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HEADS OF AGENCIES – CMDh

No updates since April 3rd 2024.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
19/04/2024	Medicine: Lymphoseek	Updated
19/04/2024	Event: Paediatric Oncology Strategy Forum: 24-25 October 2024	New
19/04/2024	Event: Product Management Service (PMS) Info-Day	Updated
19/04/2024	News: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 16-18 April 2024	New
19/04/2024	Medicine: Tevimbra	Updated
19/04/2024	Medicine: Cyramza	Updated
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19/04/2024	Event: Network Update webinar on Regulatory Procedure Management for Product Lifecycle Management on IRIS	New
19/04/2024	Medicine: Respivac TRT	New
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19/04/2024	Document: Annex II to the call for proposals - Vendor financial identification form	New
19/04/2024	Document: Annex Va to the call for proposals - Draft grant agreement for an action with one beneficiary	New
19/04/2024	Document: Annex Vb to the call for proposals - Draft grant agreement for an action with multiple beneficiaries	New
19/04/2024	Event: Product Management Service (PMS) Product UI and API training (access & navigation)	New
19/04/2024	Event: EMA multi-stakeholder workshop on psychedelics – Towards an EU regulatory framework	Updated

19/04/2024	Event: Committee for Medicinal Products for Human Use (CHMP): 19-22 February 2024	Updated
19/04/2024	Medicine: Abiraterone Accord	Updated
19/04/2024	Event: SPOR Status Update	New
19/04/2024	Document: Timetable: Safety signal - Assessment of responses to request for supplementary information (RSI)	Updated
19/04/2024	Document: Timetable: Safety signal - Assessment of responses to request for supplementary information (RSI) - ATMP	Updated
19/04/2024	Document: Timetable: Post-authorisation measure (PAM) Paediatric art. 46 submission - ATMP	Updated
19/04/2024	Document: Timetable: Post-authorisation measure (PAM) assessed by CHMP	Updated
19/04/2024	Document: Timetable: Post-authorisation measure (PAM) Paediatric art. 46 submission	Updated
19/04/2024	Document: Timetable: Post-authorisation measure (PAM) assessed by PRAC	Updated
19/04/2024	Document: Timetable: Post-authorisation measures (PAMs) assessed by PRAC - ATMP	Updated
19/04/2024	Document: Timetable: Post-authorisation measure (PAM) assessed by CAT	Updated
19/04/2024	Document: Timetable: Initial (full) marketing authorisation application accelerated assessment timetables	Updated
19/04/2024	Document: Timetable: Initial (full) marketing authorisation application assessment	Updated
19/04/2024	Document: Timetable: Informed consent and multiple application	Updated
19/04/2024	PSUSA: PSUSA/00010752/202308 - periodic safety update report single assessment	New
18/04/2024	Document: Timetable: Initial (full) marketing authorisation application accelerated assessment timetables - Advanced therapy medicinal product (ATMP)	Updated
18/04/2024	Document: Timetable: Extension application	Updated
18/04/2024	Document: Timetable accelerated assessment request for initial marketing authorisation applications	Updated
18/04/2024	Document: Timetable: Extension application - ATMP	Updated
18/04/2024	Medicine: Sitagliptin / Metformin hydrochloride Mylan	Updated
18/04/2024	Document: Timetable: Companion diagnostic initial consultation - ATMP	Updated
18/04/2024	Medicine: Inflectra	Updated
18/04/2024	Medicine: Lenvima	Updated
18/04/2024	Medicine: Cystagon	Updated
18/04/2024	Medicine: Ponvory	Updated
18/04/2024	Medicine: Kisplyx	Updated
18/04/2024	Medicine: Ayvakyt	Updated
18/04/2024	Medicine: Alymsys	Updated
18/04/2024	Medicine: Javlor	Updated
18/04/2024	Document: Timetable: Accelerated assessment request for initial marketing authorisations - ATMP	Updated
18/04/2024	Event: Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) - March 2024	Updated
18/04/2024	Page: European Shortages Monitoring Platform	New
18/04/2024	Medicine: MenQuadfi	Updated
18/04/2024	Medicine: Betmiga	Updated
18/04/2024	Document: Draft template for assessment report for the development of European herbal monographs and European Union list entries - Revision 6	New

18/04/2024	Document: Draft guideline on good agricultural and collection practice (GACP) for starting materials of herbal origin - Revision 1	New
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18/04/2024	Medicine: Kinzalkomb	Updated
18/04/2024	Medicine: Dabigatran Etexilate Leon Farma	Updated
18/04/2024	Document: Timetable: Initial (full) marketing authorisation application accelerated assessment timetables - Advanced therapy medicinal product (ATMP)	Updated
18/04/2024	Event: Clinical Trials Information System (CTIS): Walk-in clinic - May 2024	Updated
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17/04/2024	Document: Timetable: Companion diagnostic initial consultation	Updated
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17/04/2024	Medicine: Ocaliva	Updated
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16/04/2024	Medicine: Zoonotic Influenza Vaccine Seqirus	Updated
16/04/2024	Page: Clinical Trials Information System: training and support	Updated
16/04/2024	Event: Clinical Trials Information System Webinar: Last Year of Transition	Updated
16/04/2024	Document: Final Minutes – HMA-EMA joint Big Data Steering Group teleconference - 26 February 2024	Updated
16/04/2024	Event: Committee for Advanced Therapies (CAT): 17-19 April 2024	Updated

16/04/2024	Event: ACT EU Clinical Trials Analytics Workshop - January 2024	Updated
16/04/2024	Event: Committee for Medicinal Products for Veterinary Use (CVMP): 16-18 April 2024	Updated
16/04/2024	Event: Committee for Orphan Medicinal Products (COMP): 16-18 April 2024	Updated
16/04/2024	Event: Simultaneous National Scientific Advice - information and training webinar	Updated
16/04/2024	Document: Organisation chart: Advisory functions	Updated
16/04/2024	Document: Organisation chart: Stakeholders and Communication	Updated
15/04/2024	Document: Template - Application for transfer of marketing authorisation from transferor to transferee, cover letter	Updated
15/04/2024	PSUSA: PSUSA/00010224/202308 - periodic safety update report single assessment	New
15/04/2024	PSUSA: PSUSA/00010242/202308 - periodic safety update report single assessment	New
15/04/2024	PSUSA: PSUSA/00003151/202308 - periodic safety update report single assessment	New
15/04/2024	PSUSA: PSUSA/00000435/202308 - periodic safety update report single assessment	New
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15/04/2024	PSUSA: PSUSA/00003012/202308 - periodic safety update report single assessment	New
15/04/2024	Medicine: Xevudy	Updated
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15/04/2024	PSUSA: PSUSA/00002834/202308 - periodic safety update report single assessment	New
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15/04/2024	Event: Meeting of the Medicine Shortages Single Point of Contact (SPOC) Working Party	Updated
15/04/2024	Herbal: Pilosellae herba cum radice - herbal medicinal product	Updated
15/04/2024	Herbal: Eucalypti aetheroleum - herbal medicinal product	Updated
15/04/2024	Page: Template for a European Union herbal monograph	Updated
15/04/2024	Document: Template for a European Union herbal monograph	New

NOTICE TO APPLICANTS

No updates since January 30th 2023.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

19.04.2024	Umsetzung des Durchführungsbeschlusses der Europäischen Kommission zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Fentanyl (transmukosale Anwendung) vom 25.03.2024

	Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Fentanyl (transmukosale Anwendung) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
19.04.2024	Informationsbrief zu Aptivus 250 mg Weichkapseln: Fehlender oder schwach lesbarer Kapselaufdruck Wirkstoff: Tipranavir Die Firma Boehringer Ingelheim Pharma GmbH & Co. KG informiert darüber, dass bei der Charge 308715 des Arzneimittels Aptivus 250 mg Weichkapseln (120 Kapseln pro Flasche), Kapseln mit nur schwachem Aufdruck „TPV 250“ oder auch ganz ohne diesen Aufdruck auftreten können.
16.04.2024	Informationen zu Rote-Hand-Briefen und Informationsbriefen Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht neue Hinweise zu anstehenden Rote-Hand-Briefen und Informationsbriefen.
15.04.2024	Pseudoephedrin: Risiko für posteriores reversibles Enzephalopathiesyndrom und reversibles zerebrales Vasokonstriktionssyndrom Wirkstoff: Pseudoephedrin Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) setzt mit Bescheid vom 10. April 2024 den Durchführungsbeschluss der EU-Kommission vom 27.03.2024 national um.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

17.04.2024	Wissenswertes zu DiGA Ergänzung Schreiben der DiGA in die ePA/Implementierung der GesundheitsID

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since February 27th 2024.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.