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02 September 2019

UPDATE - List of safety concerns per approved Risk Management Plan (RMP) of active substances per product

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04/09/2019	Human medicines European public assessment report (EPAR): Elmiron, pentosan polysulfate sodium, Cystitis, Interstitial, 02/06/2017, 6, Authorised (updated)
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02/09/2019	Periodic safety update single assessment: Tapentadol: CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - PSUSA/00002849/201811
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02/09/2019	Human medicines European public assessment report (EPAR): Pixuvri, pixantrone dimaleate, Lymphoma, Non-Hodgkin, 10/05/2012, 20, Authorised (updated)

NOTICE TO APPLICANTS

No updates since December 15th 2017.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

09.09.2019	Rote-Hand-Brief zu Retinoiden: Teratogenität und neuropsychiatrische Erkrankungen Wirkstoff Acitretin, Adapalen, Alitretinoin, Bexaroten, lsotretinoin, Tazaroten, Tretinoin Die Zulassungsinhaber von retinoidhaltigen Arzneimitteln informieren über Aktualisierungen zu Teratogenität und neuropsychiatrischen Erkrankungen.
06.09.2019	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/366974/2017 vom 21.06.2017 betreffend die Zulassungen für Humanarzneimittel mit der Wirkstoffkombination Carbidopa/Levodopa (mit Ausnahme der zentral zugelassenen Produkte) Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffkombination Carbidopa/Levodopa (mit Ausnahme der zentral zugelassenen Produkte) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
06.09.2019	Umsetzung des Durchführungsbeschlusses der Europäischen Kommission zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit der Wirkstoffkombination Carbidopa/Entacapon/Levodopa vom 31.07.2019 Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffkombination Carbidopa/Entacapon/Levodopa infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
06.09.2019	Picato® (Ingenolmebutat): Überprüfung des Risikos für die Entstehung von Hautkrebs Wirkstoff Ingenolmebutat Die Europäische Arzneimittel-Agentur (EMA) überprüft Daten zur Auslösung von Hautkrebs bei Patienten unter der Anwendung von Picato®.
05.09.2019	Retinoide: Aktualisierte Maßnahmen zur Schwangerschaftsverhütung sowie Warnhinweise zu neuropsychiatrischen Erkrankungen bei oraler Anwendung Wirkstoff Acitretin, Adapalen, Alitretinoin, Bexaroten, Isotretinoin, Tazaroten, Tretinoin Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) hat mit Bezug auf den Bescheid vom 16. Juli 2018 und die Aktualisierungen der Verordnung über die Verschreibungspflicht von Arzneimitteln für die oral anzuwendenden Arzneimittel einen ergänzenden Bescheid erlassen.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since September 2nd 2019.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since September 2nd 2019.

PHARMEUROPA TEXTS FOR COMMENT

Text	Monograph number	Group	Issue	Deadline
Ticagrelor tablets	3097	P4	31.4	31.12.2019
Titanium dioxide	150	9	31.4	31.12.2019