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NOTICE TO APPLICANTS

No updates since December 15th 2017.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

03.06.2019	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/184248/2019 vom 27.03.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Adapalen Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Adapalen infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

03.06.2019	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/183397/2019 vom 27.03.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Alprostadil (mit der Indikation Offenhalten des Ductus arteriosus) Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Alprostadil (mit der Indikation Offenhalten des Ductus arteriosus) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
31.05.2019	Robaxisal® (Methocarbamol/Paracetamol): Wissenschaftliche Neubewertung Wirkstoff Methocarbamol, Paracetamol Der Ausschuss für Humanarzneimittel (CHMP) der Europäischen Arzneimittelagentur EMA hat auf seiner Mai-Sitzung 2019 ein Verfahren nach Artikel 31 der Richtlinie 2001/83/EG eingeleitet, welches vom BfArM initiiert worden war.
28.05.2019	Xeljanz® (Tofacitinib): Einschränkungen bei der Anwendung wegen des Risikos von Blutgerinnseln in der Lunge Wirkstoff Tofacitinib Der Ausschuss für Risikobewertung im Bereich der Pharmakovigilanz (PRAC) hat empfohlen, dass Ärzte die zweimal täglich zu verabreichende Dosis von 10 mg Xeljanz® (Tofacitinib) nicht bei Patienten verschreiben dürfen, die einem hohen Risiko für Blutgerinnsel in der Lunge ausgesetzt sind.
28.05.2019	Rote-Hand-Brief zu Xeljanz® (Tofacitinib): Einschränkung der Anwendung von zweimal täglich 10 mg bei Patienten mit erhöhtem Risiko für Lungenembolien Wirkstoff Tofacitinib Die Firma Pfizer informiert darüber, dass die Europäische Arzneimittel-Agentur (EMA) den Nutzen und die Risiken von Xeljanz® (Tofacitinib) in allen zugelassenen Indikationen überprüft.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since April 4th 2019.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

28.05.2019	Rote-Hand-Brief: Haemocomplettan und Riastap	zum Beitrag

PHARMEUROPA TEXTS FOR COMMENT

No updates since May 10th 2019.