

## TABLE OF CONTENTS

|                                                       |   |
|-------------------------------------------------------|---|
| HEADS OF AGENCIES – CMDH .....                        | 1 |
| HEADS OF AGENCIES – PAEDIATRIC REGULATION .....       | 1 |
| EUROPEAN MEDICINES AGENCY (EMA) .....                 | 1 |
| NOTICE TO APPLICANTS .....                            | 2 |
| BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY) ..... | 3 |
| BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY) .....  | 3 |
| PEI - VIGILANZ (SPECIFIC FOR GERMANY) .....           | 3 |
| PHARMEUROPA TEXTS FOR COMMENT .....                   | 3 |

## HEADS OF AGENCIES – CMDh

### 11 August

[Update: List of safety concerns per approved Risk Management Plan \(RMP\) of active substances per product](#)

## HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

## EUROPEAN MEDICINES AGENCY (EMA)

| Date       | Content                                                                                        | Status  |
|------------|------------------------------------------------------------------------------------------------|---------|
| 14/08/2025 | Medicine: <a href="#">Fluenz Tetra</a>                                                         | Updated |
| 14/08/2025 | Medicine: <a href="#">Sixmo</a>                                                                | Updated |
| 14/08/2025 | Medicine: <a href="#">Keytruda</a>                                                             | Updated |
| 14/08/2025 | Medicine: <a href="#">Spikevax (previously COVID-19 Vaccine Moderna)</a>                       | Updated |
| 14/08/2025 | Medicine: <a href="#">Nintedanib Accord</a>                                                    | Updated |
| 14/08/2025 | Medicine: <a href="#">Imjudo</a>                                                               | Updated |
| 14/08/2025 | Medicine: <a href="#">Comirnaty</a>                                                            | Updated |
| 14/08/2025 | Document: <a href="#">Annex to 22-25 April 2025 CHMP Minutes</a>                               | New     |
| 14/08/2025 | Document: <a href="#">Minutes of the CHMP meeting 22-25 April 2025</a>                         | New     |
| 14/08/2025 | Document: <a href="#">CHMP PROM minutes for the meeting on 17 February 2025</a>                | New     |
| 14/08/2025 | Event: <a href="#">Quarterly System Demo – Q3 2025</a>                                         | New     |
| 14/08/2025 | Medicine: <a href="#">Syfovre</a>                                                              | Updated |
| 14/08/2025 | Page: <a href="#">Everolimus product-specific bioequivalence guidance</a>                      | Updated |
| 14/08/2025 | Page: <a href="#">Deferasirox product-specific bioequivalence guidance</a>                     | Updated |
| 14/08/2025 | Event: <a href="#">Eighth EMA-Medicines for Europe bilateral meeting</a>                       | New     |
| 13/08/2025 | Medicine: <a href="#">Jivi</a>                                                                 | Updated |
| 13/08/2025 | PSUSA: <a href="#">PSUSA/00001789/202411 - periodic safety update report single assessment</a> | New     |
| 13/08/2025 | Medicine: <a href="#">Amvuttra</a>                                                             | Updated |
| 13/08/2025 | Medicine: <a href="#">Apixaban Accord</a>                                                      | Updated |
| 13/08/2025 | Medicine: <a href="#">Breyanzi</a>                                                             | Updated |
| 13/08/2025 | Medicine: <a href="#">Veklury</a>                                                              | Updated |
| 13/08/2025 | Medicine: <a href="#">Kovaltry</a>                                                             | Updated |

| Date       | Content                                                                                                                                                                                                                                          | Status  |
|------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------|
| 13/08/2025 | Medicine: <a href="#">Exparel liposomal</a>                                                                                                                                                                                                      | Updated |
| 13/08/2025 | Medicine: <a href="#">Stribild</a>                                                                                                                                                                                                               | Updated |
| 13/08/2025 | Medicine: <a href="#">Lokelma</a>                                                                                                                                                                                                                | Updated |
| 13/08/2025 | Medicine: <a href="#">Wyost</a>                                                                                                                                                                                                                  | Updated |
| 13/08/2025 | Medicine: <a href="#">Instanyl</a>                                                                                                                                                                                                               | Updated |
| 13/08/2025 | Medicine: <a href="#">Ferriprox</a>                                                                                                                                                                                                              | Updated |
| 13/08/2025 | Medicine: <a href="#">Humira</a>                                                                                                                                                                                                                 | Updated |
| 13/08/2025 | News: <a href="#">EMA closed on 15 August for Assumption Day</a>                                                                                                                                                                                 | New     |
| 13/08/2025 | Medicine: <a href="#">Chenodeoxycholic acid Leadiant (previously Chenodeoxycholic acid sigma-tau)</a>                                                                                                                                            | Updated |
| 13/08/2025 | Medicine: <a href="#">Enbrel</a>                                                                                                                                                                                                                 | Updated |
| 12/08/2025 | Document: <a href="#">List of changes to combined Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) list of clinical terms for reporting suspected adverse events in animal and humans to veterinary medicinal products for 2025</a> | Updated |
| 12/08/2025 | Medicine: <a href="#">Dazublys</a>                                                                                                                                                                                                               | New     |
| 12/08/2025 | Page: <a href="#">Good agricultural and collection practice for starting materials of herbal origin - Scientific guideline</a>                                                                                                                   | Updated |
| 12/08/2025 | Document: <a href="#">Combined VeDDRA list of clinical terms for reporting suspected adverse events in animals and humans to veterinary medicinal products</a>                                                                                   | Updated |
| 12/08/2025 | Medicine: <a href="#">Nurzigma</a>                                                                                                                                                                                                               | Updated |
| 12/08/2025 | Medicine: <a href="#">Dyrupeg</a>                                                                                                                                                                                                                | Updated |
| 12/08/2025 | PSUSA: <a href="#">PSUSA/00002052/202410 - periodic safety update report single assessment</a>                                                                                                                                                   | New     |
| 12/08/2025 | Medicine: <a href="#">Targretin</a>                                                                                                                                                                                                              | Updated |
| 12/08/2025 | Medicine: <a href="#">Jelrix</a>                                                                                                                                                                                                                 | Updated |
| 12/08/2025 | Medicine: <a href="#">Hizentra</a>                                                                                                                                                                                                               | Updated |
| 12/08/2025 | Medicine: <a href="#">Rotarix</a>                                                                                                                                                                                                                | Updated |
| 12/08/2025 | Page: <a href="#">Pre-authorisation guidance</a>                                                                                                                                                                                                 | Updated |
| 12/08/2025 | Medicine: <a href="#">Naveruclif</a>                                                                                                                                                                                                             | Updated |
| 12/08/2025 | Medicine: <a href="#">Sogroya</a>                                                                                                                                                                                                                | Updated |
| 11/08/2025 | Medicine: <a href="#">Zometa</a>                                                                                                                                                                                                                 | Updated |
| 11/08/2025 | Document: <a href="#">European Medicines Agency Write PMS API implementation Guide (zip)</a>                                                                                                                                                     | Updated |
| 11/08/2025 | Document: <a href="#">European Medicines Agency Write PMS API implementation Guide</a>                                                                                                                                                           | Updated |
| 11/08/2025 | Medicine: <a href="#">Brukinsa</a>                                                                                                                                                                                                               | Updated |
| 11/08/2025 | Medicine: <a href="#">Wezenla</a>                                                                                                                                                                                                                | Updated |

## NOTICE TO APPLICANTS

No updates since July 07<sup>th</sup>, 2025.

## BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

| Date       | Title                                                                                                                                                                                                                                                                                                                                                                                           |
|------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 15.08.2025 | <b>Informationen zu Einreichung und Genehmigung von Schulungsmaterial</b><br>Aktualisierung der Hilfestellungsdokumente zur Einreichung und Genehmigung von behördlich genehmigten Schulungsmaterialien                                                                                                                                                                                         |
| 13.08.2025 | <b>Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/0000248448 vom 19.06.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Benzydamin</b><br>Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Benzydamin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.         |
| 11.08.2025 | <b>Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/0000248487 vom 19.06.2025 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Methylphenidat</b><br>Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Methylphenidat 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 August 05<sup>th</sup>, 2025.

## PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since May 22<sup>nd</sup>, 2025.

## PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedeuropa updates will be presented quarterly.

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