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HEADS OF AGENCIES – PAEDIATRIC REGULATION

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09/08/2019	Scientific guideline: Fingolimod capsules 0.25 and 0.5 mg product-specific bioequivalence guidance (updated)
09/08/2019	Newsletter: What's new in pharmacovigilance - QPPV Update - Issue 1 - 2019
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09/08/2019	Orphan designation: (S)-5-(1-(6-chloro-2-oxo-1,2-dihydroquinolin-3-yl)ethylamino-1-methyl-6-oxo-1,6-dihydropyridine-2-carbonitrile for the: Treatment of acute myeloid leukaemia, 29/05/2019, Positive
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08/08/2019	Periodic safety update single assessment: Dextromethorphan: Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - PSUSA/00001009/201811
08/08/2019	Other: Coordinating group of the European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA) (updated)
08/08/2019	Periodic safety update single assessment: Dextromethorphan: List of nationally authorised medicinal products - PSUSA/00001009/201811
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08/08/2019	Committee for Medicinal Products for Human Use (CHMP): 24-27 June 2019 , European Medicines Agency, Amsterdam, the Netherlands, from 24/06/2019 to 27/06/2019 (updated)
08/08/2019	Committee for Medicinal Products for Human Use (CHMP): 22-25 July 2019 , European Medicines Agency, Amsterdam, the Netherlands, from 22/07/2019 to 25/07/2019 (updated)
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05/08/2019	Quality of medicines questions and answers: Part 1 (updated)
05/08/2019	Human medicines European public assessment report (EPAR): Intelence, Etravirine, HIV Infections, 28/08/2008, 24, Authorised (updated)
05/08/2019	Human medicines European public assessment report (EPAR): Cometriq, cabozantinib, Thyroid Neoplasms, 21/03/2014, 14, Authorised (updated)
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05/08/2019	Template or form: Template to report an allegation concerning an impropriety in an area of EMA's responsibility (authorisation, supervision and maintenance of human and veterinary medicinal products) (updated)

NOTICE TO APPLICANTS

No updates since December 15th 2017.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

08.08.2019	81. Sitzung (27. Juni 2019) – Ergebnisprotokoll Sachverständigen-Ausschuss für Verschreibungspflicht nach § 53 Absatz 2 AMG

06.08.2019	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/280716/2019 vom 29.05.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Permethrin (Anwendungsgebiet: Kopflausbefall) Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Permethrin (Anwendungsgebiet: Kopflausbefall) 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 July 31th 2019.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since July 2nd 2019.

PHARMEUROPA TEXTS FOR COMMENT

No updates since August 5th 2019.