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HEADS OF AGENCIES – CMDh

No updates since January 8th 2020.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

20/01/2020	Big data (updated)
20/01/2020	News and press releases: Ten recommendations to unlock the potential of big data for public health in the EU
17/01/2020	Human medicines European public assessment report (EPAR): Orencia, Abatacept, Arthritis, Psoriatic, Arthritis, Juvenile Rheumatoid, Arthritis, Rheumatoid, 21/05/2007, 31, Authorised (updated)
17/01/2020	Human medicines European public assessment report (EPAR): Tovanor Breezhaler, Glycopyrronium bromide, Pulmonary Disease, Chronic Obstructive, 28/09/2012, 13, Authorised (updated)
17/01/2020	Other: Article 57 product data (updated)
17/01/2020	Report: Applications for new human medicines under evaluation by the CHMP: January 2020
17/01/2020	Newsletter: Human medicines highlights - January 2020
17/01/2020	News and press releases: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 13-16 January 2020
17/01/2020	Referral: Picato , ingenol mebutate , Article 20 procedures, Recommendation provided by Pharmacovigilance Risk Assessment Committee, 17/01/2020 (updated)
17/01/2020	News and press releases: EMA suspends Picato as a precaution while review of skin cancer risk continues
17/01/2020	News and press releases: PRAC confirms four-week limit for use of high-strength estradiol creams
17/01/2020	Human medicines European public assessment report (EPAR): Tadalafil Mylan, tadalafil, Erectile Dysfunction, 21/11/2014, 11, Authorised (updated)
17/01/2020	Human medicines European public assessment report (EPAR): Xarelto, rivaroxaban, Arthroplasty, Replacement, Venous Thromboembolism, 30/09/2008, 32, Authorised (updated)

17/01/2020	Human medicines European public assessment report (EPAR): Imbruvica, Ibrutinib, Lymphoma, Mantle-Cell, Leukemia, Lymphocytic, Chronic, B-Cell, 21/10/2014, 17, Authorised (updated)
17/01/2020	Periodic safety update single assessment: Tirofiban: List of nationally authorised medicinal products - PSUSA/00002974/201905
17/01/2020	Human medicines European public assessment report (EPAR): Symkevi, tezacaftor, ivacaftor, Cystic Fibrosis, 31/10/2018, 4, Authorised (updated)
17/01/2020	Human medicines European public assessment report (EPAR): Akynzeo, netupitant, palonosetron hydrochloride, Vomiting, Cancer, Nausea, 27/05/2015, 6, Authorised (updated)
17/01/2020	Veterinary medicines European public assessment report (EPAR): Imrestor, Pegbovigrastim, 09/12/2015, 2, Authorised (updated)
17/01/2020	Veterinary medicines European public assessment report (EPAR): Vaxxitek HVT+IBD, live vHVT013-69 recombinant virus, 09/08/2002, 11, Authorised (updated)
17/01/2020	Veterinary medicines European public assessment report (EPAR): Onsior, robenacoxib, 16/12/2008, 12, Authorised (updated)
17/01/2020	Human medicines European public assessment report (EPAR): Rapiscan, regadenoson, Myocardial Perfusion Imaging, 06/09/2010, 11, Authorised (updated)
17/01/2020	Human medicines European public assessment report (EPAR): Harvoni, ledipasvir 90 mg, sofosbuvir 400 mg, Hepatitis C, Chronic, 17/11/2014, 19, Authorised (updated)
17/01/2020	Human medicines European public assessment report (EPAR): Revlimid, lenalidomide, Multiple Myeloma, Lymphoma, Mantle-Cell, Myelodysplastic Syndromes, 14/06/2007, 39, Authorised (updated)
17/01/2020	Human medicines European public assessment report (EPAR): Tafinlar, dabrafenib mesylate, Melanoma, 26/08/2013, 21, Authorised (updated)
16/01/2020	Orphan designation: monoclonal antibody against human CD30 covalently linked to the cytotoxin monomethylauristatin E for the: Treatment of peripheral T-cell lymphoma, 21/09/2019, Positive (updated)
16/01/2020	Orphan designation: Poly(oxy-1,2-ethanediyl), alpha-hydro-omega-hydroxy-,15,15'-diester with N-acetyl-L-isoleucyl-L-cysteinyl-L-valyl-1-methyl-L-tryptophyl-L-glutaminyl-L-alpha-aspartyl-L-tryptophylglycyl-L-alanyl-L-histidyl-L-arginyl-L-cysteinyl-L-threonyl-2-[2-(2-aminoethoxy)ethoxy]acetyl-N6-carboxy-L-lysinamide cyclic (2.fwdarw.12)-(disulfide); where two identical synthetic peptide domains are covalently linked at the ends of the polyethylene glycol chain for the: Treatment of C3 glomerulopathy, 21/08/2019, Positive
16/01/2020	Orphan designation: Adenoviral vector serotype 5 encoding the human interleukin-12 p70 transgene under the control of activator ligand veledimex for the: Treatment of glioma, 21/08/2019, Positive
16/01/2020	Orphan designation: Veledimex for the: Treatment of glioma, 21/08/2019, Positive
16/01/2020	Orphan designation: Clofazimine for the: Treatment of nontuberculous mycobacterial lung disease, 21/08/2019, Positive
16/01/2020	Human medicines European public assessment report (EPAR): Bortezomib Hospira, bortezomib, Multiple Myeloma, 22/07/2016, 8, Authorised (updated)
16/01/2020	Human medicines European public assessment report (EPAR): Gardasil 9, human papillomavirus vaccine [types 6, 11, 16, 18, 31, 33, 45, 52, 58] (recombinant, adsorbed), Condylomata Acuminata, Papillomavirus Infections, Immunization, Uterine Cervical Dysplasia, 09/06/2015, 12, Authorised (updated)
16/01/2020	Other: Extension of reserve lists for external selection procedures: Temporary Agent reserve lists (updated)
16/01/2020	Referral: Estradiol-containing (0.01% w/w) medicinal products for topical use , estradiol , Linoladiol,Linoladiol N,Linoladiol Estradiol,Estradiol

	Wolff,Montadiol, Article 31 referrals, Recommendation provided by Pharmacovigilance Risk Assessment Committee, 16/01/2020 (updated)
16/01/2020	Orphan designation: Recombinant self-complementary adeno-associated viral vector serotype 9 containing the human CLN6 gene for the: Treatment of neuronal ceroid lipofuscinosis, 21/08/2019, Positive
16/01/2020	Human medicines European public assessment report (EPAR): Zonisamide Mylan, zonisamide, Epilepsy, 31/03/2016, 4, Authorised (updated)
16/01/2020	Orphan designation: Recombinant self-complementary adeno-associated viral vector serotype 9 containing the human CLN3 gene for the: Treatment of neuronal ceroid lipofuscinosis, 21/08/2019, Positive
16/01/2020	Human medicines European public assessment report (EPAR): Ceprotin, human protein C, Purpura Fulminans, Protein C Deficiency, 15/07/2001, 13, Authorised (updated)
16/01/2020	Orphan designation: 1-(2,2-diphenyltetrahydrofuran-3-yl)-N,N-dimethylmethanamine hydrochloride for the: Treatment of Rett syndrome, 21/08/2019, Positive
16/01/2020	Orphan designation: Herpes simplex 1 virus-thymidine kinase and truncated low affinity nerve growth factor receptor transfected donor lymphocytes for the: Adjunctive treatment in haematopoietic cell transplantation, 20/10/2003, Withdrawn (updated)
16/01/2020	Orphan designation: Triheptanoin for the: Treatment of glucose transporter type-1 deficiency syndrome, 21/05/2015, Withdrawn (updated)
16/01/2020	Orphan designation: 6-(2-hydroxy-2-methylpropoxy)-4-(6-(6-((6-methoxypyridin-3-yl)methyl)-3,6-diazabicyclo[3.1.1]heptan-3-yl)pyridin-3-yl)pyrazolo[1,5-a]pyridine-3-carbonitrile for the: Treatment of medullary thyroid carcinoma, 26/10/2018, Withdrawn (updated)
16/01/2020	News and press releases: EMA welcomes new Head of Information Management Division
16/01/2020	Executive Director (updated)
16/01/2020	Information Management (updated)
16/01/2020	Other: Organisation chart: Information Management (updated)
15/01/2020	Human medicines European public assessment report (EPAR): Roteas, edoxaban tosylate, Stroke, Venous Thromboembolism, 19/04/2017, 4, Authorised (updated)
15/01/2020	Human medicines European public assessment report (EPAR): Tecfidera, dimethyl fumarate, Multiple Sclerosis, 30/01/2014, 18, Authorised (updated)
15/01/2020	Human medicines European public assessment report (EPAR): Benlysta, belimumab, Lupus Erythematosus, Systemic, 13/07/2011, 20, Authorised (updated)
15/01/2020	Human medicines European public assessment report (EPAR): Aerivio Spiromax, salmeterol xinafoate, fluticasone propionate, Pulmonary Disease, Chronic Obstructive, Asthma, 18/08/2016, 2, Withdrawn (updated)
15/01/2020	Leaflet: Responsible use of antibiotics protects animals and people - 2011-2017 Sales of antibiotics for veterinary use are down - Infographic (updated)
15/01/2020	Committee for Advanced Therapies (CAT): 11-13 September 2019 , European Medicines Agency, Amsterdam, the Netherlands, from 11/09/2019 to 13/09/2019 (updated)
15/01/2020	Minutes: Minutes of the CAT meeting 11-13 September 2019
15/01/2020	Paediatric Committee (PDCO): 12-15 November 2019 , European Medicines Agency, Amsterdam, The Netherlands, from 12/11/2019 to 15/11/2019 (updated)
15/01/2020	Committee meeting report: PDCO monthly report of opinions on paediatric investigation plans and other activities 12-15 November 2019
15/01/2020	Committee for Herbal Medicinal Products (HMPC): 13-15 January 2020 , European Medicines Agency, Amsterdam, the Netherlands, from 13/01/2020 to 15/01/2020 (updated)
15/01/2020	Agenda: Agenda - HMPC agenda of the 13-15 January 2020 meeting

15/01/2020	Veterinary medicines European public assessment report (EPAR): Zactran, gamithromycin, 24/07/2008, 11, Authorised (updated)
15/01/2020	Human medicines European public assessment report (EPAR): Talmanco (previously Tadalafil Generics), tadalafil, Hypertension, Pulmonary, 09/01/2017, 4, Authorised (updated)
15/01/2020	Human medicines European public assessment report (EPAR): Infanrix Hexa, Diphtheria toxoid, tetanus toxoid, Bordetella pertussis antigens (pertussis toxoid, filamentous haemagglutinin, pertactin), hepatitis B surface antigen, poliovirus (inactivated) (type-1 (Mahoney strain), type-2 (MEF-1 strain), type-3 (Saukett strain)), Haemophilus influenzae type-b polysaccharide, Hepatitis B, Tetanus, Immunization, Meningitis, Haemophilus, Whooping Cough, Poliomyelitis, Diphtheria, 23/10/2000, 41, Authorised (updated)
15/01/2020	Orphan designation: Olaratumab for the: Treatment of soft tissue sarcoma, 12/02/2015, Withdrawn (updated)
15/01/2020	EudraVigilance (updated)
15/01/2020	News and press releases: Mandatory use of international standard for the reporting of side effects to improve safety of medicines
15/01/2020	Other: Announcement of the EMA Management Board - Confirmation of the mandatory use of the ISO Individual Case Report standard based on ICH E2B(R3) modalities and related ISO standard terminology
14/01/2020	Human medicines European public assessment report (EPAR): Forxiga, dapagliflozin propanediol monohydrate, Diabetes Mellitus, Type 2, Diabetes Mellitus, Type 1, 11/11/2012, 17, Authorised (updated)
14/01/2020	Veterinary medicines European public assessment report (EPAR): ProZinc, insulin human, 12/07/2013, 9, Authorised (updated)
14/01/2020	Human medicines European public assessment report (EPAR): Retacrit, epoetin zeta, Anemia, Blood Transfusion, Autologous, Kidney Failure, Chronic, Cancer, 18/12/2007, 25, Authorised (updated)
14/01/2020	Orphan designation: 4-(2-chloro-4-methoxy-5-methylphenyl)-N-[(1S)-2-cyclopropyl-1-(3-fluoro-4-methylphenyl)ethyl]-5-methyl-N-(2-propynyl)-1,3-thiazol-2-amine for the: Treatment of congenital adrenal hyperplasia, 21/08/2019, Positive
14/01/2020	Periodic safety update single assessment: Lisdexamfetamine: List of nationally authorised medicinal products - PSUSA/00010289/201902
14/01/2020	Periodic safety update single assessment: Lisdexamfetamine: CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - PSUSA/00010289/201902
14/01/2020	Orphan designation: acetazolamide for the: Treatment of periodic paralysis, 21/08/2019, Positive
14/01/2020	Other: Extension of reserve lists for external selection procedures: Contract Agent reserve list (updated)
14/01/2020	Periodic safety update single assessment: Erythromycin: List of nationally authorised medicinal products - PSUSA/00001257/201903
14/01/2020	Periodic safety update single assessment: Erythromycin: CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - PSUSA/00001257/201903
14/01/2020	Human medicines European public assessment report (EPAR): Pradaxa, Dabigatran etexilate mesilate, Arthroplasty, Replacement, Venous Thromboembolism, 17/03/2008, 30, Authorised (updated)
14/01/2020	Human medicines European public assessment report (EPAR): Lucentis, ranibizumab, Wet Macular Degeneration, Macular Edema, Myopia, Degenerative, Diabetes Complications, 22/01/2007, 36, Authorised (updated)
14/01/2020	Orphan designation: Relacorilant for the: Treatment of pancreatic cancer, 21/08/2019, Positive

14/01/2020	Orphan designation: Setmelanotide for the: Treatment of Bardet-Biedl syndrome, 21/08/2019, Positive
14/01/2020	Orphan designation: Peginterferon lambda-1a for the: Treatment of hepatitis D virus infection, 21/08/2019, Positive
14/01/2020	Human medicines European public assessment report (EPAR): Darunavir Krka, darunavir, HIV Infections, 26/01/2018, 4, Authorised (updated)
14/01/2020	Human medicines European public assessment report (EPAR): Trazimera, trastuzumab, Stomach Neoplasms, Breast Neoplasms, 26/07/2018, 4, Authorised (updated)
14/01/2020	Orphan designation: gallium citrate for the: Treatment of cystic fibrosis, 21/08/2019, Positive
14/01/2020	Orphan designation: temozolomide for the: Treatment of neuroblastoma, 21/08/2019, Positive
14/01/2020	Human medicines European public assessment report (EPAR): Scenesse, afamelanotide, Protoporphyria, Erythropoietic, 22/12/2014, 6, Authorised (updated)
14/01/2020	Human medicines European public assessment report (EPAR): Zinforo, Ceftaroline fosamil, Community-Acquired Infections, Skin Diseases, Infectious, Pneumonia, 22/08/2012, 22, Authorised (updated)
14/01/2020	Human medicines European public assessment report (EPAR): Yescarta, axicabtagene ciloleucel, Lymphoma, Follicular, Lymphoma, Large B-Cell, Diffuse, 23/08/2018, 3, Authorised (updated)
13/01/2020	Agenda: Agenda - PRAC draft agenda of meeting 13-16 January 2020
13/01/2020	Human medicines European public assessment report (EPAR): Ziextenzo, pegfilgrastim, Neutropenia, 22/11/2018, 2, Authorised (updated)
13/01/2020	Orphan designation: lenalidomide for the: Treatment of marginal zone lymphoma, 24/04/2015, Withdrawn (updated)
13/01/2020	Orphan designation: lenalidomide for the: Treatment of diffuse large B-cell lymphoma, 13/05/2011, Withdrawn (updated)
13/01/2020	Orphan designation: lenalidomide for the: Treatment of chronic lymphocytic leukaemia, 19/11/2007, Withdrawn (updated)
13/01/2020	Orphan designation: lenalidomide for the: Treatment of mantle cell lymphoma, 27/10/2011, Withdrawn (updated)
13/01/2020	Orphan designation: "3-(4'Aminoisoindoline-1'-one)-1-piperidine-2,6-dione (lenalidomide) for the: Treatment of myelodysplastic syndromes, 08/03/2004, Withdrawn (updated)
13/01/2020	Orphan designation: lenalidomide for the: Treatment of follicular lymphoma, 24/01/2013, Withdrawn (updated)
13/01/2020	Human medicines European public assessment report (EPAR): Teysuno, tegafur, gimeracil, oteracil, Stomach Neoplasms, 14/03/2011, 17, Authorised (updated)
13/01/2020	Human medicines European public assessment report (EPAR): Duloxetine Zentiva, duloxetine, Anxiety Disorders, Depressive Disorder, Major, Neuralgia, Diabetes Mellitus, 20/08/2015, 5, Authorised (updated)
13/01/2020	Human medicines European public assessment report (EPAR): Riximyo, rituximab, Lymphoma, Non-Hodgkin, Arthritis, Rheumatoid, Microscopic Polyangiitis, Wegener Granulomatosis, 15/06/2017, 4, Authorised (updated)
13/01/2020	Human medicines European public assessment report (EPAR): Aranesp, darbepoetin alfa, Anemia, Cancer, Kidney Failure, Chronic, 08/06/2001, 42, Authorised (updated)

NOTICE TO APPLICANTS

No updates since November 28th 2019.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

17.01.2020	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/490480/2019 vom 19.09.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff 5-Fluorouracil (topische Anwendung) bzw. – unter Beachtung der Bezeichnungsverordnung – Fluorouracil (topische Anwendung) Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Fluorouracil (topische Anwendung) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
17.01.2020	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/473080/2019 vom 19.09.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Testosteron (topische Anwendung) Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Testosteron (topische Anwendung) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
17.01.2020	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/598299/2019 vom 26.06.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Methylphenidat Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Methylphenidat infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
17.01.2020	Umsetzung des Durchführungsbeschlusses der Europäischen Kommission zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Vardenafil vom 19.12.2019 Das BfArM veröffentlicht den Umsetzungsbescheid für den Vardenafil infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
17.01.2020	Picato® (Ingenolmebutat): EMA empfiehlt das Ruhen der Zulassungen als Vorsichtsmaßnahme, während die Überprüfung des Hautkrebsrisikos fortgesetzt wird Wirkstoff Ingenolmebutat Die Europäische Arzneimittel-Agentur (EMA) empfiehlt das Ruhen der Zulassungen als Vorsichtsmaßnahme, während die Überprüfung des Hautkrebsrisikos fortgesetzt wird.
17.01.2020	Hochdosierte, estradiolhaltige Cremes: Neue Überprüfung der Risiken Wirkstoff Estradiol Der Ausschuss für Risikobewertung im Bereich der Pharmakovigilanz (PRAC) bestätigt seine Empfehlung die Anwendung auf einen einmaligen Zeitraum von maximal vier Wochen zu begrenzen.
15.01.2020	Rote-Hand-Brief zu Implanon NXT® – Etonogestrel 68 mg zur subkutanen Anwendung: Aktualisierte Anweisungen zur Einlage und Entfernung des Implantats

	Wirkstoff Etonogestrel Die Firma MSD Sharp & Dohme GmbH informiert in Abstimmung mit dem Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM), dass die Anweisungen zur Einlage und Entfernung des Implantats aktualisiert wurden, um das Risiko einer neurovaskulären Verletzung und einer Wanderung des Implantats weiter zu minimieren.
13.01.2020	Dihydroergotamin und Dihydroergotoxin: Ungünstiges Nutzen-Risiko-Verhältnis Wirkstoff Dihydroergotamin; Dihydroergotoxin Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) ordnet mit Bescheid vom 10. Januar 2020 für Arzneimittel mit dem Ergotaminderivat Dihydroergotamin das weitere Ruhen der Zulassung bis zum 01.02.2022 an.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since January 9th 2020

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since November 15th 2019.

PHARMEUROPA TEXTS FOR COMMENT

Text	Monograph number	Group	Issue	Deadline
2.8.26. Contaminant pyrrolizidine alkaloids	20826	PA	32.1	31.03.2020
2.1.7. Balances	20107	MG	32.1	31.03.2020
Allergen products	1063	ALG	32.1	31.03.2020
Zinc oxide	252	9	32.1	31.03.2020
Zinc acetate dihydrate	1482	9	32.1	31.03.2020