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17/05/2019	Human medicines European public assessment report (EPAR): Inflectra, infliximab, Arthritis, Psoriatic, Spondylitis, Ankylosing, Colitis, Ulcerative, Psoriasis, Crohn Disease, Arthritis, Rheumatoid, 09/09/2013, 21, Authorised (updated)
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15/05/2019	Veterinary medicines European public assessment report (EPAR): MiPet Easecto, sarolaner, 31/01/2018, 1, Authorised (updated)
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13/05/2019	Regulatory and procedural guideline: Rules of procedure for the Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP) (updated)
13/05/2019	Other: Mandate, objectives and composition of the Patients and Consumers Working Party (PCWP) (updated)
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NOTICE TO APPLICANTS

No updates since December 15th 2017.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

17.05.2019	Rote-Hand-Brief zu Tyverb® (Lapatinib): Information zu wichtigen Änderungen in der Fachinformation

	Wirkstoff Lapatinib Die Firma Novartis informiert über Änderungen des Anwendungsgebiets.
17.05.2019	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/129027/2019 vom 27.02.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Manidipin Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Manidipin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
17.05.2019	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/124026/2019 vom 27.02.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Daunorubicin Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Daunorubicin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
17.05.2019	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/25855/2019 vom 30.01.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Ebastin Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Ebastin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
17.05.2019	Umsetzung des Durchführungsbeschlusses der Europäischen Kommission zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Aripiprazol vom 29.04.2019 Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Aripiprazol infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
17.05.2019	Fenspiridhaltige Arzneimittel: Potenzielles Risiko von Herzrhythmusstörungen Wirkstoff Fenspirid Der Ausschuss für Risikobewertung im Bereich der Pharmakovigilanz (PRAC) hat zu Fenspirid auf seiner Mai-Sitzung 2019 eine Empfehlung zum Widerruf der Zulassungen abgegeben.
17.05.2019	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.
15.05.2019	Rote-Hand-Brief zu biotinhaltigen Arzneimitteln: Risiko falscher Ergebnisse von Laboruntersuchungen durch Biotininterferenzen Wirkstoff Biotin Die Einnahme biotinhaltiger Produkte ist mit dem Risiko falsch erhöhter oder falsch erniedrigter Laborwerte verbunden.

13.05.2019	Rote-Hand-Brief zu Candesartan-comp PUREN Tabletten (Candesartan und Hydrochlorothiazid): Fehlerhafte Angabe der Stärke auf der Faltschachtel weiterer Chargen Wirkstoff Candesartan und Hydrochlorothiazid Candesartan-comp PUREN Tabletten (Candesartan und Hydrochlorothiazid): Fehlerhafte Angabe der Stärke auf der Faltschachtel weiterer Chargen

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since 4th April 2019.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since 7th May 2019.

PHARMEUROPA TEXTS FOR COMMENT

No updates since 10th May 2019.