <i>Text number: 2923</i>	10C	36.1	31.03.2024
Ethylmorphine hydrochloride dihydrate <i>Reference number: PA/PH/Exp. 11/T (23) 78 ANP</i> <i>Text number: 0491</i>	11	36.1	31.03.2024
Homatropine hydrobromide <i>Reference number: PA/PH/Exp. 11/T (23) 77 ANP</i> <i>Text number: 0500</i>	11	36.1	31.03.2024
Aluminium hydroxide, hydrated, for adsorption <i>Reference number: PA/PH/Exp. 9/T (21) 37 ANP</i> <i>Text number: 1664</i>	9	36.1	31.03.2024
Escitalopram <i>Reference number: PA/PH/Exp. 10B/T (23) 73 ANP</i> <i>Text number: 2758</i>	10b	36.1	31.03.2024
Esomeprazole magnesium trihydrate <i>Reference number: PA/PH/Exp. 10C/T (23) 30 ANP</i> <i>Text number: 2372</i>	10C	36.1	31.03.2024
Pregabalin <i>Reference number: PA/PH/Exp. 10C/T (23) 32 ANP</i> <i>Text number: 2777</i>	10C	36.1	31.03.2024
Clove <i>Reference number: PA/PH/Exp. 13A/T (23) 28 ANP</i> <i>Text number: 0376</i>	13A	36.1	31.03.2024
Escitalopram oxalate <i>Reference number: PA/PH/Exp. 10B/T (23) 64 ANP</i> <i>Text number: 2733</i>	10B	36.1	31.03.2024
Etodolac <i>Reference number: PA/PH/Exp. 10D/T (23) 41 ANP</i> <i>Text number: 1422</i>	10D	36.1	31.03.2024
Arachis oil, hydrogenated <i>Reference number: PA/PH/Exp. 13H/T (23) 107 ANP</i> <i>Text number: 1171</i>	13H	36.1	31.03.2024
Magnesium phosphoricum for homoeopathic preparations <i>Reference number: PA/PH/Exp. HOM/T (23) 45 ANP</i> <i>Text number: 2505</i>	HOM	36.1	31.03.2024
Rotigotine <i>Reference number: PA/PH/Exp. P4/T (23) 27 ANP</i> <i>Text number: 3014</i>	P4	36.1	31.03.2024
Tapentadol hydrochloride <i>Reference number: PA/PH/Exp. P4/T (23) 29 ANP</i> <i>Text number: 3035</i>	P4	36.1	31.03.2024
Lacosamide <i>Reference number: PA/PH/Exp. P4/T (23) 24 ANP</i> <i>Text number: 2992</i>	P4	36.1	31.03.2024
Cadmium sulfuricum for homoeopathic preparations <i>Reference number: PA/PH/Exp. HOM/T (23) 44 ANP</i>	HOM	36.1	31.03.2024

Text	Group	Issue	Deadline
<i>Text number: 2143</i>			
Cuprum metallicum for homoeopathic preparations <i>Reference number: PA/PH/Exp. HOM/T (23) 43 ANP</i> <i>Text number: 1610</i>	HOM	36.1	31.03.2024
Fluconazole <i>Reference number: PA/PH/Exp. 10B/T (23) 108 ANP</i> <i>Text number: 2287</i>	10B	36.1	31.03.2024
Clove oil <i>Reference number: PA/PH/Exp. 13A/T (23) 41 ANP</i> <i>Text number: 1091</i>	13A	36.1	31.03.2024
Ferrum metallicum for homoeopathic preparations <i>Reference number: PA/PH/Exp. HOM/T (23) 40 ANP</i> <i>Text number: 2026</i>	HOM	36.1	31.03.2024
Liquorice root <i>Reference number: PA/PH/Exp. 13A/T (20) 33 ANP</i> <i>Text number: 0277</i>	13A	36.1	31.03.2024
Nitrendipine <i>Reference number: PA/PH/Exp. 10B/T (23) 109 ANP</i> <i>Text number: 1246</i>	10B	36.1	31.03.2024
Liquorice dry extract for flavouring purposes <i>Reference number: PA/PH/Exp. 13A/T (20) 32 ANP</i> <i>Text number: 2378</i>	13A	36.1	31.03.2024
Remifentanil hydrochloride <i>Reference number: PA/PH/Exp. 10B/T (23) 63 ANP</i> <i>Text number: 2644</i>	10B	36.1	31.03.2024
Nicotine ditartrate dihydrate <i>Reference number: PA/PH/Exp. 11/T (23) 86 ANP</i> <i>Text number: 2599</i>	11	36.1	31.03.2024
Salicylic acid <i>Reference number: PA/PH/Exp. 10A/T (23) 6 ANP</i> <i>Text number: 0366</i>	10A	36.1	31.03.2024
Indometacin <i>Reference number: PA/PH/Exp. 10A/T (23) 65 ANP</i> <i>Text number: 0092</i>	10A	36.1	31.03.2024

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