TABLE OF CONTENTS

HEADS OF AGENCIES – CMDh

20 February 2020

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 here2*

EUROPEAN MEDICINES AGENCY (EMA)

21/02/2020	Maximum Residue Limits - Summary of opinion: Bupivacaine - Summary opinion of the CVMP on the establishment of maximum residue limits (new)
21/02/2020	Human medicines European public assessment report (EPAR): Bexsero, outer membrane vesicles from neisseria meningitidis group b (strain nz 98/254), recombinant Neisseria meningitidis group B fHbp fusion protein, recombinant Neisseria meningitidis group B NadA protein, recombinant Neisseria meningitidis group B NHBA fusion protein, Meningitis, Meningococcal, 13/01/2013, 23, Authorised (updated)
21/02/2020	News and press releases: Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 18-20 February 2020
21/02/2020	Summary of opinion: Clynav, Salmon pancreas disease vaccine (recombinant DNA plasmid), 20/02/2020, Positive
21/02/2020	Summary of opinion: Vectormune FP ILT + AE, fowlpox, avian infectious laryngotracheitis vaccine (live, recombinant) and avian encephalomyelitis vaccine (live), 20/02/2020, Positive
21/02/2020	Summary of opinion: Tulissin, tulathromycin, 20/02/2020, Positive
21/02/2020	Summary of opinion: Tulaven, tulathromycin, 20/02/2020, Positive
21/02/2020	Human medicines European public assessment report (EPAR): Levetiracetam Accord, levetiracetam, Epilepsy, 03/10/2011, 11, Authorised (updated)
21/02/2020	Human medicines European public assessment report (EPAR): Fycompa, perampanel, Epilepsies, Partial, 23/07/2012, 16, Authorised (updated)
21/02/2020	Human medicines European public assessment report (EPAR): Latuda, lurasidone, Schizophrenia, 20/03/2014, 18, Authorised (updated)

21/02/2020	Human medicines European public assessment report (EPAR): Azacitidine Accord, azacitidine, Myelodysplastic Syndromes, Leukemia, Myelomonocytic, Chronic, Leukemia, Myeloid, Acute, 13/02/2020, Authorised
21/02/2020	From data to evidence in medicines regulation , European Medicines Agency, Amsterdam, The Netherlands, from 22/04/2020 to 22/04/2020
21/02/2020	Human medicines European public assessment report (EPAR): Aimovig, erenumab, Migraine Disorders, 26/07/2018, 3, Authorised (updated)
21/02/2020	Human medicines European public assessment report (EPAR): Hexyon, diphtheria toxoid adsorbed on aluminium hydroxide, hydrated, filamentous haemagglutinin, Haemophilus influenzae type B polysaccharide (polyribosylribitol phosphate), hepatitis B surface antigen, pertussis toxoid, poliovirus (inactivated) type 1 (Mahoney strain) produced on Vero cells, poliovirus (inactivated) type 2 (MEF-1 strain) produced on Vero cells, poliovirus (inactivated) type 3 (Saukett strain) produced on Vero cells, tetanus protein, tetanus toxoid adsorbed on aluminium hydroxide, hydrated, Hepatitis B, Tetanus, Immunization, Meningitis, Haemophilus, Whooping Cough, Poliomyelitis, Diphtheria, 17/04/2013, 22/02/2013, 20, Authorised (updated)
21/02/2020	Human medicines European public assessment report (EPAR): Adcirca (previously Tadalafil Lilly), tadalafil, Hypertension, Pulmonary, 01/10/2008, 12, Authorised (updated)
21/02/2020	Hexaxim H-W-2495 (updated)
21/02/2020	Human medicines European public assessment report (EPAR): Hexacima, diphtheria toxoid / tetanus toxoid, two-component acellular pertussis (pertussis toxoid and filamentous haemagglutinin) / inactivated poliomyelitis virus types 1,2 and 3 / Haemophilus influenzae type-b polysaccharide (polyribosylribitol phosphate) conjugated to tetanus protein, hepatitis-B surface antigen, Hepatitis B, Tetanus, Immunization, Meningitis, Haemophilus, Whooping Cough, Poliomyelitis, Diphtheria, 17/04/2013, 22/02/2013, 19, Authorised (updated)
21/02/2020	Human medicines European public assessment report (EPAR): Cinacalcet Mylan, cinacalcet hydrochloride, Hyperparathyroidism, Secondary, Hypercalcemia, 19/11/2015, 5, Authorised (updated)
21/02/2020	Human medicines European public assessment report (EPAR): NovoEight, turoctocog alfa, Hemophilia A, 13/11/2013, 11, Authorised (updated)
21/02/2020	Periodic safety update single assessment: Clebopride: List of nationally authorised medicinal products - PSUSA/00000789/201906 (new)
21/02/2020	Human medicines European public assessment report (EPAR): Vyndaqel, tafamidis, Amyloidosis, 16/11/2011, 16, Authorised (updated)
20/02/2020	Human medicines European public assessment report (EPAR): Avastin, bevacizumab, Carcinoma, Non-Small-Cell Lung, Breast Neoplasms, Ovarian Neoplasms, Colorectal Neoplasms, Carcinoma, Renal Cell, 12/01/2005, 53, Authorised (updated)
20/02/2020	Human medicines European public assessment report (EPAR): Lifmior, etanercept, Arthritis, Psoriatic, Spondylitis, Ankylosing, Psoriasis, 13/02/2017, 8, Withdrawn (updated)
20/02/2020	Human medicines European public assessment report (EPAR): Orkambi, Lumacaftor, ivacaftor, Cystic Fibrosis, 18/11/2015, 19, Authorised (updated)
20/02/2020	Direct healthcare professional communication: Risks associated with systemic exposure to estradiol creams (new)
20/02/2020	Good manufacturing practice (updated)
20/02/2020	Human medicines European public assessment report (EPAR): Cialis, tadalafil, Erectile Dysfunction, 12/11/2002, 27, Authorised (updated)
20/02/2020	Human medicines European public assessment report (EPAR): Quinsair, levofloxacin, Cystic Fibrosis, Respiratory Tract Infections, 25/03/2015, 10, Authorised (updated)

20/02/2020	Periodic safety update single assessment: Lidocaine hydrochloride / phenylephrine hydrochloride / tropicamide: List of nationally authorised medicinal products - PSUSA/00010390/201907 (new)
19/02/2020	Report: Applications for new human medicines under evaluation by the CHMP: February 2020 (updated)
19/02/2020	Committee for Advanced Therapies (CAT): 19-21 February 2020 , European Medicines Agency, Amsterdam, the Netherlands, from 19/02/2020 to 21/02/2020 (updated)
19/02/2020	Agenda: Agenda - CAT agenda of the 19-21 February 2020 meeting (new)
19/02/2020	Pharmacovigilance Risk Assessment Committee (PRAC): 30 September-3 October 2019 , European Medicines Agency, Amsterdam, the Netherlands, from 30/09/2019 to 03/10/2019 (updated)
19/02/2020	Minutes: Minutes of the PRAC meeting 30 September-03 October 2019 (new)
19/02/2020	Human medicines European public assessment report (EPAR): Brineura, cerliponase alfa, Neuronal Ceroid-Lipofuscinoses, 30/05/2017, 3, Authorised (updated)
19/02/2020	Human medicines European public assessment report (EPAR): Sirturo, bedaquiline fumarate, Tuberculosis, Multidrug-Resistant, 05/03/2014, 16, Authorised (updated)
19/02/2020	Human medicines European public assessment report (EPAR): NeuroBloc, botulinum toxin type B, Torticollis, 22/01/2001, 32, Authorised (updated)
19/02/2020	Human medicines European public assessment report (EPAR): Tadalafil Lilly, tadalafil, Erectile Dysfunction, 22/03/2017, 2, Authorised (updated)
19/02/2020	Other: European Medicines Agency's privacy statement for the pre-employment medical examination (new)
19/02/2020	Orphan designation: Combretastatin A1 diphosphate- for the: Treatment of acute myeloid leukaemia, 14/12/2015, Positive (updated)
19/02/2020	Orphan designation: Variant of recombinant human fibroblast growth factor 19 for the: Treatment of primary biliary cirrhosis, 22/08/2014, Positive (updated)
19/02/2020	Orphan designation: N-[(1R)-1-phenylethyl]-6-{1H-pyrazolo[3,4-d]pyrimidin-4-yl}quinazolin-2-amine for the: Treatment of fragile X syndrome, 20/04/2017, Positive (updated)
19/02/2020	Orphan designation: Recombinant adeno-associated viral vector containing the human CNGB3 gene for the: Treatment of achromatopsia caused by mutations in the CNGB3 gene, 08/02/2013, Positive (updated)
19/02/2020	Orphan designation: 2-Methoxy-5-[(1Z)-2-(3,4,5-trimethoxyphenyl)ethenyl]-phenol (fosbretabulin tromethamine) for the: Treatment of anaplastic thyroid cancer, 14/04/2004, Positive (updated)
19/02/2020	Orphan designation: Ovine specific immunoglobulin (Fab) fragments raised against Vipera berus veno for the: Treatment of snakebite envenomation, 09/10/2015, Positive (updated)
19/02/2020	Orphan designation: Recombinant adeno-associated viral vector containing human alpha-1 antitrypsin gene for the: Treatment of congenital alpha-1 antitrypsin deficiency, 20/03/2007, Positive (updated)
19/02/2020	Orphan designation: Fosbretabulin tromethamine for the: Treatment of gastro-entero-pancreatic neuroendocrine tumours, 21/03/2016, Positive (updated)
19/02/2020	Orphan designation: Recombinant adeno-associated viral vector containing the human retinoschisin gene for the: Treatment of X-linked juvenile retinoschisis, 12/03/2013, Positive (updated)
19/02/2020	Orphan designation: Recombinant adeno-associated viral vector expressing the human CNGA3 gene for the: Treatment of achromatopsia caused by mutations in the CNGA3 gene, 09/10/2015, Positive (updated)
19/02/2020	Orphan designation: Variant of recombinant human fibroblast growth factor 19 for the: Treatment of primary sclerosing cholangitis, 14/12/2015, Positive (updated)

19/02/2020	Orphan designation: Fosbretabulin tromethamine for the: Treatment of ovarian cancer, 17/07/2013, Positive (updated)
19/02/2020	Orphan designation: Autologous dendritic cells pulsed with tumour antigen-derived synthetic peptides (MAGE-1, HER-2, AIM-2, TRP-2, gp-100, and interleukin-13 receptor alpha) for the: Treatment of glioma, 19/02/2014, Positive (updated)
19/02/2020	Orphan designation: Recombinant adeno-associated viral vector containing the human RPGR gene for the: Treatment of retinitis pigmentosa caused by mutations in the RPGR gene, 30/05/2016, Positive (updated)
19/02/2020	Human medicines European public assessment report (EPAR): Dexmedetomidine Accord, dexmedetomidine, Premedication, 13/02/2020, Authorised
18/02/2020	Human medicines European public assessment report (EPAR): Hirobriz Breezhaler, indacaterol maleate, Pulmonary Disease, Chronic Obstructive, 30/11/2009, 16, Authorised (updated)
18/02/2020	Human medicines European public assessment report (EPAR): Isturisa, Osilodrostat phosphate, Cushing Syndrome, 09/01/2020, Authorised
18/02/2020	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, 5, Authorised (updated)
18/02/2020	Human medicines European public assessment report (EPAR): Vokanamet, canagliflozin, metformin hydrochloride, Diabetes Mellitus, Type 2, 23/04/2014, 15, Authorised (updated)
18/02/2020	Human medicines European public assessment report (EPAR): Iblias, octocog alfa, Hemophilia A, 18/02/2016, 4, Withdrawn (updated)
18/02/2020	ICH S5 (R3) guideline on reproductive toxicology: Detection of toxicity to reproduction for human pharmaceuticals - step 5 (updated)
18/02/2020	Scientific guideline: ICH S5 (R3) guideline on reproductive toxicology: Detection of toxicity to reproduction for human pharmaceuticals - step 5 - Revision 3 (new)
18/02/2020	ICH E9 statistical principles for clinical trials (updated)
18/02/2020	Scientific guideline: ICH E9 (R1) addendum on estimands and sensitivity analysis in clinical trials to the guideline on statistical principles for clinical trials Step 5 (new)
18/02/2020	Agenda: Agenda - CVMP agenda of the 18-20 February 2020 meeting (new)
18/02/2020	Other: EU Innovation Network: E-mail addresses for users (updated)
18/02/2020	Human medicines European public assessment report (EPAR): Nonafact, human coagulation factor IX, Hemophilia B, 03/07/2001, 9, Withdrawn (updated)
18/02/2020	Human medicines European public assessment report (EPAR): Beovu, brolucizumab, Wet Macular Degeneration, 13/02/2020, Authorised
18/02/2020	Orphan designation: Milatuzumab for the: Treatment of chronic lymphocytic leukaemia, 19/01/2009, Withdrawn (updated)
18/02/2020	Orphan designation: Milatuzumab for the: Treatment of multiple myeloma, 19/01/2009, Withdrawn (updated)
18/02/2020	Human medicines European public assessment report (EPAR): Vemlidy, tenofovir alafenamide fumarate, Hepatitis B, 09/01/2017, 6, Authorised (updated)
18/02/2020	Human medicines European public assessment report (EPAR): Erleada, apalutamide, Prostatic Neoplasms, 14/01/2019, Authorised (updated)
18/02/2020	Regulatory and procedural guideline: Checklist for sponsors applying for the transfer of orphan medicinal product designation (updated)
17/02/2020	Other: European Commission-DG Health and Food Safety and European Medicines Agency action plan on advanced therapy medicinal products (ATMPs) (updated)
17/02/2020	Implementation of risk assessment requirements to control elemental impurities in veterinary medicinal products (updated)

17/02/2020	Human medicines European public assessment report (EPAR): Otezla, apremilast, Arthritis, Psoriatic, Psoriasis, 15/01/2015, 12, Authorised (updated)
17/02/2020	Withdrawn application: Luxceptar, viable T-cells, Date of withdrawal: 06/11/2019, Initial authorisation (updated)
17/02/2020	Agenda: Agenda - COMP agenda of the 18-20 February 2020 meeting (new)
17/02/2020	Human medicines European public assessment report (EPAR): Levetiracetam Teva, levetiracetam, Epilepsy, 25/08/2011, 15, Authorised (updated)
17/02/2020	Template or form: Mutual-recognition, decentralised and referral product-information template version 4.1 (updated)
17/02/2020	Human medicines European public assessment report (EPAR): Sycrest, asenapine maleate , Bipolar Disorder, 01/09/2010, 16, Authorised (updated)
17/02/2020	Withdrawn application: Opsumit, macitentan, Date of withdrawal: 08/11/2019, Post-authorisation (updated)
17/02/2020	Periodic safety update single assessment: Ganciclovir: List of nationally authorised medicinal products - PSUSA/00001516/201906 (new)
17/02/2020	Human medicines European public assessment report (EPAR): Tecfidera, dimethyl fumarate, Multiple Sclerosis, 30/01/2014, 19, Authorised (updated)
17/02/2020	Periodic safety update single assessment: Human plasma proteins with not less than 95% albumin: List of nationally authorised medicinal products - PSUSA/00010605/201907 (new)
17/02/2020	Other: HMPC: overview of assessment work - priority list (updated)
17/02/2020	Human medicines European public assessment report (EPAR): Onbrez Breezhaler, indacaterol maleate, Pulmonary Disease, Chronic Obstructive, 29/11/2009, 15, Authorised (updated)

NOTICE TO APPLICANTS

No updates since November 28th 2019.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

20.02.2020	Rote-Hand-Brief zu Linoladiol N® (Estradiol): Risiken in Verbindung mit einer systemischen Exposition Wirkstoff Estradiol Die Firma Dr. August Wolff GmbH & Co. KG Arzneimittel informiert in Abstimmung mit der Europäischen Arzneimittelagentur (EMA) und dem Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) darüber, dass die Behandlung mit Linoladiol N® (100 Mikrogramm Estradiol pro Gramm Creme) aufgrund fehlender Daten zur Langzeitsicherheit auf einen einmaligen Behandlungszeitraum von bis zu 4 Wochen zu begrenzen ist.
20.02.2020	Rückruf des Adrenalin-Autoinjektors Emerade®: Patienten sollen Notfallmedikament wegen möglicher Aktivierungsfehler zeitnah austauschen Wirkstoff Adrenalin Der Zulassungsinhaber Pharma Swiss Česká republika s.r.o. und der Mitvertreiber Dr. Gerhard Mann chem.-pharm. Fabrik GmbH informieren in Absprache mit der zuständigen Behörde (Landesamt für Gesundheit und Soziales, Berlin) darüber, dass alle Chargen des Emerade® Fertigpens (150 µg, 300 µg, 500 µg) mit einem Verfallsdatum bis einschließlich 10/2020 bis auf Patientenebene zurückgerufen

	werden. Emerade® ist zur Notfallbehandlung von schweren akuten allergischen Reaktionen (Anaphylaxie) zugelassen. Die Auftrittswahrscheinlichkeit des initialen Aktivierungsfehlers ist höher als ursprünglich auf Grund der zum damaligen Zeitpunkt vorliegenden Daten errechnet (siehe Rote-Hand-Brief vom 09.12.2019). Patienten, denen in den letzten 18 Monaten ein Emerade® Fertigpen verordnet wurde, sollen diesen daher in einer Apotheke zurückgeben. Patienten sollen betroffene Produkte trotzdem noch solange mit sich führen, bis ihr Arzt ihnen ein anderes geeignetes Arzneimittel verschrieben hat und der Apotheker ihnen dieses andere Arzneimittel ausgehändigt hat. Solange kein alternativer Adrenalin-Autoinjektor verfügbar ist, sollen die Patienten zwei ordnungsgemäß gelagerte Emerade Fertigpens jederzeit bei sich tragen und diese bei Bedarf wie angewiesen verwenden.Aufgabe des BfArM ist es, den Informationsaustausch zwischen den für die Überwachung des Arzneimittelverkehrs zuständigen Landesbehörden und den europäischen Behörden zu koordinieren. Die Europäische Arzneimittel-Agentur (EMA) und die Behörden der Länder in Deutschland sind über den Sachverhalt informiert. Die Rückrufe werden in Deutschland von den Landesbehörden überwacht. Weitere Informationen zu dem Rückruf finden Sie auf der Homepage der zuständigen Landesbehörde, dem Landesamt für Gesundheit und Soziales in Berlin.
17.02.2020	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/551305/2019 vom 17.10.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Cabergolin Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Cabergolin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
17.02.2020	Umsetzung des Durchführungsbeschlusses der Europäischen Kommission zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Tenofovirdisoproxil vom 13.01.2020 Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Tenofovirdisoproxil infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
17.02.2020	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/547798/2019 vom 17.10.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Lisdexamfetamin Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Lisdexamfetamin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

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.