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No updates since May 15th 2019

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NOTICE TO APPLICANTS

No updates since December 15th 2017.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

24.05.2019	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/843780/2018 vom 12.12.2018 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Paracetamol (i.v.-Formulierung) Das BfArM veröffentlicht den Umsetzungsbescheid für den Paracetamol (i.v.-Formulierung) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
23.05.2019	Rote-Hand-Brief zu Eliquis®, Pradaxa®, Lixiana®/Roteas® und Xarelto®: Die Anwendung bei Patienten mit Antiphospholipid-Syndrom wird nicht empfohlen Wirkstoff Apixaban, Dabigatranetexilat, Edoxaban, Rivaroxaban Die Zulassungsinhaber informieren darüber, dass die Anwendung direkter oraler Antikoagulantien (DOAK) bei Patienten mit Antiphospholipid-Syndrom nicht empfohlen wird.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since April 4th 2019.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since May 7th 2019.

PHARMEUROPA TEXTS FOR COMMENT

No updates since May 10th 2019.