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HEADS OF AGENCIES – CMDh

14 February 2020

NEW - Minutes from the CMDh meeting with Interested parties - 13 November 2019

NEW - PSUR AR for highly refined fish oil (eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA) dl-α-tocopherol), glycerol, purified egg, phosphatide);

NEW - PSUFU AR for valaciclovir;

NEW - Art. 46 PARs for Sandimmun/Sandimmun Neoral (ciclosporin), Infanrix-IPV/Hib (Diphtheria, Tetanus, Pertussis (acellular, component), Poliomyelitis (inactivated) and Haemophilus type b conjugate vaccine (adsorbed)) and Foradil Aerolizer (formoterol fumarate);

UPDATE - Chapter 1: CMDh BPG for the allocation of the mutual recognition variation number for Type I Notifications, Type II Variations, Grouping and Worksharing;

UPDATE - 'Blue-box' requirements;

UPDATE - CMDh annotated QRD template for MRP/DCP;

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here2*

EUROPEAN MEDICINES AGENCY (EMA)

17/02/2020	Other: List of signals discussed at PRAC since September 2012 (updated)
17/02/2020	Periodic safety update single assessment: Octenidine: PSUSA - List of nationally authorised medicinal products - PSUSA/00010748/201907 (new)
14/02/2020	Human medicines European public assessment report (EPAR): Amsparity, adalimumab, Arthritis, Rheumatoid, Arthritis, Juvenile Rheumatoid, Psoriasis, Arthritis, Psoriatic, Spondylitis, Ankylosing, Uveitis, Colitis, Ulcerative, Crohn Disease, Hidradenitis Suppurativa, 13/02/2020, Authorised
14/02/2020	Human medicines European public assessment report (EPAR): Herzuma, trastuzumab, Stomach Neoplasms, Breast Neoplasms, 08/02/2018, 7, Authorised (updated)

14/02/2020	Other: European Medicines Agency's privacy statement public and targeted consultations (new)
14/02/2020	Use of herbal medicinal products containing estragole (updated)
14/02/2020	Other: Second draft - Revision 1: Public statement on the use of herbal medicinal products containing estragole (new)
14/02/2020	Overview of comments: Overview of comments received on the draft revised Public statement on the use of herbal medicinal products containing estragole (EMA/HMPC/137212/2005 Rev 1) (new)
14/02/2020	Referral: Cyproterone-containing medicinal products , cyproterone , Article 31 referrals, Recommendation provided by Pharmacovigilance Risk Assessment Committee, 14/02/2020 (updated)
14/02/2020	Direct healthcare professional communications
14/02/2020	News and press releases: Restrictions in use of cyproterone due to meningioma risk
14/02/2020	News and press releases: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 10-13 February 2020
14/02/2020	Human medicines European public assessment report (EPAR): Zalmoxis, Allogeneic T cells genetically modified with a retroviral vector encoding for a truncated form of the human low affinity nerve growth factor receptor (ΔLNGFR) and the herpes simplex I virus thymidine kinase (HSV-TK Mut2), Hematopoietic Stem Cell Transplantation, Graft vs Host Disease, 18/08/2016, 1, Withdrawn (updated)
14/02/2020	Human medicines European public assessment report (EPAR): Zejula, niraparib tosylate monohydrate, Fallopian Tube Neoplasms, Peritoneal Neoplasms, Ovarian Neoplasms, 16/11/2017, 7, Authorised (updated)
14/02/2020	Periodic safety update single assessment: Rocuronium : List of nationally authorised medicinal products - PSUSA/00002656/201902 (new)
14/02/2020	Periodic safety update single assessment: Rocuronium : CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - PSUSA/00002656/201902 (new)
13/02/2020	Human medicines European public assessment report (EPAR): Cabometyx , cabozantinib s-malate, Carcinoma, Renal Cell, 09/09/2016, 7, Authorised (updated)
13/02/2020	Report: Information Management Strategy 2020-2022 (new)
13/02/2020	Human medicines European public assessment report (EPAR): Giotrif, afatinib, Carcinoma, Non-Small-Cell Lung, 25/09/2013, 12, Authorised (updated)
13/02/2020	Human medicines European public assessment report (EPAR): Emtricitabine/Tenofovir disoproxil Krka, emtricitabine, tenofovir disoproxil succinate, HIV Infections, 09/12/2016, 6, Authorised (updated)
13/02/2020	Human medicines European public assessment report (EPAR): Seebri Breezhaler, Glycopyrronium bromide, Pulmonary Disease, Chronic Obstructive, 28/09/2012, 10, Authorised (updated)
13/02/2020	Template or form: Connecting to the Agency ESTRI Gateway using an AS2 compatible product (updated)
13/02/2020	Veterinary medicines European public assessment report (EPAR): Draxxin, tulathromycin, 11/11/2003, 22, Authorised (updated)
13/02/2020	Orphan designation: Replication-incompetent, non-integrating, herpes simplex virus 1 vector expressing the human transglutaminase-1 enzyme for the: Treatment of autosomal recessive congenital ichthyosis, 13/11/2019, Positive
13/02/2020	Orphan designation: Ganaxolone for the: Treatment of CDKL5 deficiency disorder, 13/11/2019, Positive
13/02/2020	Orphan designation: Exendin (9-39) for the: Treatment of congenital hyperinsulinism, 13/11/2019, Positive
13/02/2020	Orphan designation: Chimeric fibril-reactive IgG1k monoclonal antibody 11-1F4 for the: Treatment of AL amyloidosis, 13/11/2019, Positive

13/02/2020	Orphan designation: Camsirubicin for the: Treatment of soft tissue sarcoma, 13/11/2019, Positive
13/02/2020	Orphan designation: Autologous peripheral blood T cells CD4 and CD8 selected and CD3 and CD28 activated transduced with retroviral vector expressing anti CD19 CD28/CD3-zeta chimeric antigen receptor and cultured (KTE-X19) for the: Treatment of mantle cell lymphoma, 13/11/2019, Positive
12/02/2020	Orphan designation: (2S,3R,4R,5S)-2-(hydroxymethyl)-1-pentylpiperidine-3,4,5-triol for the: Treatment of GM2 gangliosidosis, 13/11/2019, Positive
12/02/2020	Orphan designation: 4-((E)-(5-(2-(2-((S)-2-((S)-1-(L-threonyl-L-lysyl)pyrrolidine-2-carboxamido)-5-guanidinopentanamido)acetamido)-2-carboxyethyl)-2-hydroxyphenyl)diazenyl)phenyl (2-(trimethylammonio)ethyl) phosphate for the: Treatment of non-infectious uveitis, 13/11/2019, Positive
12/02/2020	Veterinary medicines European public assessment report (EPAR): Bravecto Plus, fluralaner, moxidectin, 08/05/2018, 3, Authorised (updated)
12/02/2020	Human medicines European public assessment report (EPAR): Zykadia, ceritinib, Carcinoma, Non-Small-Cell Lung, 06/05/2015, 13, Authorised (updated)
12/02/2020	Human medicines European public assessment report (EPAR): Ceprotin, human protein C, Purpura Fulminans, Protein C Deficiency, 15/07/2001, 14, Authorised (updated)
12/02/2020	Human medicines European public assessment report (EPAR): Oslif Breezhaler, indacaterol maleate, Pulmonary Disease, Chronic Obstructive, 29/11/2009, 15, Authorised (updated)
12/02/2020	Human medicines European public assessment report (EPAR): Temybric Ellipta, fluticasone furoate, umeclidinium bromide, vilanterol trifenatate, Pulmonary Disease, Chronic Obstructive, 12/06/2019, 1, Authorised (updated)
12/02/2020	Human medicines European public assessment report (EPAR): Cuprior, Trientine tetrahydrochloride, Hepatolenticular Degeneration, 05/09/2017, 4, Authorised (updated)
12/02/2020	Human medicines European public assessment report (EPAR): Xigduo, metformin hydrochloride, dapagliflozin propanediol monohydrate, Diabetes Mellitus, Type 2, 16/01/2014, 16, Authorised (updated)
12/02/2020	Human medicines European public assessment report (EPAR): Rizmoic, Naldemedine tosilate, Constipation, 18/02/2019, 3, Authorised (updated)
12/02/2020	Human medicines European public assessment report (EPAR): Cegfila (previously Pegfilgrastim Mundipharma), pegfilgrastim, Neutropenia, 19/12/2019, Authorised (updated)
12/02/2020	Human medicines European public assessment report (EPAR): Invokana, canagliflozin, Diabetes Mellitus, Type 2, 15/11/2013, 15, Authorised (updated)
12/02/2020	EudraVigilance Veterinary (updated)
12/02/2020	News and press releases: Public access to suspected side effect reports of veterinary medicines
12/02/2020	Human medicines European public assessment report (EPAR): NutropinAq, somatropin, Turner Syndrome, Dwarfism, Pituitary, 15/02/2001, 17, Authorised (updated)
12/02/2020	Veterinary medicines European public assessment report (EPAR): Inflacam, meloxicam, 09/12/2011, 10, Authorised (updated)
12/02/2020	Veterinary medicines European public assessment report (EPAR): Rheumocam, meloxicam, 10/01/2008, 13, Authorised (updated)
12/02/2020	Human medicines European public assessment report (EPAR): MabThera, rituximab, Lymphoma, Non-Hodgkin, Arthritis, Rheumatoid, Leukemia, Lymphocytic, Chronic, B-Cell, 02/06/1998, 48, Authorised (updated)
12/02/2020	Human medicines European public assessment report (EPAR): Revolade, Eltrombopag, Purpura, Thrombocytopenic, Idiopathic, 11/03/2010, 24, Authorised (updated)
12/02/2020	Substances and products data management services (updated)

12/02/2020	Human medicines European public assessment report (EPAR): Zoledronic acid Teva, zoledronic acid, Fractures, Bone, Cancer, 16/08/2012, 12, Authorised (updated)
12/02/2020	Human medicines European public assessment report (EPAR): Alofisel, darvadstrocel, Rectal Fistula, 23/03/2018, 4, Authorised (updated)
12/02/2020	Report: Applications for new human medicines under evaluation by the CHMP: February 2020 (new)
12/02/2020	Human medicines European public assessment report (EPAR): Rolufta Ellipta (previously Rolufta), umeclidinium bromide, Pulmonary Disease, Chronic Obstructive, 20/03/2017, 8, Authorised (updated)
12/02/2020	Orphan designation: 505 amino acid protein, corresponding to amino acids 2-506 of the wild-type human histidyl-tRNA synthetase for the: Treatment of limb-girdle muscular dystrophy, 27/02/2017, Withdrawn (updated)
12/02/2020	Orphan designation: 505 amino acid protein, corresponding to amino acids 2-506 of the wild type human histidyl-tRNA synthetase for the: treatment of facioscapulohumeral muscular dystrophy, 12/02/2015, Withdrawn (updated)
12/02/2020	Human medicines European public assessment report (EPAR): Epidyolex, Cannabidiol, Lennox Gastaut Syndrome, Epilepsies, Myoclonic, 19/09/2019, 1, Authorised (updated)
12/02/2020	Human medicines European public assessment report (EPAR): Glivec, imatinib, Precursor Cell Lymphoblastic Leukemia-Lymphoma, Gastrointestinal Stromal Tumors, Dermatofibrosarcoma, Myelodysplastic-Myeloproliferative Diseases, Leukemia, Myelogenous, Chronic, BCR-ABL Positive, Hypereosinophilic Syndrome, 07/11/2001, 37, Authorised (updated)
12/02/2020	Orphan designation: 2-Hydroxyoleic acid for the: Treatment of glioma, 27/10/2011, Positive (updated)
12/02/2020	Orphan designation: Adenovirus-specific T-cells derived from allogeneic donor leukocytes, expanded ex vivo for the: Treatment of adenovirus infection in allogeneic haematopoietic stem cell transplant recipients, 16/01/2014, Withdrawn (updated)
12/02/2020	Human medicines European public assessment report (EPAR): Yondelis, trabectedin, Ovarian Neoplasms, Sarcoma, 17/09/2007, 24, Authorised (updated)
12/02/2020	Human medicines European public assessment report (EPAR): Votubia, everolimus, Tuberous Sclerosis, 02/09/2011, , 25, Authorised (updated)
12/02/2020	Committee meeting report: CAT monthly report of application procedures, guidelines and related documents on advanced therapies: January 2020 (new)
12/02/2020	Human medicines European public assessment report (EPAR): Lifmior, etanercept, Arthritis, Psoriatic, Spondylitis, Ankylosing, Psoriasis, 13/02/2017, 8, Authorised (updated)
12/02/2020	Scientific publications (updated)
11/02/2020	Human medicines European public assessment report (EPAR): Bydureon, exenatide, Diabetes Mellitus, Type 2, 17/06/2011, 19, Authorised (updated)
11/02/2020	Human medicines European public assessment report (EPAR): GONAL-f, follitropin alfa, Anovulation, Reproductive Techniques, Assisted, Infertility, Female, Hypogonadism, 20/10/1995, 23, Authorised (updated)
11/02/2020	Veterinary medicines European public assessment report (EPAR): Stelfonta, tigilanol tiglate, 15/01/2020, Authorised
11/02/2020	Human medicines European public assessment report (EPAR): Prolia, denosumab, Bone Resorption, Osteoporosis, Postmenopausal, 26/05/2010, 22, Authorised (updated)
11/02/2020	Human medicines European public assessment report (EPAR): Puregon, follitropin beta, Infertility, Hypogonadism, 02/05/1996, 27, Authorised (updated)
11/02/2020	Plasma master file certificates (updated)

11/02/2020	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, 3, Authorised (updated)
11/02/2020	Human medicines European public assessment report (EPAR): Trelegy Ellipta, fluticasone furoate, umeclidinium bromide, vilanterol trifenatate, Pulmonary Disease, Chronic Obstructive, 15/11/2017, 5, Authorised (updated)
11/02/2020	Human medicines European public assessment report (EPAR): Tavlesse, Fostamatinib disodium, Thrombocytopenia, 09/01/2020, Authorised
11/02/2020	Orphan designation: lenalidomide for the: Treatment of follicular lymphoma, 24/01/2013, Withdrawn (updated)
11/02/2020	Human medicines European public assessment report (EPAR): Zoely, Nomegestrol acetate, estradiol, Contraception, 26/07/2011, 18, Authorised (updated)
11/02/2020	Orphan designation: Beraprost sodium for the: Treatment of pulmonary arterial hypertension, 10/07/2008, Withdrawn (updated)
11/02/2020	Human medicines European public assessment report (EPAR): Revlimid, lenalidomide, Multiple Myeloma, Lymphoma, Mantle-Cell, Myelodysplastic Syndromes, 14/06/2007, 40, Authorised (updated)
11/02/2020	Regulatory and procedural guideline: Products Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 1 (new)
11/02/2020	Regulatory and procedural guideline: Product Management Services - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 2 (new)
11/02/2020	Regulatory and procedural guideline: Products Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 6 (new)
11/02/2020	Regulatory and procedural guideline: Products Management Services (PMS) - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe - Chapter 7 (new)
11/02/2020	Regulatory and procedural guideline: Substances, Products, Organisations, Referentials (SPOR): SPOR API v2 Specification (new)
11/02/2020	Regulatory and procedural guideline: Products Management Services - Implementation of International Organization for Standardization (ISO) standards for the identification of medicinal products (IDMP) in Europe: Introduction - EU Implementation Guide (new)
11/02/2020	Human medicines European public assessment report (EPAR): Revestive, teduglutide, Malabsorption Syndromes, 30/08/2012, 14, Authorised (updated)
11/02/2020	Human medicines European public assessment report (EPAR): Liprolog, insulin lispro, Diabetes Mellitus, 01/08/2001, 26, Authorised (updated)
11/02/2020	Other: Information Technology Directors Group - List of nominated members (alphabetically by country) (updated)
11/02/2020	Other: Nominations to the European Union Telematics governance bodies (updated)
11/02/2020	ICH M9 on biopharmaceutics classification system based biowaivers (updated)
11/02/2020	Other: Article 57 product data (updated)
11/02/2020	Report: List of products granted eligibility to PRIME (updated)
11/02/2020	Report: Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 27-30 January 2020 (new)
11/02/2020	Human medicines European public assessment report (EPAR): Evotaz, atazanavir sulfate, cobicistat, HIV Infections, 13/07/2015, 8, Authorised (updated)
11/02/2020	Withdrawn application: Xyndari, glutamine, Date of withdrawal: 18/09/2019, Initial authorisation (updated)

11/02/2020	Human medicines European public assessment report (EPAR): Xoterna Breezhaler, indacaterol, Glycopyrronium bromide, Pulmonary Disease, Chronic Obstructive, 18/09/2013, 14, Authorised (updated)
11/02/2020	Rewards and incentives for paediatric medicines (updated)
11/02/2020	Template or form: Dossier administrative validation checklist (updated)
11/02/2020	Work programme: Committee for Medicinal Products for Human Use (CHMP): Work Plan 2020 (new)
10/02/2020	PRAC recommendation on signal: PRAC recommendations on signals adopted at the 13-16 January 2020 PRAC meeting (new)
10/02/2020	Newsletter: Human medicines highlights - February 2020 (new)
10/02/2020	Committee meeting report: Monthly report on application procedures, guidelines and related documents for veterinary medicines: December 2019 (new)
10/02/2020	Agenda: Agenda - PRAC draft agenda of meeting 10-13 February 2020 (new)
10/02/2020	Minutes: Minutes - PDCO minutes of the 23-26 July 2019 meeting (new)
10/02/2020	Minutes: Minutes - PDCO minutes of the 17-20 September 2019 meeting (new)
10/02/2020	Human medicines European public assessment report (EPAR): Verzenios, abemaciclib, Breast Neoplasms, 26/09/2018, 4, Authorised (updated)

NOTICE TO APPLICANTS

No updates since November 28th 2019.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

14.02.2020	Umsetzung des Durchführungsbeschlusses der Europäischen Kommission zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Dexmedetomidin vom 20.01.2020 Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Dexmedetomidin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
14.02.2020	Cyproteron: Überprüfung des Meningeomrisikos Wirkstoff Cyproteron Der Ausschuss für Risikobewertung im Bereich der Pharmakovigilanz (PRAC) empfiehlt Einschränkung bei der Anwendung von cyproteronhaltigen Arzneimitteln aufgrund des Meningiomrisikos.
13.02.2020	Picato® (Ingenolmebutat): Widerruf der Genehmigung des Inverkehrbringens auf Antrag des bisherigen Zulassungsinhabers Wirkstoff Ingenolmebutat Die Europäische Kommission hat vorläufig das Ruhen der Zulassungen angeordnet.

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.