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UPDATE - Best Practice Guide for the Decentralised and Mutual Recognition Procedures;

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EUROPEAN MEDICINES AGENCY (EMA)

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NOTICE TO APPLICANTS

20.03.2020	Targeted stakeholders' consultation - Annex 21: Importation of medicinal products, of the Eudralex volume 4 (20 March 2020 - 20 June 2020)

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

23.03.2020	Rote-Hand-Brief zu Ulipristalacetat 5 mg: Keine Anwendung zur Behandlung von Gebärmuttermyomen während des laufenden Bewertungsverfahrens zum Risiko für Leberschädigungen Wirkstoff Ulipristalacetat Die Firma Gedeon Richter Pharma GmbH informiert in Abstimmung mit der Europäischen Arzneimittelagentur (EMA) und dem Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), dass Ulipristalacetat 5 mg während des laufenden Risikobewertungsverfahrens vorübergehend vom Markt genommen wird und die Therapie bei neuen Patientinnen nicht eingeleitet werden soll.
20.03.2020	Rote-Hand-Brief zu XELJANZ® (Tofacitinib): Erhöhtes Risiko für venöse thromboembolische Ereignisse und erhöhtes Risiko für schwerwiegende und tödlich verlaufende Infektionen Wirkstoff Tofacitinib Die Firma Pfizer informiert in Abstimmung mit der Europäischen Arzneimittelagentur (EMA) und dem Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) darüber, dass bei Patienten unter Behandlung mit Tofacitinib ein dosisabhängiges erhöhtes Risiko für schwerwiegende venöse thromboembolische Ereignisse beobachtet wurde.
17.03.2020	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/497436/2019 vom 19.09.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Botulinum-Toxin Typ A zur Injektion (Ph.Eur.)

	Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Botulinum-Toxin Typ A zur Injektion (Ph.Eur.) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
16.03.2020	Fluorouracil, Capecitabin, Tegafur und Flucytosin: Empfehlung zur Testung und Behandlung Wirkstoff Fluorouracil; Capecitabin; Tegafur; Flucytosin Der Ausschuss für Risikobewertung im Bereich der Pharmakovigilanz (PRAC) hat für Fluorouracil, Capecitabin, Tegafur und Flucytosin Empfehlungen zur Testung und Behandlung abgegeben.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

20.03.2020	Formulare - Medizinprodukte Neues Meldeformular für Hersteller und Bevollmächtigte: Die europäischen Behörden haben sich zusammen mit den Herstellerverbänden auf ein neues Meldeformular geeinigt. Das BfArM hat die Version 2.27 am 31.12.2019 offiziell zurückgezogen. Damit ist per 1.1.2020 ausschließlich die Version 7.2 für Vorkommnismeldungen zu verwenden. Auf § 7 Absatz 2 der Medizinprodukte-Sicherheitsplanverordnung wird hingewiesen.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since January 24th 2020.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.