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HEADS OF AGENCIES – CMDh

8 January 2020

[UPDATE - Information on national timeslot booking systems and recommendations for requests to act as RMS](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

13/01/2020	Human medicines European public assessment report (EPAR): Faslodex , fulvestrant, Breast Neoplasms, 09/03/2004, 21, Authorised (updated)
13/01/2020	Human medicines European public assessment report (EPAR): Blitzima , rituximab, Lymphoma, Non-Hodgkin, Leukemia, Lymphocytic, Chronic, B-Cell, 13/07/2017, 8, Authorised (updated)
13/01/2020	Human medicines European public assessment report (EPAR): Nordimet , Methotrexate, Arthritis, Psoriatic, Psoriasis, Arthritis, Juvenile Rheumatoid, Arthritis, Rheumatoid, 18/08/2016, 10, Authorised (updated)
13/01/2020	Orphan designation: Two allogeneic irradiated pancreatic tumour cell lines for the: Treatment of pancreatic cancer, 11/01/2016, Withdrawn (updated)
13/01/2020	Orphan designation: Live attenuated Listeria monocytogenes delta actA/delta inlB strain expressing human mesothelin for the: Treatment of pancreatic cancer, 11/01/2016, Withdrawn (updated)
13/01/2020	Orphan designation: Live attenuated Listeria monocytogenes delta actA/delta inlB strain expressing human mesothelin for the: Treatment of malignant mesothelioma, 14/12/2015, Withdrawn (updated)
13/01/2020	Orphan designation: Ulocuplumab for the: Treatment of acute myeloid leukaemia, 12/02/2015, Withdrawn (updated)
13/01/2020	Orphan designation: Autologous CD34+ haematopoietic stem cells transduced with lentiviral vector encoding the human beta A-T87Q-globin gene for the treatment of sickle cell disease for the: The treatment of sickle cell disease, 29/04/2014, Positive (updated)
13/01/2020	Human medicines European public assessment report (EPAR): Lorviqua , Lorlatinib, Carcinoma, Non-Small-Cell Lung, 06/05/2019, 1, Authorised (updated)

10/01/2020	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, 75, Authorised (updated)
10/01/2020	Veterinary medicines European public assessment report (EPAR): Purevax RCP FeLV , Attenuated feline rhinotracheitis herpesvirus (FHV F2 strain), inactivated feline Calicivirus antigens (FCV 431 and G1 strains), attenuated feline panleucopenia virus (PLI IV), FeLV recombinant canarypox virus (vCP97), 23/02/2005, 10, Authorised (updated)
10/01/2020	Human medicines European public assessment report (EPAR): Iscover , clopidogrel, Stroke, Peripheral Vascular Diseases, Atrial Fibrillation, Myocardial Infarction, Acute Coronary Syndrome, 14/07/1998, 41, Authorised (updated)
10/01/2020	Human medicines European public assessment report (EPAR): Zydelig , Idelalisib, Lymphoma, Non-Hodgkin, Leukemia, Lymphocytic, Chronic, B-Cell, 18/09/2014, 16, Authorised (updated)
10/01/2020	Human medicines European public assessment report (EPAR): Tenofovir disoproxil Mylan , tenofovir disoproxil, HIV Infections, 08/12/2016, 8, Authorised (updated)
10/01/2020	Human medicines European public assessment report (EPAR): Kuvan , Sapropterin dihydrochloride, Phenylketonurias, 02/12/2008, 19, Authorised (updated)
10/01/2020	Periodic safety update single assessment: Ezetimibe / simvastatin: CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - PSUSA/00001347/201903
10/01/2020	Human medicines European public assessment report (EPAR): Poteligeo , Mogamulizumab, Sezary Syndrome, Mycosis Fungoides, 22/11/2018, 1, Authorised (updated)
10/01/2020	Human medicines European public assessment report (EPAR): Ketoconazole HRA , Ketoconazole, Cushing Syndrome, 18/11/2014, 10, Authorised (updated)
10/01/2020	Regulatory and procedural guideline: IRIS guide for Parallel Distribution applicants (updated)
10/01/2020	Human medicines European public assessment report (EPAR): Trumenba , Neisseria meningitidis serogroup B fHbp (recombinant lipidated fHbp (factor H binding protein)) subfamily A; Neisseria meningitidis serogroup B fHbp (recombinant lipidated fHbp (factor H binding protein)) subfamily B, Meningitis, Meningococcal, 24/05/2017, 6, Authorised (updated)
10/01/2020	Human medicines European public assessment report (EPAR): Xofigo , radium Ra223 dichloride, Prostatic Neoplasms, 13/11/2013, 10, Authorised (updated)
10/01/2020	Human medicines European public assessment report (EPAR): Xiapex , collagenase Clostridium histolyticum, Dupuytren Contracture, 28/02/2011, 20, Authorised (updated)
10/01/2020	Periodic safety update single assessment: Ezetimibe / simvastatin: List of nationally authorised medicinal products - PSUSA/00001347/201903
10/01/2020	Human medicines European public assessment report (EPAR): Firmagon , degarelix, Prostatic Neoplasms, 17/02/2009, 14, Authorised (updated)
10/01/2020	Human medicines European public assessment report (EPAR): Jardiance , empagliflozin, Diabetes Mellitus, Type 2, 22/05/2014, 17, Authorised (updated)
10/01/2020	Human medicines European public assessment report (EPAR): Mysimba , bupropion hydrochloride, naltrexone hydrochloride, Obesity, Overweight, 26/03/2015, 13, Authorised (updated)
10/01/2020	Other: Privacy Statement regarding the Experts database and the handling of competing interests of scientific committees' members and experts
10/01/2020	Human medicines European public assessment report (EPAR): Invokana , canagliflozin, Diabetes Mellitus, Type 2, 15/11/2013, 14, Authorised (updated)
10/01/2020	Human medicines European public assessment report (EPAR): Fabrazyme , agalsidase beta, Fabry Disease, 03/08/2001, 27, Authorised (updated)

10/01/2020	Medicine evaluation figures (updated)
10/01/2020	News and press releases: Veterinary medicines: highlights of 2019
10/01/2020	Human medicines European public assessment report (EPAR): Besponsa , inotuzumab ozogamicin, Precursor Cell Lymphoblastic Leukemia-Lymphoma, 28/06/2017, 6, Authorised (updated)
10/01/2020	Report: Veterinary medicines highlights 2019
09/01/2020	Referral: Picato , ingenol mebutate , Article 20 procedures, Under evaluation, 09/01/2020 (updated)
09/01/2020	Human medicines European public assessment report (EPAR): Ixiaro , Japanese-encephalitis virus, inactivated (attenuated strain SA14-14-2 grown in vero cells), Encephalitis, Japanese, Immunization, 31/03/2009, 16, Authorised (updated)
09/01/2020	Human medicines European public assessment report (EPAR): Mepact , mifamurtide, Osteosarcoma, 06/03/2009, 15, Authorised (updated)
09/01/2020	Veterinary medicines European public assessment report (EPAR): Broadline , eprinomectin, fipronil, praziquantel, (S)-methoprene, 04/12/2013, 9, Authorised (updated)
09/01/2020	Human medicines European public assessment report (EPAR): Inflectra , infliximab, Arthritis, Psoriatic, Spondylitis, Ankylosing, Colitis, Ulcerative, Psoriasis, Crohn Disease, Arthritis, Rheumatoid, 09/09/2013, 24, Authorised (updated)
09/01/2020	Minutes: Minutes of the COMP meeting 10-12 September 2019
09/01/2020	News and press releases: Human medicines: highlights of 2019
09/01/2020	Report: Human medicines highlights 2019
09/01/2020	Veterinary medicines European public assessment report (EPAR): Purevax RC , attenuated feline rhinotracheitis herpesvirus (FHV F2 strain) / inactivated feline calicivirosis antigens (FCV 431 and G1 strains), 23/02/2005, 11, Authorised (updated)
09/01/2020	Human medicines European public assessment report (EPAR): Nivestim , filgrastim, Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer, 07/06/2010, 21, Authorised (updated)
09/01/2020	Human medicines European public assessment report (EPAR): Nityr , nitisinone, Tyrosinemias, 26/07/2018, 1, Authorised (updated)
09/01/2020	Veterinary medicines European public assessment report (EPAR): Purevax RCP , attenuated feline rhinotracheitis herpesvirus (FHV F2 strain) / inactivated feline calicivirosis antigens (FCV 431 and G1 strains), attenuated feline panleucopenia virus (PLI IV), 23/02/2005, 12, Authorised (updated)
09/01/2020	Human medicines European public assessment report (EPAR): Inhixa , enoxaparin sodium, Venous Thromboembolism, 15/09/2016, 12, Authorised (updated)
09/01/2020	Human medicines European public assessment report (EPAR): Seebri Breezhaler , Glycopyrronium bromide, Pulmonary Disease, Chronic Obstructive, 28/09/2012, 9, Authorised (updated)
09/01/2020	Human medicines European public assessment report (EPAR): Shingrix , Varicella Zoster Virus glycoprotein E antigen, Herpes Zoster, 21/03/2018, 3, Authorised (updated)
09/01/2020	Eligible healthcare professionals' organisations (updated)
09/01/2020	Human medicines European public assessment report (EPAR): Omidria , ketorolac, phenylephrine, Lens Implantation, Intraocular, Pain, Postoperative, 28/07/2015, 4, Authorised (updated)
09/01/2020	Veterinary medicines European public assessment report (EPAR): Neptra , florfenicol, Terbinafine hydrochloride, Mometasone furoate, 10/12/2019, Authorised
09/01/2020	Frequently asked questions about parallel distribution (updated)
08/01/2020	Human medicines European public assessment report (EPAR): Pregabalin Accord , pregabalin, Anxiety Disorders, Epilepsy, 28/08/2015, 7, Authorised (updated)

08/01/2020	Human medicines European public assessment report (EPAR): Xydalba , dalbavancin hcl, Soft Tissue Infections, Skin Diseases, Bacterial, 19/02/2015, 9, Authorised (updated)
08/01/2020	Human medicines European public assessment report (EPAR): Ebymect , dapagliflozin propanediol monohydrate, metformin hydrochloride, Diabetes Mellitus, Type 2, 15/11/2015, 13, Authorised (updated)
08/01/2020	Human medicines European public assessment report (EPAR): Conbriza , bazedoxifene, Osteoporosis, Postmenopausal, 17/04/2009, 13, Authorised (updated)
08/01/2020	Human medicines European public assessment report (EPAR): Tygacil , Tigecycline, Bacterial Infections, Skin Diseases, Bacterial, Soft Tissue Infections, 24/04/2006, 30, Authorised (updated)
08/01/2020	Human medicines European public assessment report (EPAR): Febuxostat Mylan , febuxostat, Hyperuricemia, Arthritis, Gouty, Gout, 15/06/2017, 3, Authorised (updated)
08/01/2020	Human medicines European public assessment report (EPAR): Daptomycin Hospira , daptomycin, Soft Tissue Infections, Skin Diseases, Bacterial, 22/03/2017, 7, Authorised (updated)
08/01/2020	Human medicines European public assessment report (EPAR): Saxenda , liraglutide, Obesity, Overweight, 23/03/2015, 8, Authorised (updated)
08/01/2020	Human medicines European public assessment report (EPAR): Ristaben , sitagliptin, Diabetes Mellitus, Type 2, 15/03/2010, 20, Authorised (updated)
08/01/2020	Veterinary medicines European public assessment report (EPAR): Mirataz , mirtazapine, 10/12/2019, Authorised
08/01/2020	Human medicines European public assessment report (EPAR): Darzalex , Daratumumab, Multiple Myeloma, 28/04/2017, 10, Authorised (updated)
08/01/2020	Regulatory and procedural guideline: IRIS guide to registration (updated)
08/01/2020	Regulatory and procedural guideline: IRIS guide for applicants (updated)
07/01/2020	Human medicines European public assessment report (EPAR): Tremfya , guselkumab, Psoriasis, 10/11/2017, 4, Authorised (updated)
07/01/2020	Human medicines European public assessment report (EPAR): Flixabi , infliximab, Spondylitis, Ankylosing, Arthritis, Rheumatoid, Crohn Disease, Colitis, Ulcerative, Arthritis, Psoriatic, Psoriasis, 26/05/2016, 11, Authorised (updated)
07/01/2020	Other: List of signals discussed at PRAC since September 2012 (updated)
07/01/2020	PRAC recommendation on signal: PRAC recommendations on signals adopted at the 25-28 November 2019 PRAC meeting
07/01/2020	Human medicines European public assessment report (EPAR): Kyprolis , carfilzomib, Multiple Myeloma, 19/11/2015, 15, Authorised (updated)
07/01/2020	Human medicines European public assessment report (EPAR): Edistride , dapagliflozin propanediol monohydrate, Diabetes Mellitus, Type 2, Diabetes Mellitus, Type 1, 09/11/2015, 12, Authorised (updated)
07/01/2020	Human medicines European public assessment report (EPAR): Vfend , voriconazole, Candidiasis, Mycoses, Aspergillosis, 19/03/2002, 46, Authorised (updated)
07/01/2020	Human medicines European public assessment report (EPAR): Tasigna , nilotinib, Leukemia, Myelogenous, Chronic, BCR-ABL Positive, 19/11/2007, 34, Authorised (updated)
07/01/2020	Other: Questions and answers on impact of European Union-United States mutual recognition agreement on marketing authorisation applications and relevant variations (updated)
07/01/2020	Human medicines European public assessment report (EPAR): TachoSil , human fibrinogen, human thrombin, Hemostasis, Surgical, 08/06/2004, 23, Authorised (updated)
07/01/2020	Human medicines European public assessment report (EPAR): Qtern , Saxagliptin, dapagliflozin propanediol monohydrate, Diabetes Mellitus, Type 2, 15/07/2016, 4, Authorised (updated)

07/01/2020	Eligible patients and consumers organisations (updated)
07/01/2020	Human medicines European public assessment report (EPAR): Senshio , ospemifene, Postmenopause, 14/01/2015, 9, Authorised (updated)
07/01/2020	Human medicines European public assessment report (EPAR): Neofordex , dexamethasone, Multiple Myeloma, 16/03/2016, 7, Authorised (updated)
06/01/2020	Human medicines European public assessment report (EPAR): Cerdelga , eliglustat, Gaucher Disease, 19/01/2015, 11, Authorised (updated)
06/01/2020	Human medicines European public assessment report (EPAR): SomaKit TOC , edotreotide, Neuroendocrine Tumors, Radionuclide Imaging, 08/12/2016, 4, Authorised (updated)
06/01/2020	Veterinary medicines European public assessment report (EPAR): Purevax RCPCCh FeLV , Attenuated feline rhinotracheitis herpesvirus (FHV F2 strain), inactivated feline Calicivirus antigens (FCV 431 and G1 strains), attenuated feline panleucopenia virus (PLI IV), FeLV recombinant canarypox virus (vCP97), 23/02/2005, 10, Authorised (updated)
06/01/2020	Human medicines European public assessment report (EPAR): NovoEight , turoctocog alfa, Hemophilia A, 13/11/2013, 9, Authorised (updated)
06/01/2020	EPAR - Procedural steps taken and scientific information after authorisation: SomaKit TOC : EPAR - Procedural steps taken and scientific information after authorisation (updated)
06/01/2020	Veterinary medicines European public assessment report (EPAR): Previcox , firocoxib, 13/09/2004, 22, Authorised (updated)
06/01/2020	Human medicines European public assessment report (EPAR): VeraSeal , human fibrinogen, human thrombin, Hemostasis, Surgical, 10/11/2017, 1, Authorised (updated)
06/01/2020	Human medicines European public assessment report (EPAR): Extavia , interferon beta-1b, Multiple Sclerosis, 20/05/2008, 22, Authorised (updated)
06/01/2020	Orphan designation: Three human monoclonal antibodies against the EBOV glycoprotein for the: Treatment of Ebola virus disease, 25/05/2018, Positive (updated)
06/01/2020	Orphan designation: Tipifarnib for the: Treatment of acute myeloid leukaemia, 10/03/2005, Positive (updated)
06/01/2020	Orphan designation: human monoclonal antibody against activin A for the: Treatment of fibrodysplasia ossificans progressiva, 18/11/2016, Positive (updated)
06/01/2020	Human medicines European public assessment report (EPAR): Vanflyta , quizartinib dihydrochloride, Leukemia, Myeloid, Acute, 19/12/2019, Refused
06/01/2020	Veterinary medicines European public assessment report (EPAR): Afoxolaner Merial , afoxolaner, 20/05/2019, Authorised (updated)
06/01/2020	Veterinary medicines European public assessment report (EPAR): Bravecto , fluralaner, 11/02/2014, 10, Authorised (updated)
06/01/2020	Veterinary medicines European public assessment report (EPAR): Purevax FeLV , feline leukaemia virus recombinant canarypox virus (vCP97), 13/04/2000, 7, Authorised (updated)
06/01/2020	Human medicines European public assessment report (EPAR): Rxulti , brexpiprazole, Schizophrenia, 26/07/2018, 2, Authorised (updated)
06/01/2020	Human medicines European public assessment report (EPAR): Tegsedi , inotersen sodium, Amyloidosis, 05/07/2018, 4, Authorised (updated)
06/01/2020	Human medicines European public assessment report (EPAR): Ocrevus , ocrelizumab, Multiple Sclerosis, 08/01/2018, 5, Authorised (updated)
06/01/2020	Procurement (updated)
06/01/2020	Procurement: Guidebook for Tenderers (revised December 2019) (updated)
06/01/2020	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)
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NOTICE TO APPLICANTS

No updates since November 28th 2019.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

No updates since January 02nd 2020.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

09.01.2020	Formulare - Medizinprodukte Neues Meldeformular für Hersteller und Bevollmächtigte: Die europäischen Behörden haben sich zusammen mit den Herstellerverbänden auf ein neues Meldeformular geeinigt. Das BfArM hat die Version 2.27 am 31.12.2019 offiziell zurückgezogen. Damit ist per 1.1.2020 ausschließlich die Version 7.2 für Vorkommismeldungen zu verwenden. Auf § 7 Absatz 2 der Medizinprodukte-Sicherheitsplanverordnung wird hingewiesen.
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PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since November 15th 2019.

PHARMEUROPA TEXTS FOR COMMENT

No updates since January 06th 2020.