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2 May

NEW - Report from the meeting held on 23-25 April 2024

UPDATE - Request for MRP/RUP / Update assessment report

NEW - Art 45 PAR on Alphanate (human von Willebrand factor, human coagulation factor VIII)

NEW - Art 46 PAR on Riamet (artemether / lumefantrine)

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

30 April

NEW - 19-20 March 2024 CMDh minutes

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

Date	Content	Status
03/05/2024	Medicine: MenQuadfi	Updated
03/05/2024	PIP: EMEA-002754-PIP01-19 - paediatric investigation plan	Updated
03/05/2024	PIP: EMEA-002693-PIP01-19 - paediatric investigation plan	Updated
03/05/2024	PIP: EMEA-003157-PIP01-21 - paediatric investigation plan	Updated
03/05/2024	PIP: EMEA-001666-PIP01-14-M01 - paediatric investigation plan	Updated
03/05/2024	Document: Agenda - Joint HMA/EMA Big Data Steering Group Workshop on RWE methods	Updated
03/05/2024	Document: Agenda - Twelfth meeting of the industry stakeholder platform on the operation of the centralised procedure for human medicines	Updated
03/05/2024	Event: Third European Medicines Agency and Affordable Medicines Europe bilateral meeting	Updated

03/05/2024	PSUSA: PSUSA/00002589/202307 - periodic safety update report single assessment	New
03/05/2024	Medicine: Briumvi	Updated
03/05/2024	Document: Sponsors' guide: Transition of trials from EudraCT to CTIS - CTIS Training Programme - Module 23	Updated
03/05/2024	Medicine: Tevimbra	Updated
03/05/2024	Event: Q&A Clinic for IRIS Network users for transitioned regulatory procedures	New
03/05/2024	Medicine: Sivextro	Updated
03/05/2024	Medicine: Talzenna	Updated
03/05/2024	Page: ICH M10 on bioanalytical method validation - Scientific guideline	Updated
03/05/2024	Page: Plasma master file certificates	Updated
03/05/2024	Page: Big data	Updated
03/05/2024	Page: Real-world evidence	New
03/05/2024	Page: Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence - Scientific guideline	New
03/05/2024	Document: Reflection paper on use of real-world data in non-interventional studies to generate real-world evidence	New
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02/05/2024	Event: CVMP Interested Parties' meeting	New
02/05/2024	Document: Scientific recommendations on classification of advanced therapy medicinal products	Updated
02/05/2024	Document: Appendix 1: Acceptable intakes established for N-nitrosamines	Updated
02/05/2024	Page: Information Management	Updated
02/05/2024	Herbal: Malvae sylvestris flos - herbal medicinal product	Updated
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02/05/2024	Medicine: Stayveer	Updated
02/05/2024	Document: Addendum to EMA/CHMP/CVMP/QWP/17760/2009 Rev 3: Defining the Scope of an NIRS Procedure	New
02/05/2024	Event: EU NTC ten year anniversary event	New
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02/05/2024	Herbal: Malvae folium - herbal medicinal product	Updated
02/05/2024	Medicine: Vafseo	Updated
02/05/2024	Medicine: Incellipan	Updated
02/05/2024	Page: Handling competing interests	Updated
02/05/2024	Medicine: Celldemic	Updated
02/05/2024	Medicine: Zynyz	Updated
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02/05/2024	Medicine: Mirapexin	Updated

02/05/2024	Document: Concept paper on revision of the Guideline on Risk Assessment of Medicinal Products on Human Reproduction and Lactation: from Data to Labelling	New
02/05/2024	Document: List of eligible industry stakeholder organisations	Updated
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29/04/2024	Medicine: Nuvaxovid	Updated
29/04/2024	Document: Minutes of the CAT meeting 13-15 March 2024	New
29/04/2024	Document: Creon (pancrelipase/pancreas powder) supply shortage	New
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29/04/2024	Document: Final Minutes – HMA-EMA joint Big Data Steering Group teleconference - 22 March 2024	New
29/04/2024	Referral: Ocaliva - referral	Updated
29/04/2024	Medicine: Sunlenca	Updated
29/04/2024	Medicine: Hemlibra	Updated
29/04/2024	Medicine: Carvykti	Updated
29/04/2024	Medicine: Xgeva	Updated
29/04/2024	News: EMA closed 1 May	New
29/04/2024	Event: Information and Q&A session on updated CAPs in web-based eAF	Updated

NOTICE TO APPLICANTS

No updates since January 30th 2023.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

02.05.2024	Hinweis zur Korrektur der am 13.03.2024 publizierten Textänderung im Rahmen eines Outcomes of imposed non-interventional PASS-Verfahrens zu Chlormadinonacetat (CMA), Ethinylestradiol (EE) Wirkstoff: Chlormadinonacetat, EthinylestradiolIm Verfahren EMEA/H/N/PSR/J/0042 Chlormadinonacetat (CMA), Ethinylestradiol (EE) gibt es im aktuell publizierten Dokument einen Fehler. Die CMDh wird die korrigierte Fassung zeitnah publizieren.
02.05.2024	Rote-Hand-Brief zu oralen Retinoiden (Acitretin, Alitretinoin und Isotretinoin): Erinnerung an die bestehenden Einschränkungen zur Verhinderung der Exposition während der Schwangerschaft Wirkstoff: Acitretin, Alitretinoin, Isotretinoin Die Zulassungsinhaber von acitretin-, alitretinoin- und isotretinoinhaltigen Arzneimitteln erinnern an das Schwangerschaftsverhütungsprogramm für orale Retinoide.
30.04.2024	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

02.05.2024	Wissenswertes zu DiGA Ab sofort steht im DiGA-Antragsportal ein FHIR-Validator zur Überprüfung der Anforderungen an die Interoperabilität gemäß DiGAV zur Verfügung.
02.05.2024	Kurzanleitung zur Nutzung des FHIR-Validators im DiGA-Antragsportal Kurzanleitung zur Nutzung des FHIR-Validators im DiGA-Antragsportal im Rahmen der Anforderungen an die Interoperabilität gemäß DiGAV
30.04.2024	Antrag auf Klassifizierung und/oder Abgrenzung Klassifizierung und/oder Abgrenzung
30.04.2024	DiGA und DiPA Datensicherheitskriterien Hinweis: Hersteller von digitalen Gesundheits- und Pflegeanwendungen müssen die Erfüllung der Anforderungen an die Datensicherheit anhand der Technischen Richtlinien gemäß § 139e Absatz 10 SGB V und § 78a Absatz 7 SGB XI spätestens ab dem 1. Januar 2025 unter Vorlage eines entsprechenden Zertifikats nachweisen.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since February 27th 2024.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.