

TABLE OF CONTENTS

| | |
|--|---|
| HEADS OF AGENCIES – CMDH | 1 |
| HEADS OF AGENCIES – PAEDIATRIC REGULATION | 1 |
| EUROPEAN MEDICINES AGENCY (EMA) | 1 |
| NOTICE TO APPLICANTS..... | 8 |
| BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)..... | 8 |
| BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)..... | 8 |
| PEI - VIGILANZ (SPECIFIC FOR GERMANY) | 8 |
| PHARMEUROPA TEXTS FOR COMMENT | 8 |

HEADS OF AGENCIES – CMDh

28 January 2020

[NEW - January 2020 CMDh Agenda](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

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| 03/02/2020 | Human medicines European public assessment report (EPAR): VeraSeal , human fibrinogen, human thrombin, Hemostasis, Surgical, 10/11/2017, 2, Authorised (updated) |
| 03/02/2020 | Herbal medicinal product: Taraxaci folium , Taraxaci folium , F: Assessment finalised (updated) |
| 03/02/2020 | Administration and Corporate Management (updated) |
| 03/02/2020 | Other: Organisation chart: Administration and Corporate Management (updated) |
| 01/02/2020 | Pharmacovigilance fees: questions and answers (updated) |
| 31/01/2020 | Herbal medicinal product: Agropyri repentis rhizoma , Agropyri repentis rhizoma , F: Assessment finalised (updated) |
| 31/01/2020 | Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Agropyron repens (L.) P. Beauv., rhizoma - Revision 1 (new) |
| 31/01/2020 | Herbal medicinal product: Caryophyllii floris aetheroleum , Caryophyllii floris aetheroleum , F: Assessment finalised (updated) |
| 31/01/2020 | Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Syzygium aromaticum (L.) Merrill et L. M. Perry (Eugenia caryophyllus (C. Spreng.) Bull. et Harr.), aetheroleum - Revision 1 (new) |
| 31/01/2020 | Herbal medicinal product: Carvi fructus , Carvi fructus , F: Assessment finalised (updated) |
| 31/01/2020 | Herbal medicinal product: Carvi aetheroleum , Carvi aetheroleum , F: Assessment finalised (updated) |
| 31/01/2020 | Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Carum carvi L., aetheroleum - Revision 1 (new) |
| 31/01/2020 | Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Carum carvi L., fructus - Revision 1 (new) |

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| 31/01/2020 | Template or form: Presubmission request form for a EMA procedure prior to the submission of a marketing authorisation application or Article 58 Application (updated) |
| 31/01/2020 | Herbal medicinal product: Zingiberis rhizoma, Zingiberis rhizoma, F: Assessment finalised (updated) |
| 31/01/2020 | Template or form: Marketing authorisation application (MAA) - pre-submission meeting request form (human) (updated) |
| 31/01/2020 | Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Zingiber officinale Roscoe, rhizoma - Revision 1 (new) |
| 31/01/2020 | Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Chamaemelum nobile (L.) All. (Anthemis nobilis L.), flos - Revision 1 (new) |
| 31/01/2020 | Regulatory and procedural guideline: IRIS guide to registration (updated) |
| 31/01/2020 | Herbal medicinal product: Chamomillae romanae flos, Chamomillae romanae flos, F: Assessment finalised (updated) |
| 31/01/2020 | Herbal medicinal product: Colae semen, Colae semen, F: Assessment finalised (updated) |
| 31/01/2020 | Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Cola nitida (Vent.) Schott et Endl. (C. vera K. Schum.); Cola acuminata (P. Beauv.) Schott et Endl. (Sterculia acuminata P. Beauv.), semen - Revision 1 (new) |
| 31/01/2020 | Herbal medicinal product: Millefolii herba, Millefolii herba, F: Assessment finalised (updated) |
| 31/01/2020 | Herbal medicinal product: Pelargonii radix, Pelargonii radix, F: Assessment finalised (updated) |
| 31/01/2020 | Herbal - Call for data: Call for scientific data for the revision of the monograph on Pelargonium sidoides DC; Pelargonium reniforme Curt., radix - Revision 1 (new) |
| 31/01/2020 | Herbal – European Union list entry: Draft European Union list entry on Achillea millefolium L., herba - Revision 1 (new) |
| 31/01/2020 | Herbal - HMPC opinion on a European Union herbal monograph: Draft European Union herbal monograph on Achillea millefolium L., herba - Revision 1 (new) |
| 31/01/2020 | Other: European authorities working to avoid shortages of medicines due to Brexit – Questions and answers (updated) |
| 31/01/2020 | Regulatory and procedural guideline: Substances considered as not falling within the scope of Regulation (EC) No. 470/20091, with regard to residues of veterinary medicinal products in foodstuffs of animal origin (updated) |
| 31/01/2020 | Assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products (updated) |
| 31/01/2020 | Scientific guideline: Question and answer document in support of the guideline on the assessment of persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) substances in veterinary medicinal products (EMA/CVMP/ERA/52740/2012) (new) |
| 31/01/2020 | News and press releases: UK withdrawal from the EU on 31 January 2020 |
| 31/01/2020 | Brexit: the United Kingdom's withdrawal from the European Union (updated) |
| 31/01/2020 | Brexit-related guidance for companies (updated) |
| 31/01/2020 | News and press releases: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 27-30 January 2020 |
| 31/01/2020 | Referral: Estradiol-containing (0.01% w/w) medicinal products for topical use , estradiol , Linoladiol, Linoladiol N, Linoladiol Estradiol, Estradiol Wolff, Montadiol, Article 31 referrals, Position provided by CMDh, 30/01/2020, 31/01/2020 (updated) |
| 31/01/2020 | Summary of opinion: Suliqua, insulin glargine / lixisenatide, 30/01/2020, Positive |
| 31/01/2020 | Summary of opinion: Nustendi, bempedoic acid, ezetimibe, 30/01/2020, Positive |

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| 31/01/2020 | Summary of opinion: Vaxchora , Cholera vaccine (recombinant, live, oral), 30/01/2020, Positive |
| 31/01/2020 | Summary of opinion: Rezolsta , darunavir / cobicistat, 30/01/2020, Positive |
| 31/01/2020 | Withdrawn application: Idhifa , enasidenib, Date of withdrawal: 06/12/2019, Initial authorisation |
| 31/01/2020 | Summary of opinion: Ruxience , rituximab, 31/01/2020, Positive |
| 31/01/2020 | News and press releases: First treatment for acute hepatic porphyria |
| 31/01/2020 | Summary of opinion: Ameluz , 5-aminolevulinic acid hydrochloride, 30/01/2020, Positive |
| 31/01/2020 | Summary of opinion: Cinacalcet Accordpharma , cinacalcet, 30/01/2020, Positive |
| 31/01/2020 | News and press releases: First oral GLP-1 treatment for type 2 diabetes |
| 31/01/2020 | Summary of opinion: Staquis , crisaborole, 30/01/2020, Positive |
| 31/01/2020 | Summary of opinion: Arsenic trioxide Mylan , arsenic trioxide, 30/01/2020, Positive |
| 31/01/2020 | Summary of opinion: Azacitidine Mylan , azacitidine, 30/01/2020, Positive |
| 31/01/2020 | Summary of opinion: Budesonide / Formoterol Teva Pharma B.V. , budesonide / formoterol fumarate dihydrate, 30/01/2020, Positive |
| 31/01/2020 | Summary of opinion: Trepulmix , treprostinil sodium, 30/01/2020, Positive |
| 31/01/2020 | Summary of opinion: Liumjev , insulin lispro, 30/01/2020, Positive |
| 31/01/2020 | Summary of opinion: Givlaari , givosiran, 30/01/2020, Positive |
| 31/01/2020 | Summary of opinion: Tybost , cobicistat, 30/01/2020, Positive |
| 31/01/2020 | Summary of opinion: Venclyxto , venetoclax, 30/01/2020, Positive |
| 31/01/2020 | Summary of opinion: Nubeqa , darolutamide, 30/01/2020, Positive |
| 31/01/2020 | Summary of opinion: Azacitidine betapharm , azacitidine, 30/01/2020, Positive |
| 31/01/2020 | Summary of opinion: MabThera , rituximab, 30/01/2020, Positive |
| 31/01/2020 | Withdrawn application: Keytruda , pembrolizumab, Date of withdrawal: 10/12/2019, Post-authorisation |
| 31/01/2020 | Summary of opinion: Rybelsus , semaglutide, 30/01/2020, Positive |
| 31/01/2020 | Human medicines European public assessment report (EPAR): Nerlynx , neratinib, Breast Neoplasms, 31/08/2018, 4, Authorised (updated) |
| 30/01/2020 | Human medicines European public assessment report (EPAR): Miglustat Dipharma , miglustat, Gaucher Disease, 18/02/2019, 2, Authorised (updated) |
| 30/01/2020 | Human medicines European public assessment report (EPAR): Luxturna , voretigene neparvovec, Leber Congenital Amaurosis, Retinitis Pigmentosa, 22/11/2018, 2, Authorised (updated) |
| 30/01/2020 | Human medicines European public assessment report (EPAR): Zelboraf , vemurafenib, Melanoma, 17/02/2012, 19, Authorised (updated) |
| 30/01/2020 | Human medicines European public assessment report (EPAR): Rebif , interferon beta-1a, Multiple Sclerosis, 03/05/1998, 36, Authorised (updated) |
| 30/01/2020 | Human medicines European public assessment report (EPAR): Strensiq , asfotase alfa, Hypophosphatasia, 28/08/2015, 11, Authorised (updated) |
| 30/01/2020 | Summary of opinion: Nilemdo , bempedoic acid, 30/01/2020, Positive |
| 30/01/2020 | Human medicines European public assessment report (EPAR): Carmustine Obvius , carmustine, Hodgkin Disease, Lymphoma, Non-Hodgkin, 18/07/2018, 3, Authorised (updated) |
| 30/01/2020 | Human medicines European public assessment report (EPAR): Renagel , sevelamer, Renal Dialysis, Hyperphosphatemia, 28/01/2000, 32, Authorised (updated) |
| 30/01/2020 | Human medicines European public assessment report (EPAR): Benepali , etanercept, Arthritis, Psoriatic, Arthritis, Rheumatoid, Psoriasis, 13/01/2016, 11, Authorised (updated) |
| 30/01/2020 | Human medicines European public assessment report (EPAR): Esbriet , Pirfenidone, Idiopathic Pulmonary Fibrosis, 27/02/2011, 25, Authorised (updated) |
| 30/01/2020 | Human medicines European public assessment report (EPAR): Opdivo , nivolumab, Melanoma, Hodgkin Disease, Carcinoma, Renal Cell, Carcinoma, Non-Small-Cell Lung, 19/06/2015, 30, Authorised (updated) |

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| 30/01/2020 | Human medicines European public assessment report (EPAR): Zoledronic acid Actavis , zoledronic acid monohydrate, Fractures, Bone, 20/04/2012, 12, Authorised (updated) |
| 30/01/2020 | Regulatory and procedural guideline: List of centrally authorised products requiring a notification of a change for update of annexes (updated) |
| 30/01/2020 | Agenda: Agenda - PDCO agenda of the 28-31 January 2020 meeting (new) |
| 30/01/2020 | Human medicines European public assessment report (EPAR): Erbitux , cetuximab, Head and Neck Neoplasms, Colorectal Neoplasms, 29/06/2004, 28, Authorised (updated) |
| 30/01/2020 | Agenda: Agenda-CHMP agenda of the 27_30 January 2020 meeting (updated) |
| 29/01/2020 | Innovation in medicines (updated) |
| 29/01/2020 | Regulatory and procedural guideline: Guidance for applicants on a pilot for Simultaneous National Scientific Advice (SNSA) (new) |
| 29/01/2020 | Minutes: Minutes of the COMP meeting 8-10 October 2019 (new) |
| 29/01/2020 | Veterinary medicines European public assessment report (EPAR): Coliprotec F4 , live non-pathogenic Escherichia coli O8:K87, 16/03/2015, 2, Authorised (updated) |
| 29/01/2020 | European Medicines Agency EORTC workshop on novel PRO and QoL approaches in cancer clinical research , European Medicines Agency, Amsterdam, the Netherlands, from 12/03/2020 to 13/03/2020 |
| 29/01/2020 | Veterinary medicines European public assessment report (EPAR): Meloxoral , meloxicam, 19/11/2010, 6, Authorised (updated) |
| 29/01/2020 | ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the Eudra Vigilance System - Amsterdam , Amsterdam, The Netherlands, from 04/03/2020 to 06/03/2020 |
| 29/01/2020 | ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the Eudra Vigilance System - Dublin , Dublin, Ireland, from 09/03/2020 to 11/03/2020 |
| 29/01/2020 | ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the Eudra Vigilance System - Madrid , Madrid, Spain, from 25/03/2020 to 27/03/2020 |
| 29/01/2020 | ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the Eudra Vigilance System - Bucharest , Bucharest, Romania, from 01/04/2020 to 03/04/2020 |
| 29/01/2020 | ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the Eudra Vigilance System - Prague , Prague, Czechia, from 22/04/2020 to 24/04/2020 |
| 29/01/2020 | ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the Eudra Vigilance System - Amsterdam , Amsterdam, Netherlands, from 06/05/2020 to 08/05/2020 |
| 29/01/2020 | ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the Eudra Vigilance System - Lisbon , Lisbon, Portugal, from 11/05/2020 to 13/05/2020 |
| 29/01/2020 | ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the Eudra Vigilance System - Vienna , Vienna, Austria, from 11/05/2020 to 13/05/2020 |
| 29/01/2020 | ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the Eudra Vigilance System - Paris , Paris, France, from 08/06/2020 to 10/06/2020 |
| 29/01/2020 | ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the Eudra Vigilance System - Amsterdam , Amsterdam, Netherlands, from 15/06/2020 to 17/06/2020 |
| 29/01/2020 | ISO/ICH E2B(R3) Individual Case Safety Reporting in the EU: Hands-on training course using the Eudra Vigilance System - Munich , Munich, Germany, from 29/06/2020 to 01/07/2020 |

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| 29/01/2020 | Electronic product information for human medicines in the European Union – key principles (updated) |
| 29/01/2020 | Regulatory and procedural guideline: Electronic product information for human medicines in the European Union - key principles (new) |
| 29/01/2020 | Other: Electronic product information for human medicines in the European Union - Contributions received following public consultation (partially anonymised) (new) |
| 29/01/2020 | Other: Electronic product information for human medicines in the European Union - Categorised comments received following public consultation (partially anonymised) (new) |
| 29/01/2020 | Report: Report on public consultation on the 'Electronic product information for human medicines in the European Union - draft key principles' (new) |
| 29/01/2020 | News and press releases: Key principles for the use of electronic product information for EU medicines |
| 29/01/2020 | Press Release: Key principles for the use of electronic product information for EU medicines (new) |
| 29/01/2020 | Product-information requirements (updated) |
| 29/01/2020 | Human medicines European public assessment report (EPAR): Lemtrada, alemtuzumab, Multiple Sclerosis, 12/09/2013, 9, Authorised (updated) |
| 29/01/2020 | Minutes: Minutes of the HMPC 13-15 May 2019 meeting (new) |
| 29/01/2020 | 2020 European Union Good Clinical Practice Inspectors Working Group workshop , Seeheim-Jugenheim (close to Frankfurt am Main), Germany, from 30/09/2020 to 02/10/2020 |
| 29/01/2020 | Committee meeting report: COMP meeting report on the review of applications for orphan designation: January 2020 (new) |
| 29/01/2020 | Newsletter: News bulletin for small and medium-sized enterprises - Issue 48 (new) |
| 29/01/2020 | Human medicines European public assessment report (EPAR): NovoEight, turoctocog alfa, Hemophilia A, 13/11/2013, 10, Authorised (updated) |
| 29/01/2020 | Other: Extended Telematics strategy and implementation roadmap 2019-2020 (new) |
| 29/01/2020 | Other: Information Technology Directors Group - List of nominated members (alphabetically by country) (updated) |
| 29/01/2020 | Minutes: Minutes of the HMPC 8-10 July 2019 meeting (new) |
| 29/01/2020 | Minutes: Minutes of the CAT meeting 9-11 October 2019 (new) |
| 29/01/2020 | List of medicines under additional monitoring (updated) |
| 29/01/2020 | Medicines under additional monitoring: Annex V - List of hydroxyethyl starch (HES)-containing medicinal products in the European Union (updated) |
| 29/01/2020 | Medicines under additional monitoring: Annex V - List of hydroxyethyl starch (HES)-containing medicinal products in the European Union (updated) |
| 29/01/2020 | Medicines under additional monitoring: List of medicinal products under additional monitoring (updated) |
| 29/01/2020 | Medicines under additional monitoring: List of medicinal products under additional monitoring (updated) |
| 29/01/2020 | Committee meeting report: CAT monthly report of application procedures, guidelines and related documents on advanced therapies: December 2019 (new) |
| 28/01/2020 | Referral: Lemtrada , alemtuzumab, Article 20 procedures, European Commission final decision, 14/11/2019, 16/01/2020, 28/01/2020 (updated) |
| 28/01/2020 | Veterinary medicines European public assessment report (EPAR): ProteqFlu , Vcp 2242 virus / Vcp1529 virus / Vcp1533 virus / vCP3011 virus, 06/03/2003, 12, Authorised (updated) |
| 28/01/2020 | Veterinary medicines European public assessment report (EPAR): Oncept IL-2 , vCP1338 virus, 03/05/2013, 3, Authorised (updated) |
| 28/01/2020 | Veterinary medicines European public assessment report (EPAR): ProteqFlu-Te , Clostridium tetani toxoid / Vcp 2242 virus / Vcp1529 virus / Vcp1533 virus / vCP3011 virus, 06/03/2003, 12, Authorised (updated) |

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| 28/01/2020 | Veterinary medicines European public assessment report (EPAR): Proteq West Nile , West Nile recombinant canarypox virus (vCP2017 virus), 05/08/2011, 12, Authorised (updated) |
| 28/01/2020 | Human medicines European public assessment report (EPAR): Clopidogrel Zentiva (previously Clopidogrel Winthrop) , clopidogrel, Stroke, Peripheral Vascular Diseases, Myocardial Infarction, Acute Coronary Syndrome, 15/07/2008, 25, Authorised (updated) |
| 28/01/2020 | Human medicines European public assessment report (EPAR): Hizentra , human normal immunoglobulin (SCIg), Immunologic Deficiency Syndromes, 14/04/2011, 19, Authorised (updated) |
| 28/01/2020 | Human medicines European public assessment report (EPAR): Cometriq , cabozantinib, Thyroid Neoplasms, 21/03/2014, 16, Authorised (updated) |
| 28/01/2020 | Human medicines European public assessment report (EPAR): Grastofil , filgrastim, Neutropenia, 17/10/2013, 11, Authorised (updated) |
| 28/01/2020 | Human medicines European public assessment report (EPAR): HBVaxPro , hepatitis B, recombinant surface antigen, Hepatitis B, Immunization, 27/04/2001, 26, Authorised (updated) |
| 28/01/2020 | Periodic safety update single assessment: Measles vaccine (live attenuated): List of nationally authorised medicinal products - PSUSA/00001938/201905 (new) |
| 28/01/2020 | Periodic safety update single assessment: Fusidic acid (systemic use): List of nationally authorised medicinal products - PSUSA/00010226/201905 (new) |
| 28/01/2020 | News and press releases: Categorisation of antibiotics used in animals promotes responsible use to protect public and animal health |
| 28/01/2020 | Human medicines European public assessment report (EPAR): Qarziba (previously Dinutuximab beta EUSA and Dinutuximab beta Apeiron) , dinutuximab beta, Neuroblastoma, 08/05/2017, 8, Authorised (updated) |
| 28/01/2020 | Press Release: Categorisation of antibiotics used in animals promotes responsible use to protect public and animal health (new) |
| 28/01/2020 | Report: Categorisation of antibiotics for use in animals for prudent and responsible use (new) |
| 28/01/2020 | Report: Categorisation of antibiotics in the European Union - Answer to the request from the European Commission for updating the scientific advice on the impact on public health and animal health of the use of antibiotics in animals (new) |
| 28/01/2020 | Overview of comments: Overview of comments - 'Categorisation of antibiotics in the European Union - Answer to the request from the European Commission for updating the scientific advice on the impact on public health and animal health of the use of antibiotics in animals' (new) |
| 28/01/2020 | Advice on impacts of using antimicrobials in animals (updated) |
| 28/01/2020 | Human medicines European public assessment report (EPAR): Kovaltry , octocog alfa, Hemophilia A, 18/02/2016, 8, Authorised (updated) |
| 28/01/2020 | Human medicines European public assessment report (EPAR): Ultibro Breezhaler , indacaterol, Glycopyrronium bromide, Pulmonary Disease, Chronic Obstructive, 19/09/2013, 11, Authorised (updated) |
| 28/01/2020 | Human medicines European public assessment report (EPAR): Axumin , Fluciclovine (18F), Prostatic Neoplasms, Radionuclide Imaging, 21/05/2017, 8, Authorised (updated) |
| 28/01/2020 | Human medicines European public assessment report (EPAR): Stocrin , efavirenz, HIV Infections, 28/05/1999, 42, Authorised (updated) |
| 28/01/2020 | Committee meeting report: Monthly report on application procedures, guidelines and related documents for veterinary medicines: November 2019 (new) |
| 28/01/2020 | Human medicines European public assessment report (EPAR): Idacio , adalimumab, Arthritis, Rheumatoid, Arthritis, Juvenile Rheumatoid, Psoriasis, Arthritis, Psoriatic, Spondylitis, Ankylosing, Uveitis, Hidradenitis Suppurativa, Colitis, Ulcerative, Crohn Disease, 02/04/2019, 3, Authorised (updated) |

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| 28/01/2020 | Human medicines European public assessment report (EPAR): Ongentys , opicapone, Parkinson Disease, 24/06/2016, 4, Authorised (updated) |
| 28/01/2020 | Human medicines European public assessment report (EPAR): Samsca , Tolvaptan, Inappropriate ADH Syndrome, 02/08/2009, 12, Authorised (updated) |
| 28/01/2020 | Human medicines European public assessment report (EPAR): HyQvia , Human normal immunoglobulin, Immunologic Deficiency Syndromes, 16/05/2013, 13, Authorised (updated) |
| 28/01/2020 | Supporting SMEs (updated) |
| 28/01/2020 | Patients' and Consumers' Working Party (updated) |
| 28/01/2020 | Human medicines European public assessment report (EPAR): Lucentis , ranibizumab, Wet Macular Degeneration, Macular Edema, Myopia, Degenerative, Diabetes Complications, 22/01/2007, 36, Authorised (updated) |
| 28/01/2020 | Minutes: Minutes of the CHMP meeting 11-14 November 2019 (new) |
| 28/01/2020 | Orphan designation: autologous CD34+ haematopoietic stem and progenitor cells genetically modified with the lentiviral vector IDUA LV, encoding for the alpha-L-iduronidase cDNA for the: Treatment of mucopolysaccharidosis type I, 26/10/2018, Positive (updated) |
| 27/01/2020 | Human medicines European public assessment report (EPAR): Orphacol , cholic acid, Digestive System Diseases, Metabolism, Inborn Errors, 12/09/2013, 25/05/2012, 8, Authorised (updated) |
| 27/01/2020 | Human medicines European public assessment report (EPAR): Delstrigo , doravirine, lamivudine, tenofovir disoproxil fumarate, HIV Infections, 22/11/2018, 4, Authorised (updated) |
| 27/01/2020 | Periodic safety update single assessment: Cidofovir : List of nationally authorised medicinal products - PSUSA/00010558/201906 (new) |
| 27/01/2020 | Veterinary medicines European public assessment report (EPAR): Respiporc FLUpan H1N1 , inactivated influenza A virus/humanstrain: A/Jena/VI5258/2009(H1N1)pdm09, 16/05/2017, 2, Authorised (updated) |
| 27/01/2020 | Periodic safety update single assessment: Ethinylestradiol / levonorgestrel: CMDh Scientific conclusions, amendments to product information and implementation timetable - PSUSA/00001309/201904 (new) |
| 27/01/2020 | History of EMA (updated) |
| 27/01/2020 | Human medicines European public assessment report (EPAR): Ajovy , fremanezumab, Migraine Disorders, 28/03/2019, 2, Authorised (updated) |
| 27/01/2020 | Human medicines European public assessment report (EPAR): Polivy , polatuzumab vedotin, Lymphoma, B-Cell, 16/01/2020, Authorised |
| 27/01/2020 | Orphan designation: polatuzumab vedotin for the: Treatment of diffuse large B-cell lymphoma, 16/04/2018, Positive (updated) |
| 27/01/2020 | Human medicines European public assessment report (EPAR): Yervoy , Ipilimumab, Melanoma, 12/07/2011, 31, Authorised (updated) |
| 27/01/2020 | PIP - Notification of discontinuation of a paediatric development which is covered by an agreed PIP decision: Nicardipine: List of nationally authorised medicinal products - PSUSA/00002149/201905 (new) |
| 27/01/2020 | Report: PDCO monthly report of opinions on paediatric investigation plans and other activities 9-11 December 2019 (new) |
| 27/01/2020 | Human medicines European public assessment report (EPAR): Vimpat , lacosamide, Epilepsy, 29/08/2008, 31, Authorised (updated) |
| 27/01/2020 | Agenda: Agenda - CAT agenda of the 22-24 January 2020 meeting (new) |
| 27/01/2020 | Human medicines European public assessment report (EPAR): Doptelet , avatrombopag, Thrombocytopenia, 1, Authorised (updated) |
| 27/01/2020 | Periodic safety update single assessment: Ethinylestradiol / levonorgestrel: List of nationally authorised medicinal products - PSUSA/00001309/201904 (new) |

NOTICE TO APPLICANTS

No updates since November 28th 2019.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

No updates since January 27th 2020.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since January 9th 2020

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

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| 24.01.2020 | Rote-Hand-Brief: Lemtrada (Alemtuzumab) |
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PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmedeuropa updates will be presented quarterly.