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HEADS OF AGENCIES – CMDh

21 November 2019

[NEW - Report from the meeting held on 12-14 November 2019](#)

20 November 2019

[NEW - October 2019 CMDh Minutes](#)

19 November 2019

[UPDATE - List of safety concerns per approved Risk Management Plan \(RMP\) of active substances per product](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

EUROPEAN MEDICINES AGENCY (EMA)

25/11/2019	Other: List of signals discussed at PRAC since September 2012 (updated)
25/11/2019	PRAC recommendation on signal: PRAC recommendations on signals adopted at the 28-31 October 2019 PRAC meeting
25/11/2019	Other: New product information wording: extracts from PRAC recommendations on signals adopted at the 28-31 October 2019 PRAC
22/11/2019	Regulatory awareness session on medical devices (Webinar) , European Medicines Agency, Amsterdam, the Netherlands, from 02/12/2019 to 02/12/2019
22/11/2019	Ebola (updated)
22/11/2019	Human medicines European public assessment report (EPAR): Ivozall , clofarabine, Precursor Cell Lymphoblastic Leukemia-Lymphoma, 14/11/2019, Authorised
22/11/2019	Human medicines European public assessment report (EPAR): Silodyx , silodosin, Prostatic Hyperplasia, 29/01/2010, 13, Authorised (updated)
22/11/2019	Minutes: Minutes of the CAT meeting 17-19 July 2019
22/11/2019	Other: EMA tracking tool: relocation to Amsterdam - Main milestones (updated)

22/11/2019	Human medicines European public assessment report (EPAR): Trevicta (previously Paliperidone Janssen) , paliperidone palmitate, Schizophrenia, 05/12/2014, 9, Authorised (updated)
22/11/2019	Human medicines European public assessment report (EPAR): Inlyta , axitinib, Carcinoma, Renal Cell, 03/09/2012, 12, Authorised (updated)
22/11/2019	Ethanol (updated)
22/11/2019	Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (updated)
22/11/2019	Scientific guideline: Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (SANTE-2017-11668) - Revision 1
22/11/2019	Scientific guideline: Information for the package leaflet regarding ethanol used as an excipient in medicinal products for human use
21/11/2019	Minor uses / minor species and limited markets (updated)
21/11/2019	Scientific guideline: Concept paper for the revision of scientific guidelines on limited market for veterinary medicinal products
21/11/2019	Concept paper for the revision of scientific guidelines on limited market for veterinary medicinal products
21/11/2019	Report: Decision on amending budget No 1-2019
21/11/2019	Human medicines European public assessment report (EPAR): Instanyl , Fentanyl citrate, Pain, Cancer, 20/07/2009, 22, Authorised (updated)
21/11/2019	Human medicines European public assessment report (EPAR): Edistride , dapagliflozin propanediol monohydrate, Diabetes Mellitus, Type 2, Diabetes Mellitus, Type 1, 09/11/2015, 11, Authorised (updated)
21/11/2019	Human medicines European public assessment report (EPAR): Erelzi , etanercept, Arthritis, Psoriatic, Psoriasis, Arthritis, Juvenile Rheumatoid, Arthritis, Rheumatoid, Spondylitis, Ankylosing, 23/06/2017, 5, Authorised (updated)
21/11/2019	Human medicines European public assessment report (EPAR): Fulphila , pegfilgrastim, Neutropenia, 20/11/2018, 2, Authorised (updated)
21/11/2019	Periodic safety update single assessment: Acetylsalicylic acid: List of nationally authorised medicinal products - PSUSA/00000039/201902
21/11/2019	Periodic safety update single assessment: Acetylsalicylic acid: CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - PSUSA/00000039/201902
21/11/2019	Other: From laboratory to patient: the journey of a centrally authorised medicine (updated)
21/11/2019	Report: Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 11-14 November 2019
21/11/2019	Report: List of products granted eligibility to PRIME (updated)
21/11/2019	Human medicines European public assessment report (EPAR): Otezla , apremilast, Arthritis, Psoriatic, Psoriasis, 15/01/2015, 11, Authorised (updated)
21/11/2019	Regulatory and procedural guideline: Procedural advice for orphan medicinal product designation: Guidance for sponsors (updated)
21/11/2019	Other: Procedural advice for post-orphan medicinal product designation activities: Guidance for sponsors (updated)
21/11/2019	Human medicines European public assessment report (EPAR): NovoSeven , eptacog alfa (activated), Hemophilia B, Thrombasthenia, Factor VII Deficiency, Hemophilia A, 23/02/1996, 33, Authorised (updated)
21/11/2019	Medicines under additional monitoring (updated)
21/11/2019	Report: European Medicines Agency and Member States joint report to the European Commission on the experience with the list of products subject to additional monitoring

20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Human chorionic gonadotrophin, W: decision granting a waiver in all age groups for all conditions/indications, P/0283/2019
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Istradefylline, W: decision granting a waiver in all age groups for all conditions/indications, P/0270/2019
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Botulinum toxin type A, W: decision granting a waiver in all age groups for all conditions/indications, P/0281/2019
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): eteplirsen, PM: decision on the application for modification of an agreed PIP, P/0286/2019 (updated)
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Recombinant human monoclonal antibody to GM-CSF (GSK3196165), PM: decision on the application for modification of an agreed PIP, P/0287/2019 (updated)
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Vyxeos liposomal (previously known as Vyxeos), daunorubicin, cytarabine, PM: decision on the application for modification of an agreed PIP, P/0292/2019 (updated)
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Axumin, Fluciclovine (18F), PM: decision on the application for modification of an agreed PIP, P/0285/2019 (updated)
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): lasmiditan, PM: decision on the application for modification of an agreed PIP, P/0291/2019 (updated)
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Selumetinib, PM: decision on the application for modification of an agreed PIP, P/0279/2019 (updated)
20/11/2019	Orphan designation: 4-hydroxy-6-{2-[4-(trifluoromethyl)phenyl]ethyl}pyridazin-3(2H)-one for the: Treatment of Friedreich's ataxia, 01/04/2019, Withdrawn (updated)
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Octenidine (dihydrochloride), PM: decision on the application for modification of an agreed PIP, P/0269/2019 (updated)
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Tafasitamab, W: decision granting a waiver in all age groups for all conditions/indications, P/0294/2019
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Bempegaldesleukin, P: decision agreeing on a investigation plan, with or without partial waiver(s) and or deferral(s), P/0298/2019
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): ciclosporin, W: decision granting a waiver in all age groups for all conditions/indications, P/0293/2019
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Human immunoglobulin (Ig) G4-variant monoclonal antibody that binds and neutralizes soluble human, P: decision agreeing on a investigation plan, with or without partial waiver(s) and or deferral(s), P/0275/2019
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Gallium 68-labelled Prostate-Specific Membrane Antigen-11 (68Ga-PSMA-11), W: decision granting a waiver in all age groups for all conditions/indications, P/0290/2019
20/11/2019	Human medicines European public assessment report (EPAR): Tamiflu , oseltamivir, Influenza, Human, 20/06/2002, 37, Authorised (updated)
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Deltyba, Delamanid, PM: decision on the application for modification of an agreed PIP, P/0271/2019 (updated)
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Zebinix, Eslicarbazepine (acetate), PM: decision on the application for modification of an agreed PIP, P/0272/2019 (updated)

20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Bosulif, Bosutinib, PM: decision on the application for modification of an agreed PIP, P/0282/2019 (updated)
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Taltz, ixekizumab, PM: decision on the application for modification of an agreed PIP, P/0280/2019 (updated)
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Briviact (in Italy: Nubriveo), Brivaracetam, PM: decision on the application for modification of an agreed PIP, P/0297/2019 (updated)
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): EGFR-cMET bispecific antibody, W: decision granting a waiver in all age groups for all conditions/indications, P/0289/2019
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Onglyza, Saxagliptin, PM: decision on the application for modification of an agreed PIP, P/0277/2019 (updated)
20/11/2019	Orphan designation: 5,7-dichloro-2-dimethylaminomethyl-8-hydroxyquinoline hydrochloride for the: Treatment of Huntington's disease, 21/05/2015, Withdrawn (updated)
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Anti-neonatal Fc receptor human monoclonal antibody, W: decision granting a waiver in all age groups for all conditions/indications, P/0288/2019
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Relugolix, estradiol, norethisterone acetate, RP: decision refers to a refusal on a proposed Paediatric Investigation Plan, P/0278/2019
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Prepandrix, Purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/2004 (H5N1) like strain used (NIBRG-14), Purified antigen fractions of inactivated split virion Influenza A/Indonesia/05/2005 (H5N1) like strain used (PR8-IBCDC-RG2), PM: decision on the application for modification of an agreed PIP, P/0299/2019 (updated)
20/11/2019	Referral: Veterinary medicinal products containing paromomycin to be administered parenterally to pigs , Paromomycin , Parofor, Gabbrovet, Gabbrocol, Article 35, European Commission final decision, 18/07/2019, 11/10/2019
20/11/2019	Orphan designation: Halofuginone hydrobromide for the: Treatment of systemic sclerosis, 11/12/2001, Withdrawn (updated)
20/11/2019	Veterinary medicines European public assessment report (EPAR): Vectormune ND , cell-associated live recombinant turkey herpes virus (rHVT/ND) expressing the fusion protein of Newcastle diseases virus D-26 lentogenic strain, 08/09/2015, 4, Authorised (updated)
20/11/2019	Other: List of European Union reference dates and frequency of submission of periodic safety update reports (updated)
20/11/2019	Human medicines European public assessment report (EPAR): Rixubis , nonacog gamma, Hemophilia B, 19/12/2014, 7, Authorised (updated)
20/11/2019	Human medicines European public assessment report (EPAR): Keytruda , Pembrolizumab, Melanoma, Hodgkin Disease, Carcinoma, Non-Small-Cell Lung, 17/07/2015, 23, Authorised (updated)
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Humanized anti-CD19, Fc engineered, monoclonal antibody (XmAb5871), P: decision agreeing on a investigation plan, with or without partial waiver(s) and or deferral(s), P/0274/2019
20/11/2019	Orphan designation: Recombinant human tissue non-specific alkaline phosphatase - Fc - deca-aspartate fusion protein for the: Treatment of hypophosphatasia, 04/12/2008, Positive (updated)

20/11/2019	Orphan designation: Choline tetrathiomolybdate for the: Treatment of Wilson's disease, 24/01/2013, Positive (updated)
20/11/2019	Orphan designation: Recombinant human lysosomal acid lipase for the: Treatment of lysosomal acid lipase deficiency, 17/12/2010, Positive (updated)
20/11/2019	Orphan designation: Eculizumab for the: Treatment myasthenia gravis, 29/07/2014, Positive (updated)
20/11/2019	Orphan designation: Eculizumab for the: Treatment of neuromyelitis optica spectrum disorders, 05/08/2013, Positive (updated)
20/11/2019	Orphan designation: Eculizumab for the: Treatment of paroxysmal nocturnal haemoglobinuria, 17/10/2003, Expired (updated)
20/11/2019	Orphan designation: Eculizumab for the: Treatment of atypical haemolytic uraemic syndrome (aHUS), 24/07/2009, Positive (updated)
20/11/2019	Human medicines European public assessment report (EPAR): Pelmeg , pegfilgrastim, Neutropenia, 20/11/2018, 2, Authorised (updated)
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Bulevirtide, P: decision agreeing on a investigation plan, with or without partial waiver(s) and or deferral(s), P/0296/2019
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): mifepristone, W: decision granting a waiver in all age groups for all conditions/indications, P/0295/2019
20/11/2019	Human medicines European public assessment report (EPAR): Cinacalcet Mylan , cinacalcet hydrochloride, Hyperparathyroidism, Secondary, Hypercalcemia, 19/11/2015, 4, Authorised (updated)
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Entyvio, vedolizumab, P: decision agreeing on a investigation plan, with or without partial waiver(s) and or deferral(s), P/0276/2019
20/11/2019	Human medicines European public assessment report (EPAR): Mupleo (previously Lusutrombopag Shionogi) , Lusutrombopag, Thrombocytopenia, 18/02/2019, 3, Authorised (updated)
20/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Oxalobacter formigenes strain HC-1, P: decision agreeing on a investigation plan, with or without partial waiver(s) and or deferral(s), P/0273/2019
19/11/2019	Orphan designation: Autologous collagen type II-specific regulatory T cells for the: Treatment of non-infectious uveitis, 16/12/2014, Withdrawn (updated)
19/11/2019	Periodic safety update single assessment: Germanium (68Ge) chloride / gallium (68Ga) chloride : List of nationally authorised medicinal products - PSUSA/00010364/201903
19/11/2019	Periodic safety update single assessment: Glipizide : List of nationally authorised medicinal products - PSUSA/00001535/201901
19/11/2019	Veterinary medicines European public assessment report (EPAR): Bravecto , fluralaner, 11/02/2014, 9, Authorised (updated)
19/11/2019	Human medicines European public assessment report (EPAR): Lucentis , ranibizumab, Wet Macular Degeneration, Macular Edema, Myopia, Degenerative, Diabetes Complications, 22/01/2007, 35, Authorised (updated)
19/11/2019	Human medicines European public assessment report (EPAR): Olanzapine Teva , olanzapine, Schizophrenia, Bipolar Disorder, 12/12/2007, 26, Authorised (updated)
19/11/2019	Veterinary medicines European public assessment report (EPAR): Vectra Felis , pyriproxyfen, dinotefuran, 06/06/2014, 3, Authorised (updated)
19/11/2019	Committee for Medicinal Products for Human Use (CHMP): 16-19 September 2019 , European Medicines Agency, Amsterdam, the Netherlands, from 16/09/2019 to 19/09/2019 (updated)
19/11/2019	International Coalition of Medicines Regulatory Authorities (ICMRA) (updated)
19/11/2019	Minutes: Minutes of the CHMP meeting 16-19 September 2019

19/11/2019	Referral: Veterinary medicinal products containing tylosin presented as solution for injection to be administered to sheep , tylosin , See annex I, Article 35, European Commission final decision, 20/06/2019, 20/09/2019
19/11/2019	Orphan designation: Multilamellar microvesicle comprising phosphatidylcholine, sphingomyelin, phosphatidylethanolamine, phosphatidylserine, phosphatidylinositol and cholesterol for the: Treatment of cystic fibrosis, 30/08/2011, Positive (updated)
19/11/2019	Orphan designation: Encapsulated human retinal pigment epithelial cell line transfected with plasmid vector expressing human ciliary neurotropic factor for the: Treatment of macular telangiectasia type 2, 08/11/2012, Positive (updated)
19/11/2019	Human medicines European public assessment report (EPAR): Benepali , etanercept, Arthritis, Psoriatic, Arthritis, Rheumatoid, Psoriasis, 13/01/2016, 10, Authorised (updated)
19/11/2019	Human medicines European public assessment report (EPAR): Invanz , ertapenem sodium, Community-Acquired Infections, Streptococcal Infections, Staphylococcal Infections, Gram-Negative Bacterial Infections, Surgical Wound Infection, Pneumonia, Bacterial, 18/04/2002, 22, Authorised (updated)
19/11/2019	Human medicines European public assessment report (EPAR): Defitelio , defibrotide, Hepatic Venous Occlusive Disease, 18/10/2013, 10, Authorised (updated)
19/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): pneumococcal polysaccharide serotype 1- diphtheria CRM197 conjugate, pneumococcal polysaccharide serotype 3 - diphtheria CRM197 conjugate, pneumococcal polysaccharide serotype 4 - diphtheria CRM197 conjugate, pneumococcal polysaccharide serotype 5 - diphtheria CRM197 conjugate, pneumococcal polysaccharide serotype 6A- diphtheria CRM197 conjugate, pneumococcal polysaccharide serotype 6B - diphtheria CRM197 conjugate, pneumococcal polysaccharide serotype 7F - diphtheria CRM197 conjugate, pneumococcal polysaccharide serotype 9V - diphtheria CRM197 conjugate, pneumococcal polysaccharide serotype 14 - diphtheria CRM197 conjugate, pneumococcal polysaccharide serotype 18C - diphtheria CRM197 conjugate, pneumococcal polysaccharide serotype 19A - diphtheria CRM197 conjugate, pneumococcal polysaccharide serotype 19F - diphtheria CRM197 conjugate, pneumococcal polysaccharide serotype 22F - diphtheria CRM197 conjugate, pneumococcal polysaccharide serotype 23F - diphtheria CRM197 conjugate, pneumococcal polysaccharide serotype 33F – diphtheria CRM197 conjugate (15-valent pneumococcal polysaccharide conjugate vaccine [V114]), PM: decision on the application for modification of an agreed PIP, P/0244/2019 (updated)
19/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Tremelimumab, PM: decision on the application for modification of an agreed PIP, P/0245/2019 (updated)
19/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Imfinzi, durvalumab, PM: decision on the application for modification of an agreed PIP, P/0256/2019 (updated)
19/11/2019	Human medicines European public assessment report (EPAR): Sevelamer carbonate Winthrop (previously Sevelamer carbonate Zentiva) , sevelamer carbonate, Hyperphosphatemia, Renal Dialysis, 15/01/2015, 16, Authorised (updated)
19/11/2019	Agenda: Agenda - HMPC agenda of the 18-20 November 2019 meeting
19/11/2019	Human medicines European public assessment report (EPAR): Clopidogrel ratiopharm , clopidogrel hydrogen sulphate, Myocardial Infarction, Acute Coronary Syndrome, Peripheral Vascular Diseases, Stroke, 18/02/2015, 8, Authorised (updated)

18/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Venclyxto, Venetoclax, PM: decision on the application for modification of an agreed PIP, P/0246/2019 (updated)
18/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Balovaptan, PM: decision on the application for modification of an agreed PIP, P/0247/2019 (updated)
18/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Takhzyro, Lanadelumab (DX-2930), PM: decision on the application for modification of an agreed PIP, P/0265/2019 (updated)
18/11/2019	Human medicines European public assessment report (EPAR): Zirabev , bevacizumab, Colorectal Neoplasms, Breast Neoplasms, Carcinoma, Non-Small-Cell Lung, Carcinoma, Renal Cell, Uterine Cervical Neoplasms, 14/02/2019, 2, Authorised (updated)
18/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Emgality, Galcanezumab, PM: decision on the application for modification of an agreed PIP, P/0248/2019 (updated)
18/11/2019	Human medicines European public assessment report (EPAR): Onivyde pegylated liposomal (previously known as Onivyde) , irinotecan hydrochloride trihydrate, Pancreatic Neoplasms, 14/10/2016, 4, Authorised (updated)
18/11/2019	Human medicines European public assessment report (EPAR): Matever , levetiracetam, Epilepsy, 03/10/2011, 19, Authorised (updated)
18/11/2019	Human medicines European public assessment report (EPAR): Alkindi , hydrocortisone, Adrenal Insufficiency, 09/02/2018, 5, Authorised (updated)
18/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Human normal immunoglobulin, PM: decision on the application for modification of an agreed PIP, P/0264/2019 (updated)
18/11/2019	Committee for Orphan Medicinal Products (COMP): 5-7 November 2019 , European Medicines Agency, Amsterdam, the Netherlands, from 05/11/2019 to 07/11/2019 (updated)
18/11/2019	Standard Operating Procedure - SOP: Standard operating procedure for handling of requests for information (updated)
18/11/2019	Human medicines European public assessment report (EPAR): Nucala , Mepolizumab, Asthma, 01/12/2015, 13, Authorised (updated)
18/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Symkevi, 1-(2,2-difluoro-1,3-benzodioxol-5-yl)-N-{1-[(2R)-2,3-dihydroxypropyl]-6-fluoro-2-(1-hydroxy-2-methylpropan-2-yl)-1H-indol-5-yl}cyclopropanecarboxamide (VX-661), ivacaftor, PM: decision on the application for modification of an agreed PIP, P/0250/2019 (updated)
18/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): tezepelumab, PM: decision on the application for modification of an agreed PIP, P/0263/2019 (updated)
18/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Giotrif, afatinib, PM: decision on the application for modification of an agreed PIP, P/0235/2019 (updated)
18/11/2019	Opinion/decision on a Paediatric investigation plan (PIP): Xerava, eravacycline, PM: decision on the application for modification of an agreed PIP, P/0251/2019 (updated)
18/11/2019	Human medicines European public assessment report (EPAR): Nexavar , sorafenib, Carcinoma, Hepatocellular, Carcinoma, Renal Cell, 19/07/2006, 28, Authorised (updated)
18/11/2019	Committee meeting report: COMP meeting report on the review of applications for orphan designation: November 2019

18/11/2019	Periodic safety update single assessment: Methylphenidate: CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - PSUSA/00002024/201810
18/11/2019	Human medicines European public assessment report (EPAR): Slenyto , melatonin, Sleep Initiation and Maintenance Disorders, Autistic Disorder, 20/09/2018, 5, Authorised (updated)
18/11/2019	Human medicines European public assessment report (EPAR): Abraxane , paclitaxel, Breast Neoplasms, Pancreatic Neoplasms, Carcinoma, Non-Small-Cell Lung, 10/01/2008, 25, Authorised (updated)
18/11/2019	Procurement (updated)
18/11/2019	Procurement: Ex ante publicity of a negotiated procedure: EMA/2019/40/LD – Legal advice in relation to procurement matters and contracts under EU procurement and Dutch law
18/11/2019	Human medicines European public assessment report (EPAR): Verzenio , abemaciclib, Breast Neoplasms, 26/09/2018, 3, Authorised (updated)
18/11/2019	Scientific guideline: Draft VICH GL59 Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use
18/11/2019	VICH GL59 Harmonisation of criteria to waive laboratory animal batch safety testing for vaccines for veterinary use
18/11/2019	Human medicines European public assessment report (EPAR): Vyxeos liposomal (previously known as Vyxeos) , daunorubicin hydrochloride / cytarabine, Leukemia, Myeloid, Acute, 23/08/2018, 2, Authorised (updated)
18/11/2019	Antimicrobial resistance (updated)
18/11/2019	Leaflet: Responsible use of antibiotics: what's your role?
18/11/2019	Human medicines European public assessment report (EPAR): Myocet liposomal (previously Myocet) , doxorubicin hydrochloride, Breast Neoplasms, 13/07/2000, 21, Authorised (updated)

NOTICE TO APPLICANTS

No updates since December 15th 2017.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

19.11.2019	82. Sitzung (23. Januar 2020) – Tagesordnung Sachverständigen-Ausschuss für Verschreibungspflicht nach § 53 Absatz 2 AMG
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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.