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10 March 2020

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10/03/2020	Minutes: Minutes of the CAT meeting 22-24 January 2020 (new)
10/03/2020	Human medicines European public assessment report (EPAR): Envarsus, tacrolimus, Graft Rejection, 18/07/2014, 7, Authorised (updated)
10/03/2020	Third European Medicines Agency-Medicines for Europe bilateral meeting , European Medicines Agency, Amsterdam, the Netherlands, from 23/03/2020 to 23/03/2020
10/03/2020	Agenda: Agenda - Third European Medicines Agency-Medicines for Europe bilateral meeting (new)
10/03/2020	Minutes: Minutes of the CAT meeting 4-6 December 2019 (new)
10/03/2020	Committee for Advanced Therapies (CAT): 6-8 November 2019 , European Medicines Agency, Amsterdam, The Netherlands, from 06/11/2019 to 08/11/2019 (updated)
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10/03/2020	Human medicines European public assessment report (EPAR): Lixiana, edoxaban tosylate, Stroke, Venous Thromboembolism, 19/06/2015, 10, Authorised (updated)
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10/03/2020	Periodic safety update single assessment: Levonorgestrel: CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - PSUSA/00001856/201905 (new)
10/03/2020	Human medicines European public assessment report (EPAR): Truberzi, eluxadoline, Irritable Bowel Syndrome, Diarrhea, 19/09/2016, 6, Authorised (updated)

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09/03/2020	Human medicines European public assessment report (EPAR): Elmiron, pentosan polysulfate sodium, Cystitis, Interstitial, 02/06/2017, 8, Authorised (updated)
09/03/2020	Committee meeting report: Monthly report on application procedures, guidelines and related documents for veterinary medicines: January 2020 (new)
09/03/2020	Committee meeting report: COMP meeting report on the review of applications for orphan designation: February 2020 (new)
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09/03/2020	Human medicines European public assessment report (EPAR): Givlaari, Givosiran, Porphyrias, Hepatic, 02/03/2020, Authorised
09/03/2020	Human medicines European public assessment report (EPAR): Zepatier, elbasvir, grazoprevir, Hepatitis C, Chronic, 22/07/2016, 8, Authorised (updated)
09/03/2020	Human medicines European public assessment report (EPAR): Emgality, Galcanezumab, Migraine Disorders, 14/11/2018, 3, Authorised (updated)
09/03/2020	Human medicines European public assessment report (EPAR): Zevalin, ibritumomab tiuxetan, Lymphoma, Follicular, 16/01/2004, 22, Authorised (updated)

NOTICE TO APPLICANTS

No updates since November 28th 2019.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

16.03.2020	Rote-Hand-Brief zu Cytotec® (Misoprostol): Risiken im Zusammenhang mit einer Anwendung zur Geburtseinleitung außerhalb der Zulassung („off-label-use“) Wirkstoff Misoprostol

	Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) informiert, dass zahlreiche, neue Berichte über schwere Nebenwirkungen bei der Anwendung von Cytotec® außerhalb der zugelassenen Indikation vorliegen.
13.03.2020	Fluorouracil: Neues Risikobewertungsverfahren zum Screening von Patienten vor der Behandlung Wirkstoff Fluorouracil; Capecitabin; Tegafur; Flucytosin Der Ausschuss für Risikobewertung im Bereich der Pharmakovigilanz (PRAC) hat Empfehlung zur Testung und Behandlung von Fluorouracil, Capecitabin, Tegafur und Flucytosin gegeben. Weitere Informationen finden Sie auf der Homepage der EMA. Ausführliche Informationen hierzu folgen am Montag, den 16. März 2020.
13.03.2020	Ulipristalacetat: Vorläufiges Ruhen der Zulassung von Arzneimitteln zur Behandlung von Gebärmuttermyomen Wirkstoff Ulipristalacetat Der Ausschuss für Risikobewertung im Bereich der Pharmakovigilanz (PRAC) der EMA hat Frauen empfohlen, die Einnahme von 5 mg Ulipristalacetat (Esmya® und Generika) zur Behandlung von Uterusmyomen für den Zeitraum des laufenden Risikobewertungsverfahrens einzustellen.
13.03.2020	Ifosfamid: EMA leitet Überprüfung zum Enzephalopathierisiko ein Wirkstoff Ifosfamid Die EMA hat ein Risikobewertungsverfahren zu einigen ifosfamidhaltigen Arzneimitteln eingeleitet, um das Risiko zur Entstehung einer Enzephalopathie (Gehirnerkrankung) zu untersuchen.
13.03.2020	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/493485/2019 vom 19.09.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Botulinum-Toxin Typ A – Hämagglutinin-Komplex Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Botulinum-Toxin Typ A – Hämagglutinin-Komplex infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
13.03.2020	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/550072/2019 vom 17.10.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Acetylsalicylsäure Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Acetylsalicylsäure infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
13.03.2020	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/493844/2019 vom 19.09.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Botulinum-Toxin Typ A zur Injektion (Ph.Eur.), frei von Komplexproteinen Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Botulinum-Toxin Typ A zur Injektion (Ph.Eur.), frei von Komplexproteinen infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
12.03.2020	Informationen für Zulassungsinhaber: Bewertung des Risikos möglicher Nitrosaminverunreinigungen in Humanarzneimitteln mit chemisch synthetisierten Wirkstoffen

	Wirkstoff Verschiedene Im Dezember 2019 wurde das auf der CMDh- und EMA-Homepage veröffentlichte Q&A-Dokument, welches sich mit dem Risiko einer möglichen Nitrosaminverunreinigung beschäftigt erneut aktualisiert und ergänzt. Das Dokument richtet sich an die Zulassungsinhaber aller Humanarzneimittel, die chemisch synthetisierte pharmazeutische Wirkstoffe enthalten. Es soll die pharmazeutischen Unternehmen bei der Risikobewertung in Bezug auf das Vorhandensein von Nitrosaminen in ihren Arzneimitteln unterstützen, damit die Firmen geeignete Risikominimierungsmaßnahmen ergreifen können. Wichtigste Ergänzung im Dokument sind die Grenzwerte für Nitrosamine bei lebenslanger und kürzer als lebenslanger Anwendung der Arzneimittel.
09.03.2020	Umsetzung der einstimmigen Beschlüsse der Koordinierungsgruppe EMA/CMDh/551111/2019 vom 17.10.2019 und EMA/CMDh/725923/2016 vom 09.11.2016 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Dorzolamid Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Dorzolamid infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since January 9th 2020.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since January 24th 2020.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.