TABLE OF CONTENTS

HEADS OF AGENCIES – CMDh

9 August

UPDATE - Step 2 - No nitrosamine detected response template

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

12/08/2022	Minutes: CHMP PROM minutes for the meeting on 13 June 2022
12/08/2022	Agenda: CHMP PROM agenda for the meeting on 13 June 2022
12/08/2022	Committee for Medicinal Products for Human Use (CHMP): 16-19 May 2022 , European Medicines Agency, Amsterdam, the Netherlands, from 16/05/2022 to 19/05/2022 (updated)
12/08/2022	Minutes: CHMP PROM minutes for the meeting on 10 May 2022
12/08/2022	Minutes: CHMP PROM agenda for the meeting on 10 May 2022
12/08/2022	Human medicines European public assessment report (EPAR): Exviera, dasabuvir sodium, Hepatitis C, Chronic, 14/01/2015, 25, Authorised (updated)
12/08/2022	Human medicines European public assessment report (EPAR): Viekirax, Ombitasvir, paritaprevir, ritonavir, Hepatitis C, Chronic, 14/01/2015, 27, Authorised (updated)
12/08/2022	Human medicines European public assessment report (EPAR): Sifrol, pramipexole dihydrochloride monohydrate, Restless Legs Syndrome; Parkinson Disease, 13/10/1997, 36, Authorised (updated)
12/08/2022	Orphan designation: Recombinant truncated N-terminal fragment of human lens epithelium-derived growth factor for the: Treatment of retinitis pigmentosa, 23/08/2017, Withdrawn (updated)
12/08/2022	Other: EVVet3 EVWeb Production – Release notes (Release 1.6) (updated)
12/08/2022	COVID-19: latest updates (updated)
12/08/2022	Human medicines European public assessment report (EPAR): Vaxzevria (previously COVID-19 Vaccine AstraZeneca), ChAdOx1-SARS-COV-2, COVID-19 virus infection, 29/01/2021, 23, Authorised (updated)
12/08/2022	Human medicines European public assessment report (EPAR): Mirapexin, pramipexole dihydrochloride monohydrate, Restless Legs Syndrome; Parkinson Disease, 23/02/1998, 39, Authorised (updated)

12/08/2022	Minutes: CHMP PROM minutes for the meeting on 11 April 2022
12/08/2022	COVID-19 treatments: authorised (updated)
12/08/2022	Human medicines European public assessment report (EPAR): Veklury, remdesivir, Coronavirus Infections, 03/07/2020, 12, Authorised (updated)
12/08/2022	Agenda: CHMP PROM agenda for the meeting on 11 April 2022
12/08/2022	Minutes: CHMP PROM minutes for the meeting on 14 March 2022
12/08/2022	Agenda: CHMP PROM agenda for the meeting on 14 March 2022
12/08/2022	Other: European Medicines Agency budget for 2022 (updated)
12/08/2022	Direct healthcare professional communication (DHPC): Visudyne (verteporfin): Information on the continuing supply limitation until end of 2023, Active substance: verteporfin, DHPC type: Medicine shortage, Last updated: 12/08/2022
12/08/2022	Supply shortage: Shortage of Visudyne (verteporfin) supply shortage (updated)
11/08/2022	Work programme: CHMP work plan 2022 (updated)
11/08/2022	Human medicines European public assessment report (EPAR): Alecensa, alectinib hydrochloride, Carcinoma, Non-Small-Cell Lung, 16/02/2017, 12, Authorised (updated)
11/08/2022	Human medicines European public assessment report (EPAR): Ranexa (previously Latixa), ranolazine, Angina Pectoris, 08/07/2008, 22, Authorised (updated)
11/08/2022	Direct animal healthcare professional communications
11/08/2022	News and press releases: EMA business hours over Assumption Day, 15 August
11/08/2022	Direct healthcare professional communication (DHPC): Hiprabovis IBR Marker Live (infectious bovine rhinotracheitis vaccine (live)) - Increase in the incidence of anaphylactic-type reactions in cattle, Active substance: live gE- tk-double-gene-deleted bovine herpes virus type 1, strain CEDDEL: 106.3–107.3 CCID50, DHPC type: Adverse event, Last updated: 11/08/2022
10/08/2022	Orphan designation: allogeneic peripheral blood mononuclear cells incubated ex-vivo with 16, 16-dimethyl prostaglandin E2, dexamethasone for the: Treatment in haematopoietic stem cell transplantation, 18/11/2016, Withdrawn (updated)
10/08/2022	Human medicines European public assessment report (EPAR): Grasustek, pegfilgrastim, Neutropenia, 20/06/2019, 3, Authorised (updated)
10/08/2022	Human medicines European public assessment report (EPAR): Vaxelis, Diphtheria toxoid, tetanus toxoid, Bordetella pertussis antigens: pertussis toxoid, filamentous haemagglutinin, pertactin, fimbriae Types 2 and 3, hepatitis B surface antigen produced in yeast cells, poliovirus (inactivated): type 1 (Mahoney), type 2 (MEF-1), type 3 (Saukett) produced in Vero cells/ Haemophilus influenzae type b polysaccharide (polyribosylribitol phosphate) conjugated to meningococcal protein., Meningitis, Haemophilus; Poliomyelitis; Tetanus; Diphtheria; Whooping Cough; Hepatitis B, 15/02/2016, 11, Authorised (updated)
10/08/2022	Human medicines European public assessment report (EPAR): Metalyse, tenecteplase, Myocardial Infarction, 23/02/2001, 20, Authorised (updated)
10/08/2022	Human medicines European public assessment report (EPAR): Gliolan, 5-aminolevulinic acid hydrochloride, Glioma, 07/09/2007, 7, Authorised (updated)
10/08/2022	Recruitment: Decision of the Executive Director on rules governing the traineeship programme at the EMA (updated)
10/08/2022	Supply shortage: Cetrotide (cetrorelix acetate) supply shortage
10/08/2022	Committee meeting report: HMPC meeting report on European Union herbal monographs, guidelines and other activities - 18-20 July 2022

10/08/2022	Herbal medicinal product: Species digestivae and stomachicae, Combination: Species digestivae, F: Assessment finalised (updated)
10/08/2022	Herbal medicinal product: Paulliniae semen, Paulliniae semen, F: Assessment finalised (updated)
10/08/2022	Human medicines European public assessment report (EPAR): Kalydeco, ivacaftor, Cystic Fibrosis, 23/07/2012, 33, Authorised (updated)
10/08/2022	Herbal medicinal product: Origani dictamni herba, Origani dictamni herba, F: Assessment finalised (updated)
10/08/2022	Orphan designation: N-(2,4-di-tert-butyl-5-hydroxyphenyl)-1,4-dihydro-4-oxoquinoline-3-carboxamide (ivacaftor) for the: Treatment of cystic fibrosis, 08/07/2008, Expired (updated)
10/08/2022	Herbal medicinal product: Hyperici herba and Cimicifugae rhizoma, Hyperici herba,Cimicifugae rhizoma, D: Draft under discussion (updated)
10/08/2022	Herbal medicinal product: Liquiritiae radix, Liquiritiae radix, F: Assessment finalised (updated)
10/08/2022	Herbal medicinal product: Lichen islandicus, Lichen islandicus, F: Assessment finalised (updated)
10/08/2022	Herbal medicinal product: Cnici benedicti herba, Cnici benedicti herba, D: Draft under discussion (updated)
10/08/2022	Human medicines European public assessment report (EPAR): Comirnaty, Single-stranded, 5'-capped messenger RNA produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2, COVID-19 virus infection, 21/12/2020, 27, Authorised (updated)
10/08/2022	Opinion/decision on a Paediatric investigation plan (PIP): Elafibranor, W: decision granting a waiver in all age groups for all conditions or indications, P/0295/2020 (updated)
10/08/2022	Orphan designation: 2-Chloro-N6-(3-iodobenzyl)adenosine-5'-N-methyluronamide (namodenoson) for the: Treatment of hepatocellular carcinoma, 09/10/2015, Positive (updated)
09/08/2022	Human medicines European public assessment report (EPAR): Adenuric, febuxostat, Gout, 21/04/2008, 22, Authorised (updated)
09/08/2022	Human medicines European public assessment report (EPAR): Pemetrexed medac, pemetrexed, Carcinoma, Non-Small-Cell Lung; Mesothelioma, 26/11/2015, 8, Authorised (updated)
09/08/2022	IRIS for Good Pharmacovigilance practice (GVP) inspections training session for industry users , Online, 10:00 - 11:30 Amsterdam time (CEST), from 07/09/2022 to 07/09/2022 (updated)
09/08/2022	Agenda: Agenda - EMA IRIS industry training for GVP Inspections (updated)
09/08/2022	Other: Orientation guide for industry - EMA building (updated)
09/08/2022	Other: Orientation guide for patient representatives and healthcare professionals - EMA building (updated)
09/08/2022	Human medicines European public assessment report (EPAR): Imvanex, modified vaccinia Ankara - Bavarian Nordic (MVA-BN) virus, Smallpox Vaccine; Monkeypox virus, 31/07/2013, 21, Authorised (updated)
09/08/2022	Human medicines European public assessment report (EPAR): Imraldi, adalimumab, Spondylitis, Ankylosing; Arthritis, Rheumatoid; Uveitis; Colitis, Ulcerative; Psoriasis; Arthritis, Psoriatic; Crohn Disease; Hidradenitis Suppurativa; Arthritis, 24/08/2017, 18, Authorised (updated)
09/08/2022	Human medicines European public assessment report (EPAR): Zejula, Niraparib (tosilate monohydrate), Fallopian Tube Neoplasms; Peritoneal Neoplasms; Ovarian Neoplasms, 16/11/2017, 18, Authorised (updated)
09/08/2022	Other: Record of data processing activity EMA IT Security Operations Centre (SOC)

09/08/2022	Human medicines European public assessment report (EPAR): Kaftrio, ivacaftor, tezacaftor, elexacaftor, Cystic Fibrosis, 21/08/2020, 8, Authorised (updated)
09/08/2022	Orphan designation: Adenovirus associated viral vector serotype 4 containing the human RPE65 gene for the: Treatment of retinitis pigmentosa, 14/11/2007, Positive (updated)
09/08/2022	Orphan designation: Adenovirus associated viral vector serotype 4 containing the human RPE65 gene for the: Treatment of Leber's congenital amaurosis, 22/10/2007, Positive (updated)
09/08/2022	Orphan designation: Adeno-associated viral vector serotype 5 containing the human RLBP1 gene for the: Treatment of retinitis pigmentosa, 14/10/2016, Positive (updated)
09/08/2022	Orphan designation: adenovirus associated viral vector serotype 5 containing the human pde6β gene for the: Treatment of retinitis pigmentosa, 19/06/2013, Positive (updated)
09/08/2022	Human medicines European public assessment report (EPAR): Gilenya, fingolimod hydrochloride , Multiple Sclerosis, 17/03/2011, 32, Authorised (updated)
09/08/2022	Direct healthcare professional communication (DHPC): Cetrorelix acetate - Cetrotide 0.25 mg Powder and solvent for injection: Temporary Shortage, Active substance: cetrorelix (as acetate), DHPC type: Medicine shortage, Last updated: 09/08/2022 (updated)
09/08/2022	Referral: Daruph and Anafezyn , dasatinib (anhydrous), Article 29(4) referrals, European Commission final decision, 19/05/2022, 18/07/2022, 09/08/2022 (updated)
09/08/2022	Human medicines European public assessment report (EPAR): Signifor, pasireotide, Acromegaly; Pituitary ACTH Hypersecretion, 24/04/2012, 14, Authorised (updated)
09/08/2022	Template or form: Step 2 - No nitrosamine detected response template (updated)
08/08/2022	Human medicines European public assessment report (EPAR): Thymanax, Agomelatine, Depressive Disorder, Major, 19/02/2009, 18/11/2006, 24, Authorised (updated)
08/08/2022	Public health threats (updated)
08/08/2022	Scientific advice and protocol assistance (updated)
08/08/2022	COVID-19 guidance: research and development (updated)
08/08/2022	Human medicines European public assessment report (EPAR): Esbriet, Pirfenidone, Idiopathic Pulmonary Fibrosis; Lung Diseases; Respiratory Tract Diseases, 27/02/2011, 31, Authorised (updated)
08/08/2022	Human medicines European public assessment report (EPAR): Viagra, sildenafil, Erectile Dysfunction, 13/09/1998, 41, Authorised (updated)
08/08/2022	Human medicines European public assessment report (EPAR): Cometriq, cabozantinib, Thyroid Neoplasms, 21/03/2014, 25, Authorised (updated)
08/08/2022	Herbal medicinal product: Saccharomyces cerevisiae CBS 5926, Saccharomyces cerevisiae CBS 5926, F: Assessment finalised (updated)

NOTICE TO APPLICANTS

No updates since February 20th 2022.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

12.08.2022	Umsetzung des Durchführungsbeschlusses der Europäischen Kommission zum PSUR Single Assessment betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Mercaptopurin vom 21.06.2022 Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Mercaptopurin infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
12.08.2022	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/29450/2022 vom 27.01.2022 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Loperamid und der Wirkstoffkombination Loperamid/Simeticon Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Wirkstoff Loperamid und der Wirkstoffkombination Loperamid/Simeticon infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
12.08.2022	Informationsbrief zu Mecain 20 mg/ml Injektionslösung 5/10/50 x 5 ml Ampullen der Firma Puren Pharma: Inkorrekte Farbkodierung Wirkstoff: MepivacainhydrochloridDie Firma PUREN Pharma GmbH & Co KG informiert darüber, dass sechs Chargen des Arzneimittels Mecain 20 mg/ml Injektionslösung 5/10/50 x 5 ml mit einer inkorrekten Farbkodierung der mg/ml- und Konzentrationsangabe (2 %) auf den Kunststoffampullen versehen sind.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

09.08.2022	Therapiebegleitende Diagnostika (CDx) Mit therapiebegeleitenden Diagnostika (Companion Diagnostics, CDx) werden Biomarker nachgewiesen, mit deren Hilfe die Eignung von Patienten für die Behandlung mit einem spezifischen Arzneimittel festgestellt wird.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since June 3rd 2022.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.