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HEADS OF AGENCIES – CMDh

No updates since July 31th 2019.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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EUROPEAN MEDICINES AGENCY (EMA)

26/08/2019	Human medicines European public assessment report (EPAR): Tracleer , bosentan monohydrate, Scleroderma, Systemic, Hypertension, Pulmonary, 14/05/2002, 35, Authorised (updated)
26/08/2019	Newsletter: News bulletin for small and medium-sized enterprises - Issue 47
26/08/2019	Human medicines European public assessment report (EPAR): Voncento , Human coagulation factor VIII, human von willebrand factor, Hemophilia A, von Willebrand Diseases, 12/08/2013, 13, Authorised (updated)
23/08/2019	Human medicines European public assessment report (EPAR): Twynsta , telmisartan, amlodipine, Hypertension, 07/10/2010, 10, Authorised (updated)
23/08/2019	Human medicines European public assessment report (EPAR): Adynovi , rurioctocog alfa pegol, Hemophilia A, 08/01/2018, 3, Authorised (updated)
23/08/2019	Herbal medicinal product: Avenae fructus , Avenae fructus , F: Assessment finalised (updated)
23/08/2019	Scientific publications (updated)
23/08/2019	Herbal medicinal product: Avenae herba , Avenae herba , F: Assessment finalised (updated)
23/08/2019	Herbal medicinal product: Myrrha , gummi-resina , Myrrha , gummi-resina , F: Assessment finalised (updated)
23/08/2019	Herbal medicinal product: Bursae pastoris herba , Bursae pastoris herba , F: Assessment finalised (updated)
23/08/2019	Other: HMPC: overview of assessment work - priority list (updated)
23/08/2019	Committee for Advanced Therapies (CAT): 14-16 July 2019 , European Medicines Agency, Amsterdam, The Netherlands, from 14/07/2019 to 16/07/2019 (updated)
23/08/2019	Committee meeting report: CAT monthly report of application procedures, guidelines and related documents on advanced therapies: July 2019
23/08/2019	Orphan designation: Imetelstat sodium for the: Treatment of myelofibrosis, 14/12/2015, Positive (updated)

23/08/2019	Human medicines European public assessment report (EPAR): NovoRapid , insulin aspart, Diabetes Mellitus, 07/09/1999, 30, Authorised (updated)
23/08/2019	Referral: Methotrexate containing medicinal products , methotrexate , Jylamvo,Nordimet,Ledertrexate,Maxtrex,Metex,Metoject, Article 31 referrals, Opinion provided by Committee for Medicinal Products for Human Use, 22/08/2019, 23/08/2019 (updated)
23/08/2019	News and press releases: New measures to avoid potentially fatal dosing errors with methotrexate for inflammatory diseases
23/08/2019	Human medicines European public assessment report (EPAR): Venclyxto , Venetoclax, Leukemia, Lymphocytic, Chronic, B-Cell, 04/12/2016, 8, Authorised (updated)
23/08/2019	Other: European Medicines Agency policy on access to EudraVigilance data for medicinal products for human use - Revision 4
23/08/2019	Human medicines European public assessment report (EPAR): Lojuxta , Lomitapide, Hypercholesterolemia, 31/07/2013, 11, Authorised (updated)
22/08/2019	Herbal medicinal product: Polypodii rhizoma , Polypodii rhizoma , F: Assessment finalised (updated)
22/08/2019	Herbal medicinal product: Phaseoli fructus (sine semine) , Phaseoli fructus (sine semine) , F: Assessment finalised (updated)
22/08/2019	Herbal medicinal product: Rusci aculeati rhizoma , Rusci aculeati rhizoma , D: Draft under discussion (updated)
22/08/2019	Herbal medicinal product: Millefolii flos , Millefolii flos , F: Assessment finalised (updated)
22/08/2019	Herbal medicinal product: Leonuri cardiaca herba , Leonuri cardiaca herba , F: Assessment finalised (updated)
22/08/2019	Human medicines European public assessment report (EPAR): NeoRecormon , epoetin beta, Kidney Failure, Chronic, Anemia, Cancer, Blood Transfusion, Autologous, 16/07/1997, 28, Authorised (updated)
22/08/2019	Herbal medicinal product: Gentianae radix , Gentianae radix , F: Assessment finalised (updated)
22/08/2019	Human medicines European public assessment report (EPAR): Privigen , human normal immunoglobulin (IVIg), Purpura, Thrombocytopenic, Idiopathic, Bone Marrow Transplantation, Immunologic Deficiency Syndromes, Guillain-Barre Syndrome, Mucocutaneous Lymph Node Syndrome, 24/04/2008, 24, Authorised (updated)
22/08/2019	Herbal medicinal product: Fragariae folium , Fragariae folium , F: Assessment finalised (updated)
22/08/2019	Human medicines European public assessment report (EPAR): Nevirapine Teva , nevirapine, HIV Infections, 30/11/2009, 9, Authorised (updated)
22/08/2019	Human medicines European public assessment report (EPAR): Zutectra , human hepatitis-B immunoglobulin, Immunization, Passive, Hepatitis B, Liver Transplantation, 30/11/2009, 13, Authorised (updated)
22/08/2019	Human medicines European public assessment report (EPAR): Imfinzi , durvalumab, Carcinoma, Non-Small-Cell Lung, 21/09/2018, 1, Authorised (updated)
22/08/2019	Human medicines European public assessment report (EPAR): Onpattro , patisiran sodium, Amyloidosis, Familial, 27/08/2018, 3, Authorised (updated)
22/08/2019	Referral: Lartruvo , olaratumab , Article 20 procedures, European Commission final decision, 31/01/2019, 19/07/2019, 22/08/2019 (updated)
22/08/2019	Human medicines European public assessment report (EPAR): Vedrop , tocofersolan, Cholestasis, Vitamin E Deficiency, 23/07/2009, 13, Authorised (updated)
22/08/2019	Human medicines European public assessment report (EPAR): NeuroBloc , botulinum toxin type B, Torticollis, 22/01/2001, 31, Authorised (updated)

22/08/2019	Human medicines European public assessment report (EPAR): NovoEight , turoctocog alfa, Hemophilia A, 13/11/2013, 8, Authorised (updated)
22/08/2019	Human medicines European public assessment report (EPAR): Daklinza , daclatasvir dihydrochloride, Hepatitis C, Chronic, 22/08/2014, 15, Authorised (updated)
22/08/2019	Human medicines European public assessment report (EPAR): MabThera , rituximab, Lymphoma, Non-Hodgkin, Arthritis, Rheumatoid, Leukemia, Lymphocytic, Chronic, B-Cell, 02/06/1998, 46, Authorised (updated)
22/08/2019	Human medicines European public assessment report (EPAR): Mimpara , cinacalcet hydrochloride, Hypercalcemia, Parathyroid Neoplasms, Hyperparathyroidism, 22/10/2004, 21, Authorised (updated)
22/08/2019	Human medicines European public assessment report (EPAR): Shingrix , Varicella Zoster Virus glycoprotein E antigen, Herpes Zoster, 21/03/2018, 1, Authorised (updated)
22/08/2019	General privacy statement (updated)
21/08/2019	Agenda: Agenda - CHMP agenda of the 19-22 August 2019 written procedure
21/08/2019	Other: Questions and answers on the exemption from batch controls carried out on ATMPs imported into the European Union from a third country
21/08/2019	Human medicines European public assessment report (EPAR): Toviaz , fesoterodine fumarate, Urinary Bladder, Overactive, 20/04/2007, 21, Authorised (updated)
21/08/2019	Human medicines European public assessment report (EPAR): Ratiograstim , filgrastim, Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer, 15/09/2008, 10, Authorised (updated)
21/08/2019	Human medicines European public assessment report (EPAR): Ondexxya , andexanet alfa, Drug-Related Side Effects and Adverse Reactions, 26/04/2019, 1, Authorised (updated)
20/08/2019	Agenda: Agenda - PDCO agenda of the 20-23 August 2019 written procedure
20/08/2019	Human medicines European public assessment report (EPAR): Telzir , fosamprenavir calcium, HIV Infections, 12/07/2004, 42, Authorised (updated)
20/08/2019	Human medicines European public assessment report (EPAR): Kalydeco , ivacaftor, Cystic Fibrosis, 22/07/2012, 18, Authorised (updated)
20/08/2019	Human medicines European public assessment report (EPAR): Firazyr , icatibant, Angioedemas, Hereditary, 11/07/2008, 17, Authorised (updated)
20/08/2019	Human medicines European public assessment report (EPAR): Lifmior , etanercept, Arthritis, Psoriatic, Spondylitis, Ankylosing, Psoriasis, 13/02/2017, 7, Authorised (updated)
20/08/2019	Human medicines European public assessment report (EPAR): Waylivra , Volanesorsen sodium, Hyperlipoproteinemia Type I, 03/05/2019, 1, Authorised (updated)
20/08/2019	Referral: Angiotensin-II-receptor antagonists (sartans) containing a tetrazole group , valsartan, candesartan, irbesartan, losartan and olmesartan, Article 31 referrals, European Commission final decision, 31/01/2019, 02/04/2019, 20/08/2019 (updated)
20/08/2019	Other: Temporary interim limits for NMBA, DIPNA and EIPNA impurities in sartan blood pressure medicines (updated)
20/08/2019	Human medicines European public assessment report (EPAR): Cotellic , cobimetinib hemifumarate, Melanoma, 20/11/2015, 7, Authorised (updated)
20/08/2019	Human medicines European public assessment report (EPAR): Copalia , amlodipine (as besylate), valsartan, Hypertension, 15/01/2007, 23, Authorised (updated)
20/08/2019	Human medicines European public assessment report (EPAR): Bydureon , exenatide, Diabetes Mellitus, Type 2, 17/06/2011, 18, Authorised (updated)

20/08/2019	Human medicines European public assessment report (EPAR): Lopinavir/Ritonavir Mylan , lopinavir/ritonavir, HIV Infections, 14/01/2016, 7, Authorised (updated)
20/08/2019	Human medicines European public assessment report (EPAR): Kiovig , human normal immunoglobulin (IVIg), Purpura, Thrombocytopenic, Idiopathic, Bone Marrow Transplantation, Immunologic Deficiency Syndromes, Guillain-Barre Syndrome, Mucocutaneous Lymph Node Syndrome, 18/01/2006, 22, Authorised (updated)
20/08/2019	Human medicines European public assessment report (EPAR): Pemetrexed Pfizer (previously known as Pemetrexed Hospira UK Limited) , pemetrexed ditromethamine, Carcinoma, Non-Small-Cell Lung, Mesothelioma, 24/04/2017, 6, Authorised (updated)
20/08/2019	Human medicines European public assessment report (EPAR): Hetlioz , tasimelteon, Sleep Disorders, Circadian Rhythm, 03/07/2015, 4, Authorised (updated)
20/08/2019	Human medicines European public assessment report (EPAR): Zydelig , Idelalisib, Lymphoma, Non-Hodgkin, Leukemia, Lymphocytic, Chronic, B-Cell, 18/09/2014, 15, Authorised (updated)
20/08/2019	Human medicines European public assessment report (EPAR): Ultibro Breezhaler , indacaterol, Glycopyrronium bromide, Pulmonary Disease, Chronic Obstructive, 19/09/2013, 10, Authorised (updated)
20/08/2019	Human medicines European public assessment report (EPAR): Sylvant , siltuximab, Giant Lymph Node Hyperplasia, 22/05/2014, 9, Authorised (updated)
20/08/2019	Human medicines European public assessment report (EPAR): Rotarix , human rotavirus, live attenuated, Immunization, Rotavirus Infections, 21/02/2006, 32, Authorised (updated)
20/08/2019	Human medicines European public assessment report (EPAR): Grepid , clopidogrel besilate, Peripheral Vascular Diseases, Stroke, Myocardial Infarction, 27/07/2009, 19, Authorised (updated)
20/08/2019	European Medicines Agency and European Union payer community meeting , Zorginstituut Nederland, Diemen, The Netherlands, from 18/06/2019 to 18/06/2019 (updated)
20/08/2019	Periodic safety update single assessment: Phloroglucinol, phloroglucinol trimethylphloroglucinol: CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - PSUSA/00010355/201809
20/08/2019	Periodic safety update single assessment: Phloroglucinol, phloroglucinol trimethylphloroglucinol: List of nationally authorised medicinal products - PSUSA/00010355/201809
19/08/2019	Human medicines European public assessment report (EPAR): Thalidomide Celgene (previously Thalidomide Pharmion) , Thalidomide, Multiple Myeloma, 16/04/2008, 24, Authorised (updated)
19/08/2019	Human medicines European public assessment report (EPAR): Darzalex , Daratumumab, Multiple Myeloma, 28/04/2017, 9, Authorised (updated)
19/08/2019	Orphan designation: Lonafarnib for the: Treatment of Hutchinson-Gilford progeria, 14/12/2018, Positive (updated)
19/08/2019	Orphan designation: Exendin (9-39) for the: Treatment of noninsulinoma pancreatogenous hypoglycaemia syndrome, 14/10/2016, Positive (updated)
19/08/2019	Orphan designation: Ubenimex for the: Treatment of pulmonary arterial hypertension, 21/03/2016, Positive (updated)
19/08/2019	Orphan designation: Lonafarnib for the: Treatment of hepatitis delta virus infection, 16/01/2014, Positive (updated)
19/08/2019	Committee meeting report: COMP meeting report on the review of applications for orphan designation: April 2019

19/08/2019	Committee meeting report: COMP meeting report on the review of applications for orphan designation: March 2019
19/08/2019	Committee meeting report: COMP meeting report on the review of applications for orphan designation: February 2019
19/08/2019	Biosimilar medicines: marketing authorisation (updated)
19/08/2019	Generic and hybrid applications (updated)
19/08/2019	Regulatory and procedural guideline: European Medicines Agency procedural advice for users of the centralised procedure for generic / hybrid applications (updated)
19/08/2019	Regulatory and procedural guideline: European Medicines Agency procedural advice for users of the centralised procedure for generic / hybrid applications (track changes) (updated)
19/08/2019	Regulatory and procedural guideline: European Medicines Agency procedural advice for users of the centralised procedure for similar biological medicinal product applications (track changes) (updated)
19/08/2019	Regulatory and procedural guideline: European Medicines Agency procedural advice for users of the centralised procedure for similar biological medicinal product applications (updated)
19/08/2019	Orphan designation: Sodium benzoate for the: Treatment of hyperargininaemia, 11/01/2016, Positive (updated)
19/08/2019	Orphan designation: Sodium benzoate for the: Treatment of argininosuccinic aciduria, 11/01/2016, Positive (updated)
19/08/2019	Orphan designation: Sodium thiosulfate for the: Treatment for calciphylaxis, 15/01/2015, Positive (updated)
19/08/2019	Orphan designation: Sodium nitrite for the: Treatment of aneurysmal subarachnoid haemorrhage, 16/01/2014, Positive (updated)
19/08/2019	Orphan designation: Diacelein for the: Treatment of epidermolysis bullosa, 29/05/2019, Positive (updated)
19/08/2019	Orphan designation: Heat-killed Mycobacterium obuense (whole cell) for the: Treatment of pancreatic cancer, 16/12/2014, Positive (updated)

NOTICE TO APPLICANTS

No updates since December 15th 2017.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

23.08.2019	Methotrexat: Dosierungsfehler Wirkstoff Methotrexat Neue Maßnahmen zur Vermeidung potenziell tödlicher Dosierungsfehler mit Methotrexat bei entzündlichen Erkrankungen.
23.08.2019	Kava-Kava-haltige Arzneimittel: Risiko für das Auftreten schwerer Leberreaktionen. Änderung der betroffenen Zulassungen Wirkstoff Kava-Kava Erneute Anhörung zu Kava-Kava-haltigen Arzneimitteln, da der HMPC das Nutzen-Risiko-Verhältnis als ungünstig bewertet.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

20.08.2019	Schwere Hypersensibilitätsreaktionen bei der Verwendung von Dialysefiltern Schwere Hypersensibilitätsreaktionen bei der Verwendung von Dialysefiltern
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PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since August 19th 2019.

PHARMEUROPA TEXTS FOR COMMENT

No updates since August 19th 2019.