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HEADS OF AGENCIES – CMDh

26 June 2019

NEW - June 2019 CMDh Agenda

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

01/07/2019	Orphan designation: Tobramycin (inhalation powder) for the: Treatment of Pseudomonas aeruginosa lung infection in cystic fibrosis, 17/03/2003, Positive (updated)
01/07/2019	Report: Annual accounts: Financial year 2018
01/07/2019	Committee meeting report: CAT monthly report of application procedures, guidelines and related documents on advanced therapies: May 2019
01/07/2019	Committee meeting report: CAT monthly report of application procedures, guidelines and related documents on advanced therapies: April 2019
28/06/2019	Human medicines European public assessment report (EPAR): Adasuve, loxapine, Schizophrenia, Bipolar Disorder, 20/02/2013, 12, Authorised (updated)
28/06/2019	Human medicines European public assessment report (EPAR): Dupixent, dupilumab, Dermatitis, Atopic, 27/09/2017, 4, Authorised (updated)
28/06/2019	Periodic safety update single assessment: Meningococcal group c polysaccharide conjugate vaccine: List of nationally authorised medicinal products - PSUSA/00001971/201810
28/06/2019	Orphan designation: PEGylated recombinant factor VIII (turoctocog alfa pegol) for the: Treatment of haemophilia A, 26/04/2012, Withdrawn (updated)
28/06/2019	Human medicines European public assessment report (EPAR): Esperoct, Turoctocog alfa pegol, Hemophilia A, 20/06/2019, Authorised
28/06/2019	Periodic safety update single assessment: Didanosine: List of nationally authorised medicinal products - PSUSA/00001054/201810
28/06/2019	Other: Annual list of specific contracts based on framework contracts – 2018
28/06/2019	Stem cell-based products for veterinary use: Specific questions on extraneous agents to be addressed by Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT) (updated)
28/06/2019	Scientific publications (updated)

28/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Complex of povidone and iodine,dexamethasone (SHP640), PM: decision on the application for modification of an agreed PIP, P/0369/2018 (updated)
28/06/2019	Product-information templates (updated)
28/06/2019	Other: Annual list of contractors 2018 - contract values Euro 15,000 - 134.999
28/06/2019	Other: Annual list of contract modifications 2018
28/06/2019	PIP - Notification of discontinuation of a paediatric development which is covered by an agreed PIP decision: Complex Povidone-Iodine and Dexamethasone (SHP640) - Notification of discontinuation of a paediatric development which is covered by an agreed paediatric-investigation-plan decision
28/06/2019	Procurement activities 2018 (updated)
28/06/2019	Stem cell-based products for veterinary use: specific questions on sterility to be addressed by the Ad Hoc Expert Group on Veterinary Novel Therapies (ADVENT) (updated)
28/06/2019	Orphan designation: copper meso-5,15-bis[3-[(1,2-dicarba-closo-dodecaboranyl)methoxy]phenyl]-meso-10,20-dinitroporphyrin for the: Treatment of squamous-cell carcinoma of the head and neck in patients undergoing radiotherapy, 27/06/2013, Positive (updated)
28/06/2019	Orphan designation: melatonin for the: Treatment of perinatal asphyxia, 11/01/2019, Positive (updated)
28/06/2019	Summary of opinion: Edistride, dapagliflozin, 27/06/2019, Positive
28/06/2019	Summary of opinion: Tecentriq, atezolizumab, 27/06/2019, Positive
28/06/2019	Annex to CHMP highlights: Start of union reviews adopted during the CHMP meeting 24 - 27 June 2019
28/06/2019	Summary of opinion: Ebymect, dapagliflozin / metformin, 27/06/2019, Positive
28/06/2019	Summary of opinion: Xyndari, glutamine, 29/05/2019, Negative (updated)
28/06/2019	Summary of opinion: Lacosamide UCB, lacosamide, 27/06/2019, Positive
28/06/2019	News and press releases: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 24-27 June 2019
28/06/2019	Annex to CHMP highlights: Overview of (invented) names reviewed in May 2019 by the Name Review Group (NRG) Adopted at the CHMP meeting of 24-27 June 2019
28/06/2019	Summary of opinion: Azacitidine Celgene, azacitidine, 27/06/2019, Positive
28/06/2019	Summary of opinion: Giapreza, angiotensin II, 27/06/2019, Positive
28/06/2019	Summary of opinion: Forxiga, dapagliflozin, 27/06/2019, Positive
28/06/2019	Summary of opinion: Xigduo, dapagliflozin / metformin, 27/06/2019, Positive
28/06/2019	Summary of opinion: Victoza, liraglutide, 27/06/2019, Positive
28/06/2019	Summary of opinion: Imbruvica, ibrutinib, 28/06/2019, Positive
28/06/2019	Summary of opinion: Dupixent, dupilumab, 27/06/2019, Positive
28/06/2019	Summary of opinion: Flebogamma DIF (previously Flebogammadif), human normal immunoglobulin, 27/06/2019, Positive
28/06/2019	News and press releases: Bacterial lysate medicines for respiratory conditions to be used only for prevention of recurrent infections
28/06/2019	Summary of opinion: Evenity, romosozumab, 27/06/2019, Negative
28/06/2019	Summary of opinion: Cyramza, ramucirumab, 27/06/2019, Positive
28/06/2019	Referral: Bacterial lysates-containing medicinal products indicated for respiratory conditions , /Haemophilus influenzae / Klebsiella pneumoniae / Moraxella catarrhalis / Staphylococcus aureus / Streptococcus mitis / S. pneumoniae / S. pyogenes, H. influenzae / K. pneumoniae / M. catarrhalis / Staphylococcus aureus / Streptococcus pneumoniae / S. pyogenes, S. pneumoniae / S. agalactiae / Staphylococcus aureus / H. influenzae, H. influenzae / K. ozaenae / K. pneumoniae / M. catarrhalis / Staphylococcus aureus / Streptococcus pneumoniae / S. pyogenes / S. viridans, H. influenzae / membrane fraction of K. pneumoniae / ribosomal fractions of K. pneumoniae / S. pneumoniae / S. pyogenes, Escherichia coli / K.

	pneumoniae / S. aureus / S. epidermidis / S. salivarius / S. pneumoniae / S. pyogenes / H. influenzae / Corynebacterium pseudodiphtheriticum / M. catarrhalis/ , Article 31 referrals, Opinion provided by Committee for Medicinal Products for Human Use, 27/06/2019, 28/06/2019 (updated)
28/06/2019	Withdrawn application: ABP 710, infliximab, Date of withdrawal: 27/05/2019, Initial authorisation
28/06/2019	Veterinary medicines European public assessment report (EPAR): Ingelvac PCV FLEX, porcine circovirus type 2 ORF2 protein, 24/05/2017, 2, Withdrawn (updated)
28/06/2019	Other: Member states contact points for review of national versions of the content of mobile scanning and other technologies (updated)
28/06/2019	Regulatory and procedural guideline: Compilation of Quality Review of Documents decisions on stylistic matters in product information (updated)
28/06/2019	News and press releases: New treatment for children with type 2 diabetes
28/06/2019	Other: List of official languages per country (updated)
28/06/2019	Template or form: QRD product-information annotated template (English) version 10.1 - highlighted (updated)
28/06/2019	Template or form: QRD product-information annotated template (English) version 10.1 (updated)
28/06/2019	Template or form: QRD annex related to the Article-127a template (updated)
28/06/2019	Template or form: Appendix V - Adverse-drug-reaction reporting details (updated)
28/06/2019	Template or form: QRD annex IV standard positive template (updated)
28/06/2019	Template or form: QRD product-information template version 10.1 (updated)
28/06/2019	Regulatory and procedural guideline: Appendix IV - Terms and abbreviations for batch number and expiry date to be used on the labelling of human medicinal products (updated)
28/06/2019	Template or form: QRD product-information template version 10.1 - highlighted
28/06/2019	Template or form: PSUSA nationally authorised products template (updated)
28/06/2019	Template or form: QRD PSUR annex IV template (updated)
28/06/2019	Human medicines European public assessment report (EPAR): Grasustek, pegfilgrastim, Neutropenia, 26/04/2019, Authorised
28/06/2019	Template or form: QRD annex A template (updated)
28/06/2019	Template or form: QRD annex IV conditional positive template (updated)
28/06/2019	Template or form: QRD annex IV exceptional circumstances positive template (updated)
27/06/2019	Mutual recognition agreements (MRA) (updated)
27/06/2019	News and press releases: One additional country to benefit from EU-US mutual recognition agreement for inspections
27/06/2019	Human medicines European public assessment report (EPAR): Ondexxya, andexanet alfa, Drug-Related Side Effects and Adverse Reactions, 26/04/2019, Authorised
27/06/2019	Other: Questions and answers on the impact of mutual recognition agreement between the European Union and the United States as of 27 June 2019 (updated)
27/06/2019	European network of paediatric research at the European Medicines Agency (Enpr-EMA) Coordinating Group and networks meeting , European Medicines Agency via Adobe Connect, from 19/02/2019 to 19/02/2019
27/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): 5-(4-Fluoro-1-benzothiophen-2-yl)-8-methyl-1,9-dihydro-2H-[1,3]oxazolo[4,5-H][2,3]benzodiazepin-2-one (S44819), P: decision agreeing on a investigation plan, with or without partial waiver(s) and or deferral(s), P/0286/2017 (updated)
27/06/2019	Referral: Closantel , closantel , Article 35, European Commission final decision, 21/02/2019, 20/05/2019

27/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Dexxience, Betrixaban, PM: decision on the application for modification of an agreed PIP, P/0168/2018 (updated)
27/06/2019	Summary of opinion: Zinforo, ceftaroline fosamil, 27/06/2019, Positive
27/06/2019	Human medicines European public assessment report (EPAR): Macugen, pegaptanib, Wet Macular Degeneration, 31/01/2006, 15, Withdrawn (updated)
27/06/2019	Committee meeting report: COMP meeting report on the review of applications for orphan designation: June 2019
27/06/2019	Human medicines European public assessment report (EPAR): Levitra, vardenafil, Erectile Dysfunction, 06/03/2003, 29, Authorised (updated)
26/06/2019	Human medicines European public assessment report (EPAR): Zoledronic Acid Hospira, zoledronic acid monohydrate, Hypercalcemia, 19/11/2012, 15, Authorised (updated)
26/06/2019	Human medicines European public assessment report (EPAR): Skyrizi, Risankizumab, Psoriasis, 26/04/2019, Authorised
26/06/2019	Human medicines European public assessment report (EPAR): Ferriprox, Deferiprone, beta-Thalassemia, Iron Overload, 25/08/1999, 24, Authorised (updated)
26/06/2019	Human medicines European public assessment report (EPAR): Tafinlar, dabrafenib mesylate, Melanoma, 26/08/2013, 20, Authorised (updated)
26/06/2019	Regulatory and procedural guideline: Detailed guide regarding the monitoring of medical literature and the entry of relevant information into the EudraVigilance database by the European Medicines Agency - Addendum 1
26/06/2019	Human medicines European public assessment report (EPAR): Zepatier, elbasvir, grazoprevir, Hepatitis C, Chronic, 22/07/2016, 7, Authorised (updated)
26/06/2019	Medicines under additional monitoring: Annex I - List of cyproterone-acetate / ethinylestradiol-containing medicinal products in the European Union (updated)
26/06/2019	Medicines under additional monitoring: Annex I - List of cyproterone-acetate / ethinylestradiol-containing medicinal products in the European Union (updated)
26/06/2019	Medicines under additional monitoring: Annex XIV – retinoid containing medicinal products and related substances (acitretin, alitretinoin, isotretinoin) (updated)
26/06/2019	Medicines under additional monitoring: Annex XIV – retinoid containing medicinal products and related substances (acitretin, alitretinoin, isotretinoin) (updated)
26/06/2019	Medicine for use outside EU: List of medicinal products under additional monitoring (updated)
26/06/2019	Medicines under additional monitoring: List of medicinal products under additional monitoring (updated)
26/06/2019	Referral: Fenspiride containing medicinal products , fenspiride , Article 107i procedures, Position provided by CMDh, 29/05/2019, 26/06/2019 (updated)
26/06/2019	List of medicines under additional monitoring (updated)
26/06/2019	Medicines under additional monitoring: Annex XIII - List of Valproate and related substances in the European Union (updated)
26/06/2019	Medicines under additional monitoring: Annex XIII - List of Valproate and related substances in the European Union (updated)
26/06/2019	Agenda: Agenda - PDCO agenda of the 25-28 June 2019 meeting
26/06/2019	Human medicines European public assessment report (EPAR): Inlyta, axitinib, Carcinoma, Renal Cell, 03/09/2012, 10, Authorised (updated)
26/06/2019	Human medicines European public assessment report (EPAR): Moventig, naloxegol oxalate, Constipation, Opioid-Related Disorders, 07/12/2014, 9, Authorised (updated)
26/06/2019	Human medicines European public assessment report (EPAR): Ocrevus, ocrelizumab, Multiple Sclerosis, 08/01/2018, 4, Authorised (updated)

26/06/2019	Human medicines European public assessment report (EPAR): Zejula, niraparib tosylate monohydrate, Fallopian Tube Neoplasms, Peritoneal Neoplasms, Ovarian Neoplasms, 16/11/2017, 5, Authorised (updated)
26/06/2019	Human medicines European public assessment report (EPAR): Mekinist, trametinib, Melanoma, 30/06/2014, 17, Authorised (updated)
26/06/2019	Veterinary medicines European public assessment report (EPAR): Draxxin, tulathromycin, 11/11/2003, 20, Authorised (updated)
25/06/2019	Human medicines European public assessment report (EPAR): Spinraza, nusinersen sodium, Muscular Atrophy, Spinal, 30/05/2017, 7, Authorised (updated)
25/06/2019	Human medicines European public assessment report (EPAR): Bavencio, avelumab, Neuroendocrine Tumors, 18/09/2017, 4, Authorised (updated)
25/06/2019	Referral: Angiotensin-II-receptor antagonists (sartans) containing a tetrazole group , valsartan, candesartan, irbesartan, losartan and olmesartan , Article 31 referrals, European Commission final decision, 31/01/2019, 02/04/2019, 25/06/2019 (updated)
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Chemically modified extract of trees pollen from birch and alder, RPM: decision refers to a refusal on the application for modification of an agreed PIP, P/0086/2019 (updated)
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Chemically modified house dust mites allergen extract (Dermatophagoides pteronyssinus and Dermatophagoides farinae), RPM: decision refers to a refusal on the application for modification of an agreed PIP, P/0087/2019 (updated)
25/06/2019	Other: Temporary interim limits for NMBA, DIPNA and EIPNA impurities in sartan blood pressure medicines
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Uptravi, Selexipag, PM: decision on the application for modification of an agreed PIP, P/0123/2019 (updated)
25/06/2019	Human medicines European public assessment report (EPAR): Defitelio, defibrotide, Hepatic Veno-Occlusive Disease, 18/10/2013, 8, Authorised (updated)
25/06/2019	Human medicines European public assessment report (EPAR): Brilique, ticagrelor, Peripheral Vascular Diseases, Acute Coronary Syndrome, 03/12/2010, 13, Authorised (updated)
25/06/2019	Orphan designation: Tazemetostat for the: Treatment of diffuse large B-cell lymphoma, 21/03/2018, Positive (updated)
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Refixia, Nonacog beta pegol, PM: decision on the application for modification of an agreed PIP, P/0139/2019 (updated)
25/06/2019	Support for advanced-therapy developers (updated)
25/06/2019	Guidance on good manufacturing practice and good distribution practice: Questions and answers (updated)
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Otezla, apremilast, PM: decision on the application for modification of an agreed PIP, P/0080/2019 (updated)
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Xeljanz, Tofacitinib, PM: decision on the application for modification of an agreed PIP, P/0071/2019 (updated)
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Xeljanz, Tofacitinib, PM: decision on the application for modification of an agreed PIP, P/0134/2019 (updated)
25/06/2019	Human medicines European public assessment report (EPAR): Isentress, Raltegravir, HIV Infections, 19/12/2007, 36, Authorised (updated)
25/06/2019	Orphan designation: Tazemetostat for the: Treatment of follicular lymphoma, 21/03/2018, Positive (updated)

25/06/2019	Orphan designation: Tazemetostat for the: Treatment of malignant mesothelioma, 21/03/2018, Positive (updated)
25/06/2019	Human medicines European public assessment report (EPAR): Doptelet, avatrombopag, Thrombocytopenia, Authorised (updated)
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Stivarga, regorafenib, PM: decision on the application for modification of an agreed PIP, P/0158/2019 (updated)
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Mekinist, Trametinib (dimethyl sulfoxide), PM: decision on the application for modification of an agreed PIP, P/0076/2019 (updated)
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Onasemnogenum abeparvovecum, PM: decision on the application for modification of an agreed PIP, P/0162/2019 (updated)
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Lefamulin, PM: decision on the application for modification of an agreed PIP, P/0066/2019 (updated)
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Carotuximab, PM: decision on the application for modification of an agreed PIP, P/0072/2019 (updated)
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Avalglucosidase alfa, PM: decision on the application for modification of an agreed PIP, P/0073/2019 (updated)
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): 3-[[5-chloro-1-[3-(methylsulfonyl)propyl]-1H-indol-2-yl]methyl]-1-(2,2,2-trifluoroethyl)-1,3-dihydro-3-[[5-chloro-1-[3-(methylsulfonyl)propyl]-1H-indol-2-yl]methyl]-1-(2,2,2-trifluoroethyl)-1,3-dihydro-2H-imidazo[4,5-c]pyridine-2-one (JNJ-53718678), PM: decision on the application for modification of an agreed PIP, P/0081/2019 (updated)
25/06/2019	Patients' and Consumers' Working Party (updated)
25/06/2019	Eligible patients and consumers organisations (updated)
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Tralokinumab, PM: decision on the application for modification of an agreed PIP, P/0104/2019 (updated)
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Emgality, Galcanezumab, PM: decision on the application for modification of an agreed PIP, P/0111/2019 (updated)
25/06/2019	Report: Medicinal products for human use: monthly figures - May 2019
25/06/2019	Minutes: Minutes of the CHMP meeting 23-26 April 2019
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Inebilizumab, PM: decision on the application for modification of an agreed PIP, P/0129/2019 (updated)
25/06/2019	Other: Questions and answers on the use of out-of-specification batches of authorised cell and tissue-based advanced therapy medicinal products
25/06/2019	Opinion/decision on a Paediatric investigation plan (PIP): Angiotensin II (LJPC-501), PM: decision on the application for modification of an agreed PIP, P/0159/2019 (updated)

NOTICE TO APPLICANTS

No updates since December 15th 2017.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

28.06.2019	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/842028/2018 vom 12.12.2018 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Ivermectin (zur topischen Anwendung) Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Ivermectin (zur topischen Anwendung) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
28.06.2019	81. Sitzung (27. Juni 2019) – Kurzprotokoll Sachverständigen-Ausschuss für Verschreibungspflicht nach § 53 Absatz 2 AMG
27.06.2019	Rote-Hand-Brief zu Adenuric® (Febuxostat) und anderen febuxostathaltigen Arzneimitteln: Erhöhtes Risiko für kardiovaskulär bedingte Mortalität und Gesamtmortalität Wirkstoff Febuxostat Die Zulassungsinhaber informieren über eine signifikant erhöhte Gesamtmortalität bei mit Febuxostat behandelten Patienten in der CARES-Studie.
27.06.2019	Bulletin zur Arzneimittelsicherheit - Informationen aus BfArM und PEI Die neue Ausgabe des Bulletin zur Arzneimittelsicherheit ist erschienen

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since June 13th 2019

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since June 17th2019

PHARMEUROPA TEXTS FOR COMMENT

Text	Monograph number	Group	Issue	Deadline
5.28. Multivariate statistical process control	52800	VSADM	31. Mrz	30.09.2019
Paroxetine hydrochloride	2283	10A	31. Mrz	30.09.2019
Paroxetine hydrochloride hemihydrate	2018	10A	31. Mrz	30.09.2019
Baical skullcap root	2438	TCM	31. Mrz	30.09.2019
Xylazine hydrochloride for veterinary use	1481	10A	31. Mrz	30.09.2019
Dosulepin hydrochloride	1314	10A	31. Mrz	30.09.2019
Chlorpromazine hydrochloride	475	10A	31. Mrz	30.09.2019
Chenodeoxycholic acid	1189	11	31. Mrz	30.09.2019
Benserazide hydrochloride	1173	10A	31. Mrz	30.09.2019
Propyphenazone	636	10A	31. Mrz	30.09.2019
Promethazine hydrochloride	524	10A	31. Mrz	30.09.2019
Promazine hydrochloride	1365	10A	31. Mrz	30.09.2019

Text	Monograph number	Group	Issue	Deadline
Levomepromazine maleate	925	10A	31. Mrz	30.09.2019
Levomepromazine hydrochloride	505	10A	31. Mrz	30.09.2019
Caspofungin acetate	3029	7	31. Mrz	30.09.2019