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EUROPEAN MEDICINES AGENCY (EMA)

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05/07/2019	Human medicines European public assessment report (EPAR): Libtayo, Cemiplimab, Carcinoma, Squamous Cell, 28/06/2019, Authorised
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05/07/2019	Human medicines European public assessment report (EPAR): Menveo, meningococcal group A, C, W-135 and Y conjugate vaccine, Immunization, Meningitis, Meningococcal, 15/03/2010, 17/12/2009, 27, Authorised (updated)
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01/07/2019	Investigation of medicinal products in the term and preterm neonate (updated)
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01/07/2019	Overview of comments: Overview of comments received during the public consultation on 'Concept paper on the need for revision of the guideline on the investigation of medicinal products in the term and preterm neonate' (EMA/PDCO/362462/2016) - Revision 1
01/07/2019	Human medicines European public assessment report (EPAR): Revatio, sildenafil, Hypertension, Pulmonary, 28/10/2005, 37, Authorised (updated)

NOTICE TO APPLICANTS

No updates since December 15th 2017.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

05.07.2019	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/130161/2019 vom 27.02.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff bzw. der Wirkstoffkombination Pseudoephedrin, Acetylsalicylsäure/Pseudoephedrin. Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff bzw. die Wirkstoffkombination Pseudoephedrin, Acetylsalicylsäure/Pseudoephedrin infolge

	des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
05.07.2019	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/131887/2019 vom 27.02.2019 betreffend die Zulassungen für Humanarzneimittel mit der Wirkstoffkombination Paracetamol/Pseudoephedrin. Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffkombination Paracetamol/Pseudoephedrin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
05.07.2019	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/135894/2019 vom 20.02.2019 betreffend die Zulassungen für Humanarzneimittel mit der Wirkstoffkombination Ibuprofen/Pseudoephedrin. Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffkombination Ibuprofen/Pseudoephedrin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
05.07.2019	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/181594/2019 vom 27.03.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Everolimus (angezeigt zur Prävention der Abstoßung transplantierter Organe) Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Everolimus (angezeigt zur Prävention der Abstoßung transplantierter Organe) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
01.07.2019	Umsetzung des Durchführungsbeschlusses der Europäischen Kommission C(2019) 3844 final vom 16.05.2019 zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Tacrolimus (Formulierungen zur systemischen Anwendung) Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Tacrolimus (Formulierungen zur systemischen Anwendung) 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 June 13th 2019

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

02.07.2019	Rote-Hand-Brief: RoActemra (Tocilizumab)	zum Beitrag

PHARMEUROPA TEXTS FOR COMMENT

No updates since July 1st 2019.