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03/08/2022	Human medicines European public assessment report (EPAR): Sitagliptin / Metformin hydrochloride Accord, metformin hydrochloride, sitagliptin hydrochloride monohydrate, Diabetes Mellitus, Type 2, 22/07/2022, Authorised
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03/08/2022	Other: EMA initiatives for acceleration of development support and evaluation procedures for COVID-19 treatments and vaccines (updated)
03/08/2022	COVID-19 vaccine safety update: COVID-19 vaccines - Safety update: 14 July 2022 (updated)
03/08/2022	Herbal medicinal product: Salviae miltiorrhizae rhizoma, Salviae miltiorrhizae radix et rhizoma, F: Assessment finalised (updated)

03/08/2022	Regulatory and procedural guideline: List of centrally authorised products requiring a notification of a change for update of annexes (updated)
03/08/2022	Clinical Trials Information System (CTIS): Walk-in clinic , Online, 16:00 - 16:45 Amsterdam time (CEST), from 31/08/2022 to 31/08/2022 (updated)
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03/08/2022	EU Big Data Stakeholder Forum , from 01/12/2022 to 01/12/2022
03/08/2022	Referral: Amfepramone-containing medicinal products , amfepramone, regenon,Regenon Retard,Tenuate, Article 31 referrals, Recommendation provided by Pharmacovigilance Risk Assessment Committee, 03/08/2022 (updated)
03/08/2022	Referrals document: Amfepramone-containing medicinal products Article-31 referral - EMA recommends withdrawal of marketing authorisation for amfepramone medicines (updated)
03/08/2022	Seventh Nitrosamine Implementation Oversight Group (NIOG) meeting , Online, from 14/07/2022 to 14/07/2022 (updated)
03/08/2022	Minutes: Highlights from the seventh Nitrosamine Implementation Oversight Group (NIOG) meeting
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02/08/2022	European Medicines Agency (EMA) and Federation of Veterinarians of Europe (FVE) webinar on the Union Product Database website , Online, 11:30-13:00 Amsterdam time (CEST), from 27/06/2022 to 27/06/2022 (updated)
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02/08/2022	Human medicines European public assessment report (EPAR): Alecensa, alectinib hydrochloride, Carcinoma, Non-Small-Cell Lung, 16/02/2017, 11, Authorised (updated)
02/08/2022	Human medicines European public assessment report (EPAR): Cosentyx, Secukinumab, Arthritis, Psoriatic; Psoriasis; Spondylitis, Ankylosing, 14/01/2015, 27, Authorised (updated)
02/08/2022	Webinar on requesting access to and using EMA's substance, product, organisation and referential (SPOR) application programming interface (API) , Online, 10:30 - 12:30 Amsterdam time (CEST), from 13/09/2022 to 13/09/2022
02/08/2022	eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) Information session: Industry webinar , Online, 10:30 - 12:30 Amsterdam time (CEST), from 15/09/2022 to 15/09/2022
02/08/2022	Introduction to Organisation Management Service (OMS): Industry webinar , Online, 14:30 - 16:30 Amsterdam time (CEST), from 15/09/2022 to 15/09/2022
02/08/2022	Introduction to Referentials Management Service (RMS): Industry webinar , Online, 10:30 - 12:30 Amsterdam time (CEST), from 21/09/2022 to 21/09/2022
02/08/2022	Introduction to Substance Management Service (SMS): Industry webinar , Online, 10:30 - 12:30 Amsterdam time (CEST), from 06/09/2022 to 06/09/2022
02/08/2022	Newsletter: News bulletin for small and medium-sized enterprises - Issue 56
02/08/2022	Human medicines European public assessment report (EPAR): Lonquex, lipegfilgrastim, Neutropenia, 25/07/2013, 23, Authorised (updated)
02/08/2022	Human medicines European public assessment report (EPAR): Tecentriq, atezolizumab, Carcinoma, Transitional Cell; Carcinoma, Non-Small-Cell Lung;

	Urologic Neoplasms; Breast Neoplasms; Small Cell Lung Carcinoma, 20/09/2017, 19, Authorised (updated)
02/08/2022	Human medicines European public assessment report (EPAR): Clopidogrel / Acetylsalicylic acid Mylan, acetylsalicylic acid, clopidogrel hydrogen sulfate, Acute Coronary Syndrome; Myocardial Infarction, 09/01/2020, 4, Authorised (updated)
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02/08/2022	Human medicines European public assessment report (EPAR): COVID-19 Vaccine (inactivated, adjuvanted) Valneva, SARS-CoV-2 virus (inactivated) Wuhan strain hCoV-19 / Italy / INMI1-isl / 2020, COVID-19 virus infection, 24/06/2022, 1, Authorised (updated)
02/08/2022	Orphan designation: Pegylated recombinant arginine deiminase (pegargiminase) for the: Treatment of malignant mesothelioma, 15/01/2015, Positive (updated)
02/08/2022	Human medicines European public assessment report (EPAR): Bonviva, ibandronic acid, Osteoporosis, Postmenopausal, 23/02/2004, 29, Authorised (updated)
02/08/2022	Pharmacovigilance Risk Assessment Committee (PRAC): 25-28 October 2021 , European Medicines Agency, Amsterdam, the Netherlands, from 25/10/2021 to 28/10/2021 (updated)
02/08/2022	Minutes: Minutes of the PRAC meeting 25-28 October 2021
02/08/2022	Other: Article 57 product data (updated)
02/08/2022	Digital application dataset integration (DADI) Q&A webinar - variations form for human medicinal products , Online, 11:00 - 12:30 Amsterdam time (CEST), from 12/07/2022 to 12/07/2022 (updated)
02/08/2022	Human medicines European public assessment report (EPAR): Fluad Tetra, A/Victoria/2570/2019 (H1N1)pdm09 like strain (A/Victoria/2570/2019 IVR-215) A/Darwin/9/2021 (H3N2) like strain (A/Darwin/6/2021 IVR-227) B/Austria/1359417/2021 like strain (B/Austria/1359417/2021 BVR-26) B/Phuket/3073/2013 like strain (B/Phuket/3073/2013 BVR-1B), Influenza, Human, 20/05/2020, 4, Authorised (updated)
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01/08/2022	Human medicines European public assessment report (EPAR): Zokinvy, Lonafarnib, Progeria; Laminopathies, 18/07/2022, Authorised
01/08/2022	Human medicines European public assessment report (EPAR): Xofluza, Baloxavir marboxil, Influenza, Human, 07/01/2021, 3, Authorised (updated)
01/08/2022	Periodic safety update single assessment: Dexketoprofen : Scientific conclusions and grounds for the variation to the terms of the Marketing Authorisation(s) - PSUSA/00000997/202110
01/08/2022	Periodic safety update single assessment: Dexketoprofen : List of nationally authorised medicinal products - PSUSA/00000997/202110
01/08/2022	Human medicines European public assessment report (EPAR): Fluenz Tetra, A/Victoria/2570/2019 (H1N1)pdm09 - like strain (A/Victoria/1/2020, MEDI 340505) A/Darwin/9/2021 (H3N2) - like strain (A/Norway/16606/2021, MEDI 355293) B/Austria/1359417/2021 - like strain (B/Austria/1359417/2021, MEDI 355292) B/Phuket/3073/2013 - like strain (B/Phuket/3073/2013, MEDI 306444, Influenza, Human, 04/12/2013, 22, Authorised (updated)

01/08/2022	Human medicines European public assessment report (EPAR): Posaconazole AHCL, posaconazole, Mycoses, 25/07/2019, 4, Authorised (updated)
01/08/2022	Other: Declaration of interests: Davide Prandi
01/08/2022	Human medicines European public assessment report (EPAR): Enhertu, trastuzumab deruxtecan, Breast Neoplasms, 18/01/2021, 6, Authorised (updated)
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01/08/2022	Regulatory and procedural guideline: Draft report on the development of a harmonised approach to exposure assessment methodologies for residues from veterinary medicinal products, feed additives and pesticides residues in food of animal origin (updated)
01/08/2022	Human medicines European public assessment report (EPAR): Nuvaxovid, SARS-CoV-2 recombinant spike protein, COVID-19 virus infection, 20/12/2021, 3, Authorised (updated)
01/08/2022	Opinion on medicine for use outside EU: Fexinidazole Winthrop, fexinidazole, Trypanosomiasis, African, 15/11/2018, Positive opinion (updated)
01/08/2022	Other: Organisation chart: Human Medicines (updated)
01/08/2022	Plasma master file certificates (updated)
01/08/2022	Human medicines European public assessment report (EPAR): Okedi, Risperidone, Schizophrenia, 14/02/2022, 1, Authorised (updated)
01/08/2022	Withdrawn application: Aduhelm, aducanumab, Date of withdrawal: 20/04/2022, Initial authorisation (updated)
01/08/2022	Human medicines European public assessment report (EPAR): Strimvelis, autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with retroviral vector that encodes for the human adenosine deaminase (ADA) cDNA sequence from human haematopoietic stem/progenitor (CD34+) cells, Severe Combined Immunodeficiency, 26/05/2016, 8, Authorised (updated)
01/08/2022	Human medicines European public assessment report (EPAR): Renvela, sevelamer carbonate, Hyperphosphatemia; Renal Dialysis, 09/06/2009, 24, Authorised (updated)
01/08/2022	Human medicines European public assessment report (EPAR): Bydureon, exenatide, Diabetes Mellitus, Type 2, 17/06/2011, 22, Authorised (updated)

NOTICE TO APPLICANTS

No updates since February 20th 2022.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

08.08.2022	Rote-Hand-Brief zu Rubraca®(Rucaparib-Camsylat): Einschränkung der Indikation Wirkstoff: Rucaparib-CamsylatDie Firma Clovis Oncology Ireland Ltd informiert über eine Einschränkung der Indikation im Hinblick auf eine Monotherapie bei erwachsenen Patientinnen.
05.08.2022	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/26912/2022 vom 27.01.2022 betreffend die Zulassungen für

	Humanarzneimittel mit der Wirkstoffkombination Benazepril/Hydrochlorothiazid Das BfArM veröffentlicht den Umsetzungsbescheid für die Wirkstoffkombination Benazepril/Hydrochlorothiazid infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.
03.08.2022	Arzneimittelzulassungen unter Verwendung von Studien der Firma Micro Therapeutic Research Labs in Indien: Ruhen der Zulassungen Wirkstoff: VerschiedeneDas Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) hat mit Bescheid vom 20.07.2022 das Ruhen der Zulassungen verlängert, deren Grundlage Studien der Firma Micro Therapeutic Research Labs (MTR) in Indien waren.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

05.08.2022	Maßnahmen von Herstellern Hier veröffentlicht das BfArM Mitteilungen gemäß § 2 Nr. 4 MPSV, die der Verantwortliche nach § 5 MPG an seine Kunden versendet. Kundeninformationen enthalten beispielsweise Informationen von Herstellern über eigenverantwortlich durchgeführte Rückrufe von Medizinprodukten.
03.08.2022	Webinarreihe DiGA How to DiGA: Webinare mit Anforderungen, Erfahrungen und Tipps aus der DiGA-Antragsbewertung

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since June 3rd 2022.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.