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EUROPEAN MEDICINES AGENCY (EMA)

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13/12/2019	Veterinary medicines European public assessment report (EPAR): Eurican Herpes 205, Canine herpesvirus (F205 strain) antigens, 26/03/2001, 9, Authorised (updated)
13/12/2019	Work programme: Committee for Medicinal Products for Veterinary Use (CVMP) Work Plan 2020
13/12/2019	News and press releases: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 9-12 December 2019
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13/12/2019	Report: Medicinal products for human use: monthly figures - November 2019
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13/12/2019	Questions and answers on comparability considerations for advanced therapy medicinal products (ATMP)
13/12/2019	VICH GL58 stability testing of new veterinary drug substances and medicinal products in climatic zones III and IV (updated)
13/12/2019	Scientific guideline: VICH GL58 stability testing of new veterinary drug substances and medicinal products in climatic zones III and IV - First version
12/12/2019	Human medicines European public assessment report (EPAR): Ervebo, recombinant vesicular stomatitis virus (strain indiana) with a deletion of the envelope glycoprotein, replaced with the zaire ebolavirus (strain kikwit 1995) surface glycoprotein, Hemorrhagic Fever, Ebola, 11/11/2019, Authorised
12/12/2019	Human medicines European public assessment report (EPAR): Tecfidera, dimethyl fumarate, Multiple Sclerosis, 30/01/2014, 17, Authorised (updated)
12/12/2019	Human medicines European public assessment report (EPAR): Lyrica, pregabalin, Epilepsy, Anxiety Disorders, Neuralgia, 05/07/2004, 43, Authorised (updated)
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12/12/2019	List of medicines under additional monitoring (updated)
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12/12/2019	Medicines under additional monitoring: List of medicinal products under additional monitoring (updated)
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11/12/2019	Human medicines European public assessment report (EPAR): Prevenar 13, pneumococcal polysaccharide serotype 1 / pneumococcal polysaccharide serotype 14 / pneumococcal polysaccharide serotype 18C / pneumococcal polysaccharide serotype 19A, pneumococcal polysaccharide serotype 19F / pneumococcal polysaccharide serotype 23F / pneumococcal polysaccharide serotype 3 / pneumococcal polysaccharide serotype 4, pneumococcal polysaccharide serotype 5, pneumococcal polysaccharide serotype 6A, pneumococcal polysaccharide serotype 6B / pneumococcal polysaccharide serotype 7F / pneumococcal polysaccharide serotype 9V protein, Pneumococcal Infections, Immunization, 09/12/2009, 36, Authorised (updated)
11/12/2019	Human medicines European public assessment report (EPAR): Simbrinza, brinzolamide, brimonidine tartrate, Ocular Hypertension, Glaucoma, Open-Angle, 18/07/2014, 7, Authorised (updated)
11/12/2019	Human medicines European public assessment report (EPAR): Daptomycin Hospira, daptomycin, Soft Tissue Infections, Skin Diseases, Bacterial, 22/03/2017, 6, Authorised (updated)
11/12/2019	News and press releases: Six-year review shows success of the EU signal management system in improving safe use of medicines
11/12/2019	Scientific publications (updated)

11/12/2019	Human medicines European public assessment report (EPAR): Entresto, sacubitril, valsartan, Heart Failure, 19/11/2015, 9, Authorised (updated)
11/12/2019	Human medicines European public assessment report (EPAR): Taxotere, docetaxel, Head and Neck Neoplasms, Carcinoma, Non-Small-Cell Lung, Adenocarcinoma, Prostatic Neoplasms, Stomach Neoplasms, Breast Neoplasms, 27/11/1995, 45, Authorised (updated)
11/12/2019	Management Board meeting: 3 October 2019 , European Medicines Agency, Amsterdam, the Netherlands, from 03/10/2019 to 03/10/2019 (updated)
11/12/2019	Minutes: Minutes of the 105th meeting of the Management Board: 3 October 2019
11/12/2019	Human medicines European public assessment report (EPAR): Emgality, Galcanezumab, Migraine Disorders, 14/11/2018, 2, Authorised (updated)
11/12/2019	Referrals document: Fluorouracil and fluorouracil related substances Article 31 referral - Timetable for the procedure (updated)
11/12/2019	Human medicines European public assessment report (EPAR): Plavix, clopidogrel hydrogen sulfate, Stroke, Peripheral Vascular Diseases, Atrial Fibrillation, Myocardial Infarction, Acute Coronary Syndrome, 15/07/1998, 40, Authorised (updated)
11/12/2019	Human medicines European public assessment report (EPAR): Cufence, trientine dihydrochloride, Hepatolenticular Degeneration, 25/07/2019, 1, Authorised (updated)
11/12/2019	Referral: Fluorouracil and fluorouracil related substances (capecitabine, tegafur and flucytosine) containing medicinal products , capecitabine, fluorouracil, tegafur, flucytosine , Article 31 referrals, Under evaluation, 11/12/2019 (updated)
11/12/2019	Human medicines European public assessment report (EPAR): Visudyne, verteporfin, Myopia, Degenerative, Macular Degeneration, 27/07/2000, 34, Authorised (updated)
11/12/2019	Report: Annual report 2018 on staff engaging in an occupational activity within two years of leaving the service (article 16 of the staff regulations)
11/12/2019	Human medicines European public assessment report (EPAR): Keytruda, Pembrolizumab, Melanoma, Hodgkin Disease, Carcinoma, Non-Small-Cell Lung, 17/07/2015, 24, Authorised (updated)
11/12/2019	Regulatory and procedural guideline: Guidelines on good pharmacovigilance practices (GVP): Introductory cover note, last updated with chapter P.III on pharmacovigilance for the use of medicines by pregnant and breastfeeding women
11/12/2019	Good pharmacovigilance practices (updated)
11/12/2019	Scientific guideline: Draft guideline on good pharmacovigilance practices: Product- or population-specific considerations III: Pregnant and breastfeeding women
10/12/2019	Human medicines European public assessment report (EPAR): M-M-RVaxPro, measles virus Enders' Edmonston strain (live, attenuated), mumps virus Jeryl Lynn (level B) strain (live, attenuated), rubella virus Wistar RA 27/3 strain (live, attenuated), Rubella, Mumps, Immunization, Measles, 05/05/2006, 22, Authorised (updated)
10/12/2019	Veterinary medicines European public assessment report (EPAR): Gumbohatch, live attenuated infectious bursal disease virus (IBDV), strain 1052, 12/11/2019, Authorised
10/12/2019	Human medicines European public assessment report (EPAR): Glyxambi, empagliflozin, linagliptin, Diabetes Mellitus, Type 2, 11/11/2016, 8, Authorised (updated)
10/12/2019	Plasma master file certificates (updated)
10/12/2019	Other: Guide on access to unpublished documents (updated)
10/12/2019	Implementation of the new Veterinary Medicines Regulation (updated)
10/12/2019	Other: Open call for data on use of antimicrobials in animals
10/12/2019	Human medicines European public assessment report (EPAR): Trajenta, linagliptin, Diabetes Mellitus, Type 2, 23/08/2011, 14, Authorised (updated)

10/12/2019	News and press releases: How will pharmacovigilance look in 2030?
10/12/2019	Newsletter: Human medicines highlights - December 2019
10/12/2019	Human medicines European public assessment report (EPAR): Jentadueto, linagliptin, metformin, Diabetes Mellitus, Type 2, 19/07/2012, 16, Authorised (updated)
10/12/2019	Human medicines European public assessment report (EPAR): Ongentys, opicapone, Parkinson Disease, 24/06/2016, 3, Authorised (updated)
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10/12/2019	Agenda: Agenda - PDCO agenda of the 9-11 December 2019 meeting
09/12/2019	Multi-stakeholder workshop on draft 'Regulatory Science to 2025' strategy (stakeholders for veterinary medicines) , European Medicines Agency, Amsterdam, the Netherlands, from 05/12/2019 to 06/12/2019 (updated)
09/12/2019	Committee for Medicinal Products for Veterinary Use (CVMP): 08-10 October 2019 , European Medicines Agency, Amsterdam, the Netherlands, from 08/10/2019 to 10/10/2019 (updated)
09/12/2019	Human medicines European public assessment report (EPAR): Qarziba (previously Dinutuximab beta EUSA and Dinutuximab beta Apeiron), dinutuximab beta, Neuroblastoma, 08/05/2017, 7, Authorised (updated)
09/12/2019	Human medicines European public assessment report (EPAR): Bosulif, bosutinib (as monohydrate), Leukemia, Myeloid, 26/03/2013, 19, Authorised (updated)
09/12/2019	Committee meeting report: Monthly report on application procedures, guidelines and related documents for veterinary medicines: October 2019
09/12/2019	Advanced therapy classification (updated)
09/12/2019	Agenda: Agenda - CHMP agenda of the 9-12 December 2019 meeting
09/12/2019	Human medicines European public assessment report (EPAR): Raxone, idebenone, Optic Atrophy, Hereditary, Leber, 08/09/2015, 5, Authorised (updated)
09/12/2019	Herbal medicinal product: Hamamelidis folium, Hamamelidis folium, F: Assessment finalised (updated)
09/12/2019	Herbal - HMPC assessment report: Addendum to assessment report on Hamamelis virginiana L., folium

NOTICE TO APPLICANTS

No updates since November 28th 2019.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

10.12.2019	Rote-Hand-Brief zu Emerade®: Aktualisierung zur Thematik „initialer Aktivierungsfehler“ Wirkstoff Adrenalin Die Firma Dr. Gerhard Mann chem.-pharm. Fabrik GmbH informiert in Abstimmung mit dem zuständigen Landesamt für Gesundheit und Soziales (LaGeSo) in Berlin über Aktivierungsfehler im Zusammenhang mit der Anwendung von Emerade-Fertigpens. Es wird empfohlen, Fertigpens, die bei zu hohen Temperaturen gelagert wurden, bei Verfügbarkeit gegen Fertigpens anderer Hersteller auszutauschen. Es handelt sich nicht um einen Rückruf. Ärzte werden

	gebeten, ihre Patienten entsprechend zu informieren und ggf. eine Neuverordnung vorzunehmen. Der Rote-Hand-Brief vom 02.10.2019 wird von der Firma zurückgezogen.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since October 15th 2019.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since November 15th 2019.

PHARMEUROPA TEXTS FOR COMMENT

Text	Monograph number	Group	Issue	Deadline
Sodium sulfite heptahydrate	776	9	32.1	31.03.2020
Etomidate	1514	10B	32.1	31.03.2020
Copper sulfate pentahydrate	894	9	32.1	31.03.2020
Zinc gluconate	2164	9	32.1	31.03.2020
Substances for pharmaceutical use	2034	PCM	32.1	31.03.2020
Paracetamol	49	10A	32.1	31.03.2020
Magnesium carbonate, light	42	9	32.1	31.03.2020
Flubendazole	1721	10B	32.1	31.03.2020
Dimetindene maleate	1417	10B	32.1	31.03.2020
Calcium hydroxide	1078	9	32.1	31.03.2020
Bumetanide	1076	10B	32.1	31.03.2020