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HEADS OF AGENCIES – CMDh

No updates since November 27th 2019.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

09/12/2019	Herbal medicinal product: Tormentillae rhizoma, Tormentillae rhizoma, C: ongoing call for scientific data (updated)
06/12/2019	Human medicines European public assessment report (EPAR): Glyxambi, empagliflozin, linagliptin, Diabetes Mellitus, Type 2, 11/11/2016, 7, Authorised (updated)
06/12/2019	Human medicines European public assessment report (EPAR): Intrarosa, Prasterone, Menopause, 08/01/2018, 4, Authorised (updated)
06/12/2019	Other: European Medicines Agency's privacy statement concerning requests for information or access to documents
06/12/2019	Summary of opinion: Velactis, cabergoline, 05/12/2019, Negative (updated)
06/12/2019	News and press releases: Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 3-5 December 2019
06/12/2019	Summary of opinion: Eravac, Rabbit haemorrhagic disease vaccine (inactivated), 05/12/2019, Positive
06/12/2019	Summary of opinion: Onsior, robenacoxib, 05/12/2019, Positive
06/12/2019	Human medicines European public assessment report (EPAR): Ziagen, abacavir, HIV Infections, 08/07/1999, 38, Authorised (updated)
06/12/2019	Human medicines European public assessment report (EPAR): Aubagio, Teriflunomide, Multiple Sclerosis, 26/08/2013, 13, Authorised (updated)
06/12/2019	Regulatory and procedural guideline: List of centrally authorised products requiring a notification of a change for update of annexes (updated)
06/12/2019	Nitrosamine impurities overview (updated)
06/12/2019	News and press releases: EMA update on metformin diabetes medicines
06/12/2019	Other: Expected publication dates of PRAC recommendations on safety signals
06/12/2019	Other: Article 57 product data (updated)
06/12/2019	Human medicines European public assessment report (EPAR): Viramune, nevirapine, HIV Infections, 04/02/1998, 38, Authorised (updated)

06/12/2019	Other: Orientation guide for industry - EMA building
05/12/2019	Agenda: Agenda - CAT agenda of the 4-6 December 2019 meeting
05/12/2019	Workshop on the role of registries in the monitoring of cancer therapies based on genetic and molecular features , European Medicines Agency, Amsterdam, the Netherlands, from 29/11/2019 to 29/11/2019 (updated)
05/12/2019	Periodic safety update single assessment: Ivermectin (systemic use): List of nationally authorised medicinal products - PSUSA/00010377/201904
05/12/2019	Periodic safety update single assessment: Ivermectin (topical use): List of nationally authorised medicinal products - PSUSA/00010376/201904
05/12/2019	Report: Applications for new human medicines under evaluation by the CHMP: December 2019
05/12/2019	Frequently asked questions about parallel distribution (updated)
05/12/2019	Procurement (updated)
05/12/2019	Procurement: Ex ante publicity of a negotiated procedure: EMA/2019/21/CO – Supply of subscriptions to general and international press in all formats
05/12/2019	Referrals document: Fluorouracil and fluorouracil related substances Article 31 referral - Timetable for the procedure (updated)
05/12/2019	Scientific publications (updated)
05/12/2019	Human medicines European public assessment report (EPAR): Remsima, infliximab, Arthritis, Psoriatic, Spondylitis, Ankylosing, Colitis, Ulcerative, Psoriasis, Crohn Disease, Arthritis, Rheumatoid, 10/09/2013, 17, Authorised (updated)
05/12/2019	Regulatory and procedural guideline: Recommended submission dates for centralised and maximum-residue-limit procedures (updated)
05/12/2019	Human medicines European public assessment report (EPAR): Resolor, Prucalopride succinate, Constipation, 14/10/2009, 23, Authorised (updated)
05/12/2019	Orphan designation: Humanised IgG4 monoclonal antibody against total complement component 1, subcomponent s (sutimlimab) for the: Treatment of autoimmune haemolytic anaemia, 17/02/2016, Positive (updated)
05/12/2019	Authorisation of medicines (updated)
05/12/2019	What we do (updated)
04/12/2019	Human medicines European public assessment report (EPAR): Teysuno, tegafur, gimeracil, oteracil, Stomach Neoplasms, 14/03/2011, 16, Authorised (updated)
04/12/2019	Human medicines European public assessment report (EPAR): Foclivia, influenza virus surface antigens, inactivated: A/Viet Nam/1194/2004 (H5N1), Influenza, Human, Immunization, Disease Outbreaks, 18/10/2009, 9, Authorised (updated)
04/12/2019	Herbal medicinal product: Hamamelidis cortex, Hamamelidis cortex, F: Assessment finalised (updated)
04/12/2019	Human medicines European public assessment report (EPAR): Stayveer, bosentan monohydrate, Hypertension, Pulmonary, Scleroderma, Systemic, 24/06/2013, 11, Authorised (updated)
04/12/2019	Orphan designation: 4-hydroxy-2,2,6,6-tetramethylpiperidine-N-oxyl for the: Treatment of familial cerebral cavernous malformations, 12/12/2017, Positive (updated)
04/12/2019	Orphan designation: Ivosidenib for the: Treatment of acute myeloid leukaemia, 12/12/2016, Positive (updated)
04/12/2019	Human medicines European public assessment report (EPAR): Gardasil 9, human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed), Condylomata Acuminata, Papillomavirus Infections, Immunization, Uterine Cervical Dysplasia, 09/06/2015, 11, Authorised (updated)
04/12/2019	Human medicines European public assessment report (EPAR): Ziextenzo, pegfilgrastim, Neutropenia, 22/11/2018, 1, Authorised (updated)
04/12/2019	Agenda: Agenda - CVMP agenda of the 3-5 December 2019 meeting

04/12/2019	Herbal medicinal product: Hamamelidis folium et cortex aut ramunculus destillatum, Hamamelidis folium et cortex aut ramunculus destillatum, F: Assessment finalised (updated)
04/12/2019	Herbal medicinal product: Frangulae cortex, Frangulae cortex, F: Assessment finalised (updated)
04/12/2019	Other: European authorities working to avoid shortages of medicines due to Brexit – Questions and answers (updated)
04/12/2019	Herbal – European Union herbal monograph: Final community herbal monograph on Hamamelis virginiana L., cortex (updated)
03/12/2019	Human medicines European public assessment report (EPAR): Olumiant, baricitinib, Arthritis, Rheumatoid, 13/02/2017, 6, Authorised (updated)
03/12/2019	Human medicines European public assessment report (EPAR): Tracleer, bosentan monohydrate, Scleroderma, Systemic, Hypertension, Pulmonary, 14/05/2002, 37, Authorised (updated)
03/12/2019	Human medicines European public assessment report (EPAR): Mepsevii, vestronidase alfa, Mucopolysaccharidosis VII, 23/08/2018, 3, Authorised (updated)
03/12/2019	Other: PRAC meetings in 2019, 2020, 2021 (updated)
03/12/2019	PRAC recommendation on signal: Updated signal assessment report on birth defects following in-utero exposure during the first trimester of pregnancy arising from recent publications with ondansetr
03/12/2019	Report: Social Media and M-Health Data - Subgroup report (updated)
03/12/2019	Human medicines European public assessment report (EPAR): Toujeo (previously Optisulin), insulin glargine, Diabetes Mellitus, 26/06/2000, 28, Authorised (updated)
03/12/2019	Human medicines European public assessment report (EPAR): CellCept, mycophenolate mofetil, Graft Rejection, 14/02/1996, 31, Authorised (updated)
03/12/2019	Human medicines European public assessment report (EPAR): Xermelo, telotristat etiprate, Carcinoid Tumor, Neuroendocrine Tumors, 17/09/2017, 8, Authorised (updated)
03/12/2019	Agenda: Agenda - COMP agenda of the 03-05 December 2019 meeting
03/12/2019	Third international awareness session on science and regulation for animal health and welfare, public health and the environment , European Medicines Agency, Amsterdam, the Netherlands, from 02/04/2020 to 03/04/2020
03/12/2019	Human medicines European public assessment report (EPAR): Synagis, palivizumab, Respiratory Syncytial Virus Infections, 13/08/1999, 40, Authorised (updated)
03/12/2019	Periodic safety update single assessment: Carteolol: List of nationally authorised medicinal products - PSUSA/00000574/201903
03/12/2019	Human medicines European public assessment report (EPAR): Rhokiinsa, Netarsudil, Glaucoma, Open-Angle, Ocular Hypertension, 19/11/2019, Authorised
03/12/2019	Human medicines European public assessment report (EPAR): Feraccru, ferric maltol, Anemia, Iron-Deficiency, 18/02/2016, 9, Authorised (updated)
03/12/2019	Human medicines European public assessment report (EPAR): Strensiq, asfotase alfa, Hypophosphatasia, 28/08/2015, 10, Authorised (updated)
03/12/2019	Orphan designation: Vatiquinone for the: Treatment of RARS2 syndrome, 17/01/2018, Positive (updated)
03/12/2019	Orphan designation: (R)-troloxamide quinone for the: Treatment of amyotrophic lateral sclerosis, 12/10/2017, Positive (updated)
03/12/2019	Orphan designation: Alpha-tocotrienol quinone for the: Treatment of Leigh syndrome, 09/12/2011, Positive (updated)
03/12/2019	EPAR - All authorised presentations: Synagis : EPAR - All Authorised presentations (updated)
02/12/2019	Human medicines European public assessment report (EPAR): Aprovel, irbesartan, Hypertension, 26/08/1997, 39, Authorised (updated)

02/12/2019	Other: EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) organisations (updated)
02/12/2019	Other: EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) pharmaceutical dose forms (updated)
02/12/2019	Other: EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) substances (updated)
02/12/2019	Other: EudraVigilance eXtended Medicinal Product Dictionary (XEVMPD) routes of administration (updated)
02/12/2019	Human medicines European public assessment report (EPAR): Farydak, panobinostat lactate anhydrous, Multiple Myeloma, 28/08/2015, 7, Authorised (updated)
02/12/2019	Periodic safety update single assessment: Carvedilol / ivabradine : List of nationally authorised medicinal products - PSUSA/00010586/201904
02/12/2019	Periodic safety update single assessment: Varicella vaccine (live) : List of nationally authorised medicinal products - PSUSA/000010473/201903
02/12/2019	Paediatric strategy forum for medicinal product development for acute myeloid leukaemia in children and adolescents , Rotterdam, Netherlands, from 02/12/2019 to 02/12/2019
02/12/2019	Template or form: Template letter of intent for request of scientific advice or protocol assistance (updated)
02/12/2019	Other: HMPC meetings in 2019, 2020 and 2021
02/12/2019	Paediatric strategy forum for medicinal product development of checkpoint inhibitors for use in combination therapy in paediatric patients , European Medicines Agency, London, UK, from 05/09/2018 to 06/09/2018 (updated)

NOTICE TO APPLICANTS

No updates since November 28th 2019.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

06.12.2019	Information zu metforminhaltigen Arzneimitteln Wirkstoff Metformin Spuren einer Verunreinigung, N-Nitrosodimethylamin (NDMA), wurden in einer geringen Anzahl von metforminhaltigen Arzneimitteln außerhalb der Europäischen Union (EU) gefunden.
02.12.2019	Rote-Hand-Brief zu ▼Increlex® (Mecasermin): Risiko für gutartige und bösartige Neoplasien Wirkstoff Mecasermin Die Firma Ipsen Pharma informiert über Fälle von gutartigen und bösartigen Neoplasien bei Kindern und Jugendlichen, die nach Markteinführung von Mecasermin mit Increlex® behandelt wurden.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since October 15th 2019.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since November 15th 2019.

PHARMEUROPA TEXTS FOR COMMENT

No updates since October 7th 2019.