TABLE OF CONTENTS

HEADS OF AGENCIES – CMDh

27 March

NEW - Report from the meeting held on 19-20 March 2024

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

01/04/2024	Medicine: YURVAC RHD	New
28/03/2024	Page: Pre-authorisation guidance under the Veterinary Medicinal Products Regulation (Regulation (EU) 2019/6)	Updated
27/03/2024	Event: Quarterly System Demo Q1 2024	Updated
27/03/2024	Medicine: Cotellic	Updated
27/03/2024	Medicine: Kisqali	Updated
27/03/2024	Medicine: Fintepla	Updated
27/03/2024	Page: Data protection and privacy	Updated
27/03/2024	Page: Pre-authorisation guidance	Updated
27/03/2024	Page: Fees payable to the European Medicines Agency	Updated
27/03/2024	News: Regulatory information – adjusted fees for applications to EMA from 1 April 2024	New
27/03/2024	Document: Checklist for the submission of Type IA and Type IB (without linguistic review) product information annexes and Annex A (if applicable) - human	Updated
27/03/2024	Page: Extensions of marketing authorisations: questions and answers	Updated
27/03/2024	Page: Type-II variations: questions and answers	Updated
27/03/2024	Medicine: Emgality	Updated
27/03/2024	Document: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure: document with tracked changes	Updated
27/03/2024	Medicine: Arixtra	Updated
27/03/2024	Document: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure	Updated

27/03/2024	Document: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure	Updated
27/03/2024	Document: European Medicines Agency post-authorisation procedural advice for users of the centralised procedure: document with track changes	Updated
27/03/2024	Medicine: Gardasil	Updated
27/03/2024	Page: Post-authorisation safety studies (PASS)	Updated
27/03/2024	Page: Type-IA variations: questions and answers	Updated
27/03/2024	Medicine: Zelboraf	Updated
27/03/2024	Document: Union procedure on the preparation, conduct and reporting of EU pharmacovigilance inspections	Updated
26/03/2024	Medicine: Jcovden (previously COVID-19 Vaccine Janssen)	Updated
26/03/2024	Document: HMPC: overview of assessment work - priority list	Updated
26/03/2024	PSUSA: PSUSA/00001057/202303 - periodic safety update report single assessment	New
26/03/2024	Medicine: Zolgensma	Updated
26/03/2024	Document: List of European Union reference dates and frequency of submission of periodic safety update reports (PSURs)	Updated
26/03/2024	Medicine: Pravafenix	Updated
26/03/2024	Medicine: Karvezide	Updated
26/03/2024	Medicine: CoAprovel	Updated
26/03/2024	Page: List of medicines under additional monitoring	Updated
26/03/2024	Document: List of medicinal products under additional monitoring	Updated
26/03/2024	Document: List of medicinal products under additional monitoring	Updated
26/03/2024	Event: Committee for Herbal Medicinal Products (HMPC): 29-31 January 2024	Updated
26/03/2024	Page: Handling competing interests	Updated
26/03/2024	Event: Management Board meeting: 21 March 2024	Updated
26/03/2024	Medicine: Ximluci	Updated
26/03/2024	Medicine: Clopidogrel ratiopharm	Updated
26/03/2024	Medicine: Rystiggo	Updated
26/03/2024	Medicine: Upstaza	Updated
26/03/2024	Medicine: Spikevax (previously COVID-19 Vaccine Moderna)	Updated
26/03/2024	Medicine: Livtencity	Updated
26/03/2024	News: EMA business hours over Easter holiday period	New
26/03/2024	Medicine: Cuprior	Updated
26/03/2024	Document: Appendix 3 : Enhanced Ames Test Conditions for N-nitrosamines	Updated
26/03/2024	News: EU recommendations for 2024/2025 seasonal flu vaccine composition	New
26/03/2024	Medicine: Myalepta	Updated
26/03/2024	Page: Website outages and upgrades	Updated
26/03/2024	Page: Medical literature monitoring	Updated
25/03/2024	Document: Functionalities in support of the medical literature monitoring service User manual: EudraVigilance ICSR Downloads and tracking spreadsheets	Updated
25/03/2024	Document: Monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency - MEDLINE	Updated
25/03/2024	Document: Monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency - EMBASE	Updated
25/03/2024	Document: Monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency - Description of the Journal/Reference databases used	Updated

25/03/2024	PSUSA: PSUSA/00010378/202305 - periodic safety update report single assessment	New
25/03/2024	PSUSA: PSUSA/00001362/202307 - periodic safety update report single assessment	New
25/03/2024	PSUSA: PSUSA/00000905/202307 - periodic safety update report single assessment	New
25/03/2024	PSUSA: PSUSA/00001826/202305 - periodic safety update report single assessment	New
25/03/2024	PSUSA: PSUSA/00010441/202304 - periodic safety update report single assessment	New
25/03/2024	Document: FertiPro N.V. HSA-containing ART media - Procedural steps and scientific information after initial consultation	Updated
25/03/2024	Page: Guideline on quality, non-clinical and clinical requirements for investigational advanced therapy medicinal products in clinical trials - Scientific guideline	Updated
25/03/2024	Medicine: Tecentriq	Updated
25/03/2024	Document: List of centrally authorised products requiring a notification of a change for update of annexes	Updated
25/03/2024	Medicine: Tysabri	Updated
25/03/2024	Medicine: Vimpat	Updated
25/03/2024	Medicine: Lacosamide UCB	Updated
25/03/2024	Medicine: Pluvicto	Updated

NOTICE TO APPLICANTS

No updates since January 30th 2023.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

28.03.2024	Informationen zu Rote-Hand-Briefen und Informationsbriefen Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) veröffentlicht neue Hinweise zu anstehenden Rote-Hand-Briefen und Informationsbriefen.
26.03.2024	Informationen zu Einreichung und Genehmigung von Schulungsmaterial Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

02.04.2024	Antrag auf Klassifizierung und/oder Abgrenzung Klassifizierung und/oder Abgrenzung
27.03.2024	Webinarreihe DiGA Ankündigung Webinar "Änderungen im Bereich der DiGA aufgrund des Digital-Gesetzes" am 14.05.2024
25.03.2024	Datenbankinformation Medizinprodukte-Anzeigen Datenbankinformation Medizinprodukte-Anzeigen
25.03.2024	Datenbankinformation In-vitro-Diagnostika-Anzeigen Datenbankinformation In-vitro-Diagnostika-Anzeigen

25.03.2024	Datenbankinformation Medizinprodukte-Adressen Datenbankinformation Medizinprodukte-Adressen
14.03.2024	Häufig gestellte Fragen (FAQ) Änderungen durch das DigiG FAQ Änderungen durch das DigiG

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since February 27th 2024.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.

Trotz regelmäßiger Aktualisierung und sorgfältiger Überwachung der Veröffentlichungen können wir keine Haftung oder Garantie für die Aktualität, Richtigkeit und Vollständigkeit der hier bereitgestellten Informationen übernehmen.
Dieser Newsletter enthält Links zu anderen Websites. Trotz sorgfältiger inhaltlicher Kontrolle übernehmen wir keine Haftung für die Inhalte externer Links. Für den Inhalt der verlinkten Seiten sind ausschließlich deren Betreiber verantwortlich.

Despite regular updating and careful monitoring of the publications, we cannot take any responsibility or guarantee for the topicality, correctness and completeness of the information provided here.
This Newsletter contains links to other websites. Despite careful control of the contents we would like to point out that we are not liable for the contents of external web links. The editors of the respective websites are fully responsible for their contents.