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HEADS OF AGENCIES – CMDh

27 February 2020

[UPDATE - CMDh Best Practice Guide on Multilingual Packaging](#)

25 February 2020

[NEW - February 2020 CMDh Agenda](#)

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: [click here2](#)

EUROPEAN MEDICINES AGENCY (EMA)

02/03/2020	Human medicines European public assessment report (EPAR): Mimpara , cinacalcet hydrochloride, Hypercalcemia, Parathyroid Neoplasms, Hyperparathyroidism, 22/10/2004, 22, Authorised (updated)
02/03/2020	News and press releases: EMA organisational changes come into effect
02/03/2020	Human Medicines
02/03/2020	Other: Organisation chart: Information Management (updated)
02/03/2020	Other: Organisation chart: Advisory functions (updated)
02/03/2020	Other: Organisation chart: Human Medicines (new)
02/03/2020	Other: Organisation chart of the European Medicines Agency (updated)
02/03/2020	Other: Organisation chart: Task Forces (new)
02/03/2020	Executive Director (updated)
02/03/2020	Task Forces
02/03/2020	Stakeholders and Communication (updated)
02/03/2020	Advisory functions (updated)
02/03/2020	Who we are (updated)
02/03/2020	Information Management (updated)
02/03/2020	Other: Organisation chart: Stakeholders and Communication (updated)
02/03/2020	Human medicines European public assessment report (EPAR): Aripiprazole Mylan Pharma (previously Aripiprazole Pharmathen) , aripiprazole, Schizophrenia, Bipolar Disorder, 30/06/2015, 9, Authorised (updated)

02/03/2020	Human medicines European public assessment report (EPAR): M-M-RVaxPro , measles virus Enders' Edmonston strain (live, attenuated), mumps virus Jeryl Lynn (level B) strain (live, attenuated), rubella virus Wistar RA 27/3 strain (live, attenuated), Rubella, Mumps, Immunization, Measles, 05/05/2006, 23, Authorised (updated)
02/03/2020	Human medicines European public assessment report (EPAR): Pixuvri , pixantrone dimaleate, Lymphoma, Non-Hodgkin, 10/05/2012, 22, Authorised (updated)
02/03/2020	Human medicines European public assessment report (EPAR): Efient , prasugrel, Acute Coronary Syndrome, Angina, Unstable, Myocardial Infarction, 24/02/2009, 18, Authorised (updated)
02/03/2020	Human medicines European public assessment report (EPAR): Ratiograstim , filgrastim, Neutropenia, Hematopoietic Stem Cell Transplantation, Cancer, 15/09/2008, 11, Authorised (updated)
02/03/2020	Herbal - Call for data: Call for scientific data for use in HMPC assessment work on Taraxacum officinale F.H. Wigg., radix (new)
02/03/2020	Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Lavandula angustifolia Miller, flos (new)
02/03/2020	Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Lavandula angustifolia Miller, aetheroleum (new)
02/03/2020	Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Fumaria officinalis L., herba (new)
02/03/2020	Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Fucus vesiculosus L., thallus (new)
02/03/2020	Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Cinnamomum verum J.S. Presl, corticis aetheroleum (new)
02/03/2020	Herbal - Call for data: Call for scientific data for the periodic review of the monograph on Cinnamomum verum J.S. Presl, cortex (new)
28/02/2020	Leaflet: Leaflet - Orphan medicines in the EU (updated)
28/02/2020	Minutes: Minutes of the PRAC meeting 28-31 October 2019 (new)
28/02/2020	News and press releases: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 24-27 February 2020
28/02/2020	Summary of opinion: Fetcroja , cefiderocol, 27/02/2020, Positive
28/02/2020	Summary of opinion: Entyvio , vedolizumab, 27/02/2020, Positive
28/02/2020	Summary of opinion: Tigecycline Accord , tigecycline, 27/02/2020, Positive
28/02/2020	Summary of opinion: Otezla , apremilast, 27/02/2020, Positive
28/02/2020	Withdrawn application: Axumin , fluciclovine (18F), Date of withdrawal: 11/02/2020, Post-authorisation
28/02/2020	Referral: Yondelis , trabectedin, Article 20 procedures, Procedure started, 27/02/2020
28/02/2020	Summary of opinion: Emgality , galcanezumab, 27/02/2020, Negative
28/02/2020	Summary of opinion: Ofev , nintedanib, 27/02/2020, Positive
28/02/2020	Withdrawn application: Opdivo , nivolumab, Date of withdrawal: 30/01/2020, Post-authorisation
28/02/2020	Withdrawn application: Yervoy , ipilimumab, Date of withdrawal: 30/01/2020, Post-authorisation
28/02/2020	Referral: Panexcell , Article 31 referrals, Procedure started, 27/02/2020
28/02/2020	Summary of opinion: Alunbrig , brigatinib, 27/02/2020, Positive
28/02/2020	Veterinary medicines European public assessment report (EPAR): Aservo EquiHaler , ciclesonide, 28/01/2020, Authorised
27/02/2020	Human medicines European public assessment report (EPAR): Epclusa , Sofosbuvir, velpatasvir, Hepatitis C, Chronic, 06/07/2016, 11, Authorised (updated)
27/02/2020	Veterinary medicines European public assessment report (EPAR): Halagon , halofuginone lactate, 13/12/2016, 3, Authorised (updated)

27/02/2020	Management Board meeting: 19 March 2020 , European Medicines Agency, Amsterdam, the Netherlands, from 19/03/2020 to 19/03/2020
27/02/2020	Management Board meeting: 10-11 June 2020 , European Medicines Agency, Amsterdam, the Netherlands, from 10/06/2020 to 11/06/2020
27/02/2020	Management Board meeting: 1 October 2020 , European Medicines Agency, Amsterdam, the Netherlands, from 01/10/2020 to 01/10/2020
27/02/2020	Management Board meeting: 16-17 December 2020 , European Medicines Agency, Amsterdam, the Netherlands, from 16/12/2020 to 17/12/2020
27/02/2020	Veterinary medicines European public assessment report (EPAR): Bravecto , fluralaner, 11/02/2014, 11, Authorised (updated)
27/02/2020	European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties Joint meeting , European Medicines Agency, Amsterdam, the Netherlands, from 03/03/2020 to 04/03/2020 (updated)
27/02/2020	Agenda: Agenda - PCWP/HCPWP joint meeting on 3-4 March 2020 (new)
27/02/2020	Veterinary medicines European public assessment report (EPAR): BTVPUR , bluetongue-virus serotype-1 antigen / bluetongue-virus serotype-8 antigen , 17/12/2010, 9, Authorised (updated)
27/02/2020	Human medicines European public assessment report (EPAR): Tovanor Breezhaler , Glycopyrronium bromide, Pulmonary Disease, Chronic Obstructive, 28/09/2012, 14, Authorised (updated)
27/02/2020	Human medicines European public assessment report (EPAR): Mepsevii , vestronidase alfa, Mucopolysaccharidosis VII, 23/08/2018, 3, Authorised (updated)
27/02/2020	Human medicines European public assessment report (EPAR): Remsima , infliximab, Arthritis, Psoriatic, Spondylitis, Ankylosing, Colitis, Ulcerative, Psoriasis, Crohn Disease, Arthritis, Rheumatoid, 10/09/2013, 18, Authorised (updated)
27/02/2020	Scientific publications (updated)
27/02/2020	Other: Emerging safety issues (ESI) contact points at the national competent authority (NCA) level (updated)
27/02/2020	Template or form: Standalone signal notification form (updated)
27/02/2020	Other: National contact points for standalone signal notifications (updated)
27/02/2020	Human medicines European public assessment report (EPAR): Leganto , rotigotine, Restless Legs Syndrome, Parkinson Disease, 16/06/2011, 18, Authorised (updated)
27/02/2020	Human medicines European public assessment report (EPAR): Neupro , rotigotine, Restless Legs Syndrome, Parkinson Disease, 15/02/2006, 29, Authorised (updated)
27/02/2020	Human medicines European public assessment report (EPAR): Zinforo , Ceftaroline fosamil, Community-Acquired Infections, Skin Diseases, Infectious, Pneumonia, 22/08/2012, 23, Authorised (updated)
26/02/2020	Human medicines European public assessment report (EPAR): Crysvita , Burosumab, Hypophosphatemia, Familial, Hypophosphatemic Rickets, X-Linked Dominant, 19/02/2018, 4, Authorised (updated)
26/02/2020	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, 4, Authorised (updated)
26/02/2020	Human medicines European public assessment report (EPAR): Recarbrio , imipenem monohydrate, cilastatin sodium, relebactam monohydrate, Gram-Negative Bacterial Infections, 13/02/2020, Authorised
26/02/2020	Human medicines European public assessment report (EPAR): Adrovanse , alendronate sodium trihydrate, colecalciferol, Osteoporosis, Postmenopausal, 04/01/2007, 20, Authorised (updated)
26/02/2020	Veterinary medicines European public assessment report (EPAR): Onsior , robenacoxib, 16/12/2008, 13, Authorised (updated)

26/02/2020	List of medicines under additional monitoring (updated)
26/02/2020	Medicines under additional monitoring: List of medicinal products under additional monitoring (updated)
26/02/2020	Medicines under additional monitoring: List of medicinal products under additional monitoring (updated)
26/02/2020	Human medicines European public assessment report (EPAR): Aubagio , Teriflunomide, Multiple Sclerosis, 26/08/2013, 15, Authorised (updated)
26/02/2020	Human medicines European public assessment report (EPAR): ProQuad , virus, live attenuated, measles, virus, live attenuated, mumps, virus, live attenuated, rubella, virus, live attenuated, varicella, Chickenpox, Rubella, Measles, Mumps, Immunization, 05/04/2006, 25, Authorised (updated)
26/02/2020	Human medicines European public assessment report (EPAR): Ganfort , bimatoprost, timolol, Glaucoma, Open-Angle, Ocular Hypertension, 19/05/2006, 19, Authorised (updated)
26/02/2020	Human medicines European public assessment report (EPAR): Baraclude , Entecavir, Hepatitis B, Chronic, 26/06/2006, 25, Authorised (updated)
26/02/2020	Human medicines European public assessment report (EPAR): Menveo , meningococcal group A, C, W-135 and Y conjugate vaccine, Immunization, Meningitis, Meningococcal, 15/03/2010, 17/12/2009, 29, Authorised (updated)
26/02/2020	Human medicines European public assessment report (EPAR): Episalvan , betulae cortex dry extract (5-10 : 1); extraction solvent: n-heptane 95% (w/w), Wounds and Injuries, Wound Healing, 14/01/2016, 4, Authorised (updated)
25/02/2020	Eligible patients and consumers organisations (updated)
25/02/2020	Recruitment: Careers at European Medicines Agency (EMA) - Guidance on selection and recruitment (updated)
25/02/2020	Recruitment: Careers at EMA user-guide (updated)
25/02/2020	Paediatric Committee (PDCO): 25-28 February 2020 , European Medicines Agency, Amsterdam, The Netherlands, from 25/02/2020 to 28/02/2020 (updated)
25/02/2020	Human medicines European public assessment report (EPAR): Vosevi , Sofosbuvir, velpatasvir, voxilaprevi, Hepatitis C, Chronic, 26/07/2017, 7, Authorised (updated)
25/02/2020	Human medicines European public assessment report (EPAR): Cynamza , Ramucirumab, Stomach Neoplasms, 19/12/2014, 10, Authorised (updated)
25/02/2020	Agenda: Agenda - PDCO agenda of the 25-28 February 2020 meeting (new)
25/02/2020	Template or form: Declaration on the qualification of an enterprise as a micro, small or medium-sized enterprise (SME) (updated)
25/02/2020	Human medicines European public assessment report (EPAR): Aerinaze , desloratadine, pseudophedrine sulphate, Rhinitis, Allergic, Seasonal, 30/07/2007, 17, Authorised (updated)
25/02/2020	Human medicines European public assessment report (EPAR): Feraccru , ferric maltol, Anemia, Iron-Deficiency, 18/02/2016, 10, Authorised (updated)
25/02/2020	Human medicines European public assessment report (EPAR): Tagrisso , osimertinib mesylate, Carcinoma, Non-Small-Cell Lung, 01/02/2016, 9, Authorised (updated)
25/02/2020	Veterinary medicines European public assessment report (EPAR): Osurnia , terbinafine / florfenicol, betamethasone acetate, 31/07/2014, 8, Authorised (updated)
25/02/2020	Human medicines European public assessment report (EPAR): Ilaris , Canakinumab, Cryopyrin-Associated Periodic Syndromes, Arthritis, Juvenile Rheumatoid, Arthritis, Gouty, 23/10/2009, 24, Authorised (updated)
25/02/2020	Human medicines European public assessment report (EPAR): Oncaspar , pegaspargase, Precursor Cell Lymphoblastic Leukemia-Lymphoma, 14/01/2016, 10, Authorised (updated)
25/02/2020	Direct healthcare professional communication (DHPC): Mepact , mifamurtide, DHPC type: Quality defect, Last updated: 25/02/2020

25/02/2020	Human medicines European public assessment report (EPAR): Afinitor , everolimus, Carcinoma, Renal Cell, Breast Neoplasms, Pancreatic Neoplasms, 02/08/2009, 24, Authorised (updated)
25/02/2020	Orphan designation: Synthetic double-stranded siRNA oligonucleotide directed against SERPINA1 mRNA and containing four modified nucleosides which form a ligand cluster of four N-acetylgalactosamine residues for the: Treatment of congenital alpha-1 antitrypsin deficiency, 16/12/2019, Positive
25/02/2020	Orphan designation: N-methyl D-(2,3,4,5,6-pentahydroxy-hexyl)-ammonium; 2-(3,5-dichloro-phenyl)-benzoxazole-6-carboxylate (tafamidis) for the: Treatment of familial amyloid polyneuropathy, 28/08/2006, Positive (updated)
25/02/2020	Human medicines European public assessment report (EPAR): Vyndaqel , tafamidis, Amyloidosis, 16/11/2011, 16, Authorised (updated)
25/02/2020	Orphan designation: tafamidis for the: Treatment of senile systemic amyloidosis, 08/11/2012, Positive (updated)
25/02/2020	Orphan designation: Pamrevlumab for the: Treatment of Duchenne muscular dystrophy, 16/12/2019, Positive
25/02/2020	Orphan designation: navitoclax for the: Treatment of myelofibrosis, 16/12/2019, Positive
25/02/2020	Orphan designation: Lactobacillus plantarum for the: Treatment of amyotrophic lateral sclerosis, 16/12/2019, Positive
25/02/2020	Human medicines European public assessment report (EPAR): Stelara , Ustekinumab, Psoriasis, Arthritis, Psoriatic, Crohn Disease, 15/01/2009, 31, Authorised (updated)
25/02/2020	Herbal medicinal product: Agni casti fructus , Agni casti fructus , F: Assessment finalised (updated)
25/02/2020	Orphan designation: H-Leu-Pro-Pro-Leu-Pro-Tyr-Pro-OH for the: Treatment of amyotrophic lateral sclerosis, 16/12/2019, Positive
25/02/2020	Orphan designation: Efgartigimod alfa for the: Treatment of immune thrombocytopenia, 16/12/2019, Positive
25/02/2020	Committee for Medicinal Products for Human Use (CHMP): 24-27 February 2020 , European Medicines Agency, Amsterdam, the Netherlands, from 24/02/2020 to 27/02/2020 (updated)
25/02/2020	Orphan designation: Adeno-associated virus vector encoding human phenylalanine hydroxylase for the: Treatment of phenylalanine hydroxylase deficiency, 16/12/2019, Positive
25/02/2020	Human medicines European public assessment report (EPAR): Rebif , interferon beta-1a, Multiple Sclerosis, 03/05/1998, 37, Authorised (updated)
25/02/2020	Report: PDCO monthly report of opinions on paediatric investigation plans and other activities 28-31 January 2020 (new)
25/02/2020	Orphan designation: 5,7-dichloro-2-((ethylamino)methyl)-8-hydroxy-3-methylquinazolin-4(3H)-one mesilate for the: Treatment of multiple system atrophy, 16/12/2019, Positive
25/02/2020	Agenda: Agenda - CHMP agenda of the 24-27 February 2020 meeting (new)
25/02/2020	Medicine evaluation figures (updated)
25/02/2020	Report: Medicinal products for human use: monthly figures - January 2020 (new)
25/02/2020	European Union (EU) International Organisation for Standardization (ISO) for identification of medical products (IDMP)/Substance, Product, Organisation and Referential (SPOR) data Task Force meeting (Oct 2019) , European Medicines Agency, Amsterdam, the Netherlands, from 16/10/2019 to 16/10/2019
25/02/2020	Minutes: Minutes of the COMP meeting 5-7 November 2019 (new)
24/02/2020	Orphan designation: 2-(isopropylamino)-3-methyl-5-(6-methyl-5-((2-(1-methyl-1H-pyrazol-4-yl)pyridin-4-yl)oxy)pyridin-2-yl)pyrimidin-4(3H)-one for the: Treatment of tenosynovial giant cell tumour, localised and diffuse type, 16/12/2019, Positive

24/02/2020	Orphan designation: (E)-2-((2S,4S)-4-(((2R,4S,5S,6S)-4-amino-5-hydroxy-6-methyltetrahydro-2H-pyran-2-yl)oxy)-2,5,12-trihydroxy-7-methoxy-6,11-dioxo-1,2,3,4,6,11-hexahydrotetracen-2-yl)-10-(carboxymethyl)-1-hydroxy-13-(2-(2-(2-((E)-3-(3-(3-hydroxy-3,3-diphosphonopropyl)(methylamino)propoxy)benzylidene)hydrazine-1-carbonothioyl)hydrazineyl)-2-oxoethyl)-8-oxo-5-thioxo-3,4,6,7,10,13-hexaazapentadec-2-en-15-oic acid for the: Treatment of osteosarcoma, 16/12/2019, Positive
24/02/2020	Orphan designation: Naltrexone for the: Treatment of fibromyalgia, 07/11/2020, Negative
24/02/2020	Human medicines European public assessment report (EPAR): Evenity , Romosozumab, Osteoporosis, 09/12/2019, Authorised
24/02/2020	Human medicines European public assessment report (EPAR): Pemetrexed Hospira , pemetrexed, Carcinoma, Non-Small-Cell Lung, Mesothelioma, 19/11/2015, 8, Authorised (updated)
24/02/2020	Human medicines European public assessment report (EPAR): Brilique , ticagrelor, Peripheral Vascular Diseases, Acute Coronary Syndrome, 03/12/2010, 15, Authorised (updated)
24/02/2020	Periodic safety update single assessment: Dienogest / estradiol (HRT indication): List of nationally authorised medicinal products - PSUSA/00010443/201906 (new)
24/02/2020	Human medicines European public assessment report (EPAR): Duloxetine Mylan , duloxetine, Neuralgia, Diabetic Neuropathies, Anxiety Disorders, Depressive Disorder, Major, 19/06/2015, 11, Authorised (updated)
24/02/2020	Human medicines European public assessment report (EPAR): Rotarix , human rotavirus, live attenuated, Immunization, Rotavirus Infections, 21/02/2006, 33, Authorised (updated)
24/02/2020	Human medicines European public assessment report (EPAR): Levemir , Insulin detemir, Diabetes Mellitus, 01/06/2004, 27, Authorised (updated)

NOTICE TO APPLICANTS

No updates since November 28th 2019.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

28.02.2020	Panexcell Clinical Laboratories Priv. Ltd.: Durchführung von Studien in Indien Wirkstoff Risikobewertungsverfahren über die Durchführung von Studien bei Panexcell Clinical Laboratories Priv. Ltd., Indien, eingeleitet.
28.02.2020	Yondelis® (Trabectedin): Überprüfung der Wirksamkeit aufgrund eines Studienabbruchs Wirkstoff Trabectedin Einleitung des Risikobewertungsverfahrens für Yondelis®.
28.02.2020	Rote-Hand-Brief zu MEPACT 4 mg: Möglichkeit eines Filterlecks/einer Fehlfunktion Wirkstoff Mifamurtid

	Die Takeda GmbH informiert darüber, dass bei einer geringen Anzahl von Zubereitungen ein Filterleck oder eine Fehlfunktion während der Rekonstitution von Mepact 4 mg gemeldet wurde.
27.02.2020	Ergebnisprotokoll der 85. Routinesitzung nach § 63 AMG am 19. November 2019 Das BfArM gibt das Ergebnisprotokoll der 85. Routinesitzung vom 19. November 2019 bekannt.
26.02.2020	Informationsbrief zu Valproat: Anwendungseinschränkungen und Einführung des Schwangerschaftsverhütungsprogramms Wirkstoff Valproat Die Zulassungsinhaber Aristo Pharma GmbH, Desitin Arzneimittel GmbH und Sanofi-Aventis Deutschland GmbH informieren erneut über Anwendungseinschränkungen sowie über die Einführung des Schwangerschaftsverhütungsprogramms für valproathaltige Arzneimittel.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since January 9th 2020.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since January 24th 2020.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.