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HEADS OF AGENCIES – CMDh

No updates since July 31th 2019.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: [click here](#)

EUROPEAN MEDICINES AGENCY (EMA)

19/08/2019	Orphan designation: Recombinant fragment of human surfactant protein-D for the: Prevention of bronchopulmonary dysplasia, 23/08/2017, Positive (updated)
19/08/2019	Orphan designation: Synthetic double-stranded siRNA oligonucleotide directed against p53 mRNA (teprasiran) for the: Prevention of delayed graft function after renal transplantation, 06/06/2010, Positive (updated)
16/08/2019	Human medicines European public assessment report (EPAR): Dafiro , amlodipine, valsartan, Hypertension, 15/01/2007, 25, Authorised (updated)
16/08/2019	Human medicines European public assessment report (EPAR): Envarsus , tacrolimus, Graft Rejection, 18/07/2014, 6, Authorised (updated)
16/08/2019	Human medicines European public assessment report (EPAR): NovoMix , insulin aspart, Diabetes Mellitus, 01/08/2000, 27, Authorised (updated)
16/08/2019	Human medicines European public assessment report (EPAR): Xolair , omalizumab, Asthma, Urticaria, 25/10/2005, 38, Authorised (updated)
16/08/2019	Human medicines European public assessment report (EPAR): Skilarence , dimethyl fumarate, Psoriasis, 23/06/2017, 2, Authorised (updated)
16/08/2019	Human medicines European public assessment report (EPAR): Mysildecard , sildenafil citrate, Hypertension, Pulmonary, 15/09/2016, 1, Authorised (updated)
16/08/2019	Human medicines European public assessment report (EPAR): Exforge HCT , Amlodipine besylate, valsartan, hydrochlorothiazide, Hypertension, 15/10/2009, 16, Authorised (updated)
16/08/2019	Human medicines European public assessment report (EPAR): Copalia HCT , amlodipine, valsartan, hydrochlorothiazide, Hypertension, 03/11/2009, 15, Authorised (updated)
16/08/2019	Human medicines European public assessment report (EPAR): Humira , adalimumab, Spondylitis, Ankylosing, Arthritis, Juvenile Rheumatoid, Uveitis, Colitis, Ulcerative, Psoriasis, Arthritis, Psoriatic, Crohn Disease, Arthritis, Rheumatoid, 08/09/2003, 74, Authorised (updated)

16/08/2019	Human medicines European public assessment report (EPAR): Vantobra (previously Tobramycin PARI) , Tobramycin, Respiratory Tract Infections, Cystic Fibrosis, 18/02/2019, 1, Authorised (updated)
16/08/2019	Human medicines European public assessment report (EPAR): Exforge , amlodipine (as besylate), valsartan, Hypertension, 16/01/2007, 24, Authorised (updated)
16/08/2019	Scientific publications (updated)
16/08/2019	Human medicines European public assessment report (EPAR): Sevelamer carbonate Winthrop (previously Sevelamer carbonate Zentiva) , sevelamer carbonate, Hyperphosphatemia, Renal Dialysis, 15/01/2015, 14, Authorised (updated)
16/08/2019	News and press releases: EMA/FDA analysis shows high degree of alignment in marketing application decisions between EU and US
16/08/2019	Human medicines European public assessment report (EPAR): Afstyla , lonococog alfa, Hemophilia A, 04/01/2017, 5, Authorised (updated)
16/08/2019	Other: EudraVigilance eXtended Medicinal Product Dictionary (XEVMPPD) organisations (updated)
16/08/2019	Other: EudraVigilance eXtended Medicinal Product Dictionary (XEVMPPD) substances (updated)
16/08/2019	Report: Medicinal products for human use: monthly figures - July 2019 (updated)
16/08/2019	Human medicines European public assessment report (EPAR): Rezolsta , darunavir, cobicistat, HIV Infections, 19/11/2014, 8, Authorised (updated)
16/08/2019	Human medicines European public assessment report (EPAR): Helicobacter Test INFAI , 13C-urea, Breath Tests, Helicobacter Infections, 14/08/1997, 16, Authorised (updated)
16/08/2019	Template or form: Appendix V - Adverse-drug-reaction reporting details (updated)
16/08/2019	Human medicines European public assessment report (EPAR): Odefsey , emtricitabine, rilpivirine hydrochloride, tenofovir alafenamide, HIV Infections, 21/06/2016, 14, Authorised (updated)
16/08/2019	Human medicines European public assessment report (EPAR): Dukoral , recombinant cholera toxin B subunit, vibrio cholerae 01, Cholera, Immunization, 28/04/2004, 13, Authorised (updated)
16/08/2019	Human medicines European public assessment report (EPAR): Abasaglar (previously Abasria) , insulin glargine, Diabetes Mellitus, 09/09/2014, 7, Authorised (updated)
14/08/2019	Human medicines European public assessment report (EPAR): ReFacto AF , moroctocog alfa, Hemophilia A, 13/04/1999, 36, Authorised (updated)
14/08/2019	Human medicines European public assessment report (EPAR): Naglazyme , galsulfase, Mucopolysaccharidosis VI, 23/01/2006, 14, Authorised (updated)
14/08/2019	Other: Article 57 product data (updated)
14/08/2019	Withdrawn application: Radicava , edaravone, Date of withdrawal: 24/05/2019, Initial authorisation (updated)
14/08/2019	Human medicines European public assessment report (EPAR): Bonviva , ibandronic acid, Osteoporosis, Postmenopausal, 23/02/2004, 25, Authorised (updated)
14/08/2019	Human medicines European public assessment report (EPAR): Herzuma , trastuzumab, Stomach Neoplasms, Breast Neoplasms, 08/02/2018, 6, Authorised (updated)
14/08/2019	Human medicines European public assessment report (EPAR): Rotarix , human rotavirus, live attenuated, Immunization, Rotavirus Infections, 21/02/2006, 31, Authorised (updated)

14/08/2019	Human medicines European public assessment report (EPAR): Mysimba , bupropion hydrochloride, naltrexone hydrochloride, Obesity, Overweight, 26/03/2015, 12, Authorised (updated)
14/08/2019	Committee meeting report: Monthly report on application procedures, guidelines and related documents for veterinary medicines: June 2019
14/08/2019	Committee for Medicinal Products for Veterinary Use (CVMP): 18-20 June 2019 , European Medicines Agency, Amsterdam, the Netherlands, from 18/06/2019 to 20/06/2019 (updated)
14/08/2019	Procurement (updated)
14/08/2019	Human medicines European public assessment report (EPAR): Xarelto , rivaroxaban, Arthroplasty, Replacement, Venous Thromboembolism, 30/09/2008, 29, Authorised (updated)
14/08/2019	Referral: Leuprorelin-containing depot medicinal products , leuprorelin , Daronda, Depo-Eligard, Eligard, Eligard Depot, Eligard Mensua, Eligard Semestral, Elityran 1 Month Depot (Dps), Elityran 3 Month Depot (Dps), Enanton Depot Dual, Enanton Depot Set, Enantone, Enantone L.P, Enantone Lp, Enantone Monats-Depot, Enantone-Gyn Monats-Depot, Ginecrin Depot, Klebrocid 3-Monats-Depot, Klebrocid Depot Zweikammerspritze, Leptoprol, Lerin, Leugon, Leuprex 3, Leuprol, Leuprolin Ratiopharm, Leuprone 1-Monatsdepot, Leuprone 3-Monatsdepot, Leuprorelin 1-Month Depot Gp-Pharm, Leupro-Sandoz 3-Monats-Depot, Leuprostin, Lucrin, Lucrin Depot, Lucrin Pds Depot, Lucrin Pds Depot 1 Maand, Lucrin Pds Depot 3 Maanden, Lucrin Pds Depot 6 Maanden, Lupron Depo, Lutrate 1 Month Depot, Lutrate 3 Month Depot, Lutrate Depo, Lutrate Depot, Lutrate Depot Trimestral, Politrade, Politrade Politrade Depot, Procren Depot, Procren Depot Pds, Procrin Mensual, Procrin Semestral, Procrin Trimestral, Prostag 3 Dcs, Prostag 6 Dcs, Prostag Sr Dcs, Prostapant, Sixantone, Trenantone, Trenantone-Gyn, Zeulide, Елигард, Лутрат Дпо, Article 31 referrals, Procedure started, 14/08/2019 (updated)
14/08/2019	Human medicines European public assessment report (EPAR): Azacitidine Celgene , azacitidine, Myelodysplastic Syndromes, Leukemia, Myelomonocytic, Chronic, Leukemia, Myeloid, Acute, 02/08/2019, Authorised
13/08/2019	Paediatric Committee (PDCO): 26 February-1 March 2019 , European Medicines Agency, from 26/02/2019 to 01/03/2019 (updated)
13/08/2019	Minutes: Minutes - PDCO minutes of the 26 February-01 March 2019 meeting
13/08/2019	News and press releases: EMA closed 15 August 2019
13/08/2019	Newsletter: Human medicines highlights - August 2019
13/08/2019	Report: Applications for new human medicines under evaluation by the CHMP: August 2019
13/08/2019	Human medicines European public assessment report (EPAR): Glustin , pioglitazone hydrochloride, Diabetes Mellitus, Type 2, 11/10/2000, 25, Authorised (updated)
13/08/2019	Human medicines European public assessment report (EPAR): Renagel , sevelamer, Renal Dialysis, Hyperphosphatemia, 28/01/2000, 30, Authorised (updated)
13/08/2019	Human medicines European public assessment report (EPAR): Praluent , Alirocumab, Dyslipidemias, 23/09/2015, 11, Authorised (updated)
13/08/2019	Veterinary medicines European public assessment report (EPAR): Bovalto Ibraxion , inactivated IBR virus, 09/03/2000, 10, Withdrawn (updated)
13/08/2019	Human medicines European public assessment report (EPAR): Strensiq , asfotase alfa, Hypophosphatasia, 28/08/2015, 9, Authorised (updated)
13/08/2019	Ebola (updated)
12/08/2019	Human medicines European public assessment report (EPAR): Ecansya (previously Capecitabine Krka) , capecitabine, Colonic Neoplasms, Breast

	Neoplasms, Colorectal Neoplasms, Stomach Neoplasms, 20/04/2012, 10, Authorised (updated)
12/08/2019	Human medicines European public assessment report (EPAR): Stocrin , efavirenz, HIV Infections, 28/05/1999, 41, Authorised (updated)
12/08/2019	Human medicines European public assessment report (EPAR): Entyvio , vedolizumab, Colitis, Ulcerative, Crohn Disease, 22/05/2014, 13, Authorised (updated)
12/08/2019	Human medicines European public assessment report (EPAR): Constella , linaclotide, Irritable Bowel Syndrome, 26/11/2012, 18, Authorised (updated)
12/08/2019	Orphan designation: Zanubrutinib for the: Treatment of lymphoplasmacytic lymphoma, 29/05/2019, Positive
12/08/2019	Orphan designation: Sodium benzoate , sodium phenylacetate for the: Treatment of carbamoyl-phosphate synthase-1 deficiency, 29/05/2019, Positive
12/08/2019	Orphan designation: Sodium benzoate , sodium phenylacetate for the: Treatment of citrullinaemia type 1, 29/05/2019, Positive

NOTICE TO APPLICANTS

No updates since December 15th 2017.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

No updates since August 12th 2019.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since July 31th 2019.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

19.08.2019	Rote-Hand-Brief: Beriate	zum Beitrag
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PHARMEUROPA TEXTS FOR COMMENT

Text	Monograph number	Group	Issue	Deadline
Orientvine stem	2450	TCM	31.4	31.12.2019