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HEADS OF AGENCIES – CMDh

No updates since August 9th 2022.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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EUROPEAN MEDICINES AGENCY (EMA)

12/09/2022	Human medicines European public assessment report (EPAR): Apealea, paclitaxel, Ovarian Neoplasms, 20/11/2018, 6, Authorised (updated)
12/09/2022	Agenda: Agenda - CHMP agenda of the 12-15 September 2022 meeting
12/09/2022	Direct healthcare professional communication (DHPC): Nulojix (belatacept): Risk of medication errors due to change in maintenance dose from 5 mg/kg to 6 mg/kg, Active substance: belatacept, DHPC type: Medication error, Last updated: 12/09/2022
09/09/2022	Union Product Database: webinar on variations not requiring assessment (VNRAs) for marketing authorisation holders , Online, 10:00 - 11:30 Amsterdam time (CEST), from 08/09/2022 to 08/09/2022 (updated)
09/09/2022	Human medicines European public assessment report (EPAR): Vipdomet, alogliptin benzoate, metformin hydrochloride, Diabetes Mellitus, Type 2, 18/09/2013, 10, Authorised (updated)
09/09/2022	News and press releases: Meeting highlights from the Committee for Veterinary Medicinal Products (CVMP) 6-8 September 2022
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09/09/2022	EPAR - All authorised presentations: Pirfenidone axunia : EPAR - All Authorised Presentations (updated)

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09/09/2022	CHMP opinions on consultation procedures (updated)
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09/09/2022	Other: CooperSurgical Inc ART Media - Procedural steps and scientific information after initial consultation (updated)
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09/09/2022	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, 10/06/2015, 19, Authorised (updated)
09/09/2022	Human medicines European public assessment report (EPAR): Incresync, alogliptin, pioglitazone, Diabetes Mellitus, Type 2, 19/09/2013, 13, Authorised (updated)
09/09/2022	Orphan designation: [Gly2]-recombinant human glucagon-like peptide for the: Treatment of short bowel syndrome, 12/12/2001, Expired (updated)
09/09/2022	Human medicines European public assessment report (EPAR): Rivastigmine 1 A Pharma, rivastigmine, Alzheimer Disease; Dementia; Parkinson Disease, 11/12/2009, 13, Authorised (updated)
09/09/2022	Human medicines European public assessment report (EPAR): Vpriv, velaglucerase alfa, Gaucher Disease, 26/08/2010, 17, Authorised (updated)
09/09/2022	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, 28, Authorised (updated)
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08/09/2022	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)
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08/09/2022	Human medicines European public assessment report (EPAR): Ontozry, cenobamate, Epilepsy, 26/03/2021, 4, Authorised (updated)
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07/09/2022	Human medicines European public assessment report (EPAR): Scemblix, asciminib hydrochloride, Leukemia, Myelogenous, Chronic, BCR-ABL Positive, 25/08/2022, Authorised (updated)
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06/09/2022	News and press releases: ECDC-EMA statement on booster vaccination with Omicron adapted bivalent COVID-19 vaccines
06/09/2022	Human medicines European public assessment report (EPAR): Jardiance, empagliflozin, Diabetes Mellitus, Type 2, 22/05/2014, 26, Authorised (updated)
06/09/2022	Human medicines European public assessment report (EPAR): Zolgensma, onasemnogene abeparvovec, Muscular Atrophy, Spinal, 18/05/2020, 7, Authorised (updated)
06/09/2022	Human medicines European public assessment report (EPAR): GONAL-f, follitropin alfa, Anovulation; Reproductive Techniques, Assisted; Infertility, Female; Hypogonadism, 20/10/1995, 25, Authorised (updated)
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05/09/2022	Clinical Trials Information System (CTIS) bitesize talk: Notifications - Part 2 , Online, 14:30 - 16:00 Amsterdam time (CEST), from 20/10/2022 to 20/10/2022 (updated)
05/09/2022	Human medicines European public assessment report (EPAR): Vemlidy, tenofovir alafenamide fumarate, Hepatitis B, 09/01/2017, 14, Authorised (updated)
05/09/2022	Periodic safety update single assessment: Amino acid combinations : List of nationally authorised medicinal products - PSUSA/00010190/202112
05/09/2022	Other: IRIS guide for applicants - How to create and submit scientific applications, for industry and individual applicants (updated)
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05/09/2022	Orphan designation: 1-(4-(6-chloropyridazin-3-yl)piperazin-1-yl)-2-(4-cyclopropyl-3-fluorophenyl)ethan-1-one for the: Treatment of propionic acidaemia, 19/07/2021, Positive (updated)
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05/09/2022	Human medicines European public assessment report (EPAR): Dovato, dolutegravir sodium, lamivudine, HIV Infections, 10/06/2022, 11, Authorised (updated)

NOTICE TO APPLICANTS

No updates since February 20th 2022.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

No updates since September 2nd 2022

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

09.09.2022	Prüfkriterien für die von digitalen Gesundheitsanwendungen (DiGA) und digitalen Pflegeanwendungen (DiPA) nachzuweisenden Anforderungen an den Datenschutz Version 0.1 vom 09.08.2022
09.09.20222	DiGA und DiPA Datenschutzkriterien

	Das BfArM hat neue Prüfkriterien für die Anforderungen an den Datenschutz bei digitalen Gesundheitsanwendungen (DiGA) und digitalen Pflegeanwendungen (DiPA) veröffentlicht.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since June 3rd 2022.

PHARMEUROPA TEXTS FOR COMMENT

Text	Monograph number	Group	Issue	Deadline
Acamprosate calcium	1585	10A	34.4	2022-12-31
Grapevine leaf	2667	13A	34.4	2022-12-31
L-Malic acid	3143	10D	34.4	2022-12-31
Magnesium peroxide	1540	9	34.4	2022-12-31
Meadowsweet	1868	13A	34.4	2022-12-31
Oxytetracycline dihydrate	0199	7	34.4	2022-12-31
Quillaia bark	1843	13A	34.4	2022-12-31
Szechwan lovage rhizome	2634	TCM	34.4	2022-12-31
Walnut Leaf	2946	13B	34.4	2022-12-31