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HEADS OF AGENCIES – CMDh

No updates since January 8th 2020.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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EUROPEAN MEDICINES AGENCY (EMA)

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21/01/2020	Referrals document: Picato Article-20 referral - Assessment report on provisional measures (new)
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	Urinary Tract Infections, Gram-Negative Bacterial Infections, 23/06/2016, 8, Authorised (updated)
20/01/2020	Human medicines European public assessment report (EPAR): Vargatef, nintedanib, Carcinoma, Non-Small-Cell Lung, 21/11/2014, 12, Authorised (updated)
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20/01/2020	Referral: Flurbiprofen Geiser , flurbiprofen , Flurbiprofen Sejmet,Mentocaína Spray,Flurbiprofeno Geiser, Article 29(4) referrals, European Commission final decision, 17/10/2019, 16/12/2019, 20/01/2020 (updated)
20/01/2020	Periodic safety update single assessment: Isotretinoin (oral formulations): CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - PSUSA/00010488/201905 (new)
20/01/2020	Periodic safety update single assessment: Isotretinoin (oral formulations): List of nationally authorised medicinal products - PSUSA/00010488/201905 (new)
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20/01/2020	Scientific guideline: Reflection paper on good manufacturing practice and marketing authorisation holders (new)
20/01/2020	Other: Detailed guide regarding the EudraVigilance data management activities by the European Medicines Agency (new)
20/01/2020	Eligible healthcare professionals' organisations (updated)
20/01/2020	Human medicines European public assessment report (EPAR): Ajovy, fremanezumab, Migraine Disorders, 28/03/2019, 1, Authorised (updated)
20/01/2020	Periodic safety update single assessment: Botulinum neurotoxin type a (150 kD) free from complexing proteins: CMDh Scientific conclusions, amendments to product information and implementation timetable - PSUSA/00009084/201812 (new)

NOTICE TO APPLICANTS

No updates since November 28th 2019.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

27.01.2020	Rote-Hand-Brief zu ▼Picato® (Ingenolmebutat): Ruhen der Zulassungen aufgrund des Risikos von malignen Hautveränderungen Wirkstoff Ingenolmebutat Die LEO Pharma GmbH informiert über das Ruhen der Zulassungen von Picato® (Ingenolmebutat) aufgrund wachsender Bedenken hinsichtlich des möglichen Risikos von malignen Hautveränderungen.
24.01.2020	82. Sitzung (23. Januar 2020) – Kurzprotokoll Sachverständigen-Ausschuss für Verschreibungspflicht nach § 53 Absatz 2 AMG
23.01.2020	Informationsbrief zu Detimedac®: verkürzte Haltbarkeit nach Rekonstitution bei Raumtemperatur Wirkstoff Dacarbazin

	Der Zulassungsinhaber Medac GmbH informiert über eine verkürzte Haltbarkeit der Arzneimittel Detimedac® 100 mg, 200 mg, 500 mg und 1000 mg nach Rekonstitution bei Raumtemperatur. Untersuchungen der Stabilität der rekonstituierten Lösung zeigten bei Raumtemperatur (20-25°C) bereits nach kurzer Lagerungszeit einen Wert außerhalb der Spezifikation für ein Abbauprodukt von Dacarbazin bzw. die Färbung der Lösung. Bei Raumtemperatur (20-25°C) sollte die rekonstituierte Lösung daher sofort verwendet werden. Die Fachinformation zu Detimedac® wird entsprechend aktualisiert.
20.01.2020	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/473071/2019 vom 19.09.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Testosteron (alle Formulierungen mit Ausnahme der topischen Anwendung) Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Testosteron (alle Formulierungen mit Ausnahme der topischen Anwendung) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
20.01.2020	Picato® (Ingenolmebutat): Ruhen der Zulassungen als Vorsichtsmaßnahme angeordnet, die Überprüfung des Hautkrebsrisikos wird fortgesetzt Wirkstoff Ingenolmebutat Die Europäische Kommission hat vorläufig das Ruhen der Zulassungen angeordnet.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since January 9th 2020

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since November 15th 2019.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.