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22/01/2024	Medicine: Sugammadex Mylan	Updated
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NOTICE TO APPLICANTS

No updates since January 30th 2023.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

26.01.2024	Valproat: Potenzielles Risiko für neurologische Entwicklungsstörungen bei Kindern von Vätern, die valproathaltige Arzneimittel einnehmen Wirkstoff: Valproat CMDh-Entscheidung: PRAC empfiehlt Vorsichtsmaßnahmen aufgrund des potenziellen Risikos von neurologischen Entwicklungsstörungen bei Kindern, die von Vätern gezeugt wurden, die valproathaltige Arzneimittel eingenommen haben.
26.01.2024	Pseudoephedrin: Risiko für posteriores reversibles Enzephalopathiesyndrom und reversibles zerebrales Vasokonstriktionssyndrom Wirkstoff: Pseudoephedrin Der Ausschuss für Humanarzneimittel (CHMP) der Europäischen Arzneimittel-Agentur (EMA) bestätigte die vom Ausschuss für Risikobewertung im Bereich der Pharmakovigilanz (PRAC) empfohlenen Maßnahmen zur Minimierung der Risiken des posterioren reversiblen Enzephalopathiesyndroms (PRES) und des reversiblen zerebralen Vasokonstriktionssyndroms (RCVS) bei pseudoephedrinhaltigen Arzneimitteln
25.01.2024	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/305358/2023 vom 20.07.2023 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Apomorphin Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Apomorphin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
25.01.2024	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/305324/2023 vom 20.07.2023 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Flurbiprofen Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Flurbiprofen infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
25.01.2024	Umsetzung des Durchführungsbeschlusses der Europäischen Kommission zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Pramipexol vom 05.01.2024 Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Pramipexol infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
23.01.2024	88. Sitzung (23. Januar 2024 per Videokonferenz) – Kurzprotokoll Sachverständigen-Ausschuss für Verschreibungspflicht nach § 53 Absatz 2 AMG

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

Information on Pharmeuropa updates will be presented quarterly.