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No updates since September 2nd 2019.

HEADS OF AGENCIES – PAEDIATRIC REGULATION

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EUROPEAN MEDICINES AGENCY (EMA)

16/09/2019	Minutes: CHMP ORGAM minutes for the meeting on 15 April 2019 (updated)
16/09/2019	Agenda: Agenda - CHMP agenda of the 16-19 September 2019 meeting
13/09/2019	Periodic safety update single assessment: Bisoprolol / hydrochlorothiazide: List of nationally authorised medicinal products - PSUSA/00000420/201811
13/09/2019	Human medicines European public assessment report (EPAR): Levodopa/Carbidopa/Entacapone Orion, levodopa, carbidopa, entacapone, Parkinson Disease, 23/08/2011, 10, Authorised (updated)
13/09/2019	Human medicines European public assessment report (EPAR): Efient, prasugrel, Acute Coronary Syndrome, Angina, Unstable, Myocardial Infarction, 24/02/2009, 17, Authorised (updated)
13/09/2019	News and press releases: Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 10-12 September 2019
13/09/2019	Summary of opinion: Gumbohatch, avian infectious bursal disease vaccine (live), 12/09/2019, Positive
13/09/2019	Summary of opinion: Nobivac Myxo-RHD Plus, myxomatosis and rabbit haemorrhagic viral disease vaccine (live recombinant), 12/09/2019, Positive
13/09/2019	Summary of opinion: Bravecto, fluralaner, 13/09/2019, Positive
13/09/2019	Summary of opinion: Vectra Felis, pyriproxyfen / dinotefuran, 13/09/2019, Positive
13/09/2019	Summary of opinion: Velactis, cabergoline, 13/09/2019, Negative
13/09/2019	Human medicines European public assessment report (EPAR): Flucelvax Tetra, Influenza virus surface antigens (haemagglutinin and neuraminidase)* , inactivated, of the following strains: A/xxxxx (H3N2)-like strain (reassortant used)/ A/xxxxx H1N1- like strain (reassortant used)/ B/xxxxx (Yamagata Lineage) – like strain (reassortant used)/ B/xxxxx (Victoria Lineage) – like strain (reassortant used), Influenza, Human, 12/12/2018, 3, Authorised (updated)
13/09/2019	Other: Article 57 product data (updated)

13/09/2019	Referral: Xeljanz , tofacitinib , Article 20 procedures, Under evaluation, 13/09/2019 (updated)
13/09/2019	News and press releases: EMA to provide guidance on avoiding nitrosamines in human medicines
13/09/2019	News and press releases: EMA to review ranitidine medicines following detection of NDMA
13/09/2019	Periodic safety update single assessment: Metoclopramide: CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - PSUSA/00002036/201811
13/09/2019	Periodic safety update single assessment: Metoclopramide: List of nationally authorised medicinal products - PSUSA/00002036/201811
13/09/2019	Human medicines European public assessment report (EPAR): Ofev, nintedanib, Idiopathic Pulmonary Fibrosis, 14/01/2015, 10, Authorised (updated)
13/09/2019	Human medicines European public assessment report (EPAR): Firdapse (previously Zenas), amifampridine, Lambert-Eaton Myasthenic Syndrome, 23/12/2009, 17, Authorised (updated)
12/09/2019	Human medicines European public assessment report (EPAR): Lacosamide UCB, lacosamide, Epilepsies, Partial, 26/08/2019, Authorised
12/09/2019	Committee for Advanced Therapies (CAT): 11-13 September 2019 , European Medicines Agency, Amsterdam, The Netherlands, from 11/09/2019 to 13/09/2019 (updated)
12/09/2019	Minutes: Minutes of the CAT meeting 19-21 June 2019
12/09/2019	Agenda: Agenda - CAT agenda of the 11-13 September 2019 meeting
12/09/2019	Enpr-EMA priority activities (updated)
12/09/2019	Human medicines European public assessment report (EPAR): Flebogamma DIF (previously Flebogammadif), Human normal immunoglobulin, Mucocutaneous Lymph Node Syndrome, Guillain-Barre Syndrome, Bone Marrow Transplantation, Purpura, Thrombocytopenic, Idiopathic, Immunologic Deficiency Syndromes, 23/07/2007, 17, Authorised (updated)
12/09/2019	Other: Preparedness of medicines' clinical trials in paediatrics: Recommendations by the Enpr-EMA working group on trial preparedness
12/09/2019	Human medicines European public assessment report (EPAR): Imraldi, adalimumab, Hidradenitis Suppurativa, Psoriasis, Crohn Disease, Uveitis, Arthritis, Rheumatoid, Arthritis, Colitis, Ulcerative, Spondylitis, Ankylosing, Arthritis, Psoriatic, 24/08/2017, 10, Authorised (updated)
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12/09/2019	Human medicines European public assessment report (EPAR): Stelara, Ustekinumab, Psoriasis, Arthritis, Psoriatic, Crohn Disease, 15/01/2009, 28, Authorised (updated)
12/09/2019	Human medicines European public assessment report (EPAR): Stalevo, levodopa, carbidopa, entacapone, Parkinson Disease, 17/10/2003, 25, Authorised (updated)
12/09/2019	Human medicines European public assessment report (EPAR): Corbilta (previously Levodopa/Carbidopa/Entacapone Sandoz), levodopa, carbidopa, entacapone, Parkinson Disease, 11/11/2013, 6, Authorised (updated)
11/09/2019	Human medicines European public assessment report (EPAR): Keytruda, Pembrolizumab, Melanoma, Hodgkin Disease, Carcinoma, Non-Small-Cell Lung, 17/07/2015, 21, Authorised (updated)
11/09/2019	Periodic safety update single assessment: Hepatitis A vaccines (inactivated, adsorbed): List of nationally authorised medicinal products - PSUSA/00001596/201901
11/09/2019	Periodic safety update single assessment: Roxithromycin: List of nationally authorised medicinal products - PSUSA/00002669/201812

11/09/2019	Human medicines European public assessment report (EPAR): Gilenya, fingolimod hydrochloride , Multiple Sclerosis, 17/03/2011, 23, Authorised (updated)
11/09/2019	Periodic safety update single assessment: Dexketoprofen / tramadol: List of nationally authorised medicinal products - PSUSA/00010468/201901
11/09/2019	Veterinary medicines European public assessment report (EPAR): Advocate, imidacloprid, moxidectin, 02/04/2003, 20, Authorised (updated)
11/09/2019	Periodic safety update single assessment: Carboplatin: List of nationally authorised medicinal products - PSUSA/00000559/201901
11/09/2019	Periodic safety update single assessment: Alitretinoin (oral use): List of nationally authorised medicinal products - PSUSA/00010710/201901
11/09/2019	Periodic safety update single assessment: Pentoxyverine: List of nationally authorised medicinal products - PSUSA/00002345/201812
11/09/2019	Periodic safety update single assessment: Amino acid combinations (only combinations of pure amino acids or combination of amino acids with mineral compounds/electrolytes, i.v. application): List of nationally authorised medicinal products - PSUSA/00010187/201901
11/09/2019	Minutes: Minutes of the COMP meeting 21-23 May 2019
11/09/2019	Newsletter: Human medicines highlights - September 2019
11/09/2019	Periodic safety update single assessment: Ambrosia Artemisiifolia (302) (sublingual use, products authorised via decentralised procedure): List of nationally authorised products - PSUSA/00010693/201901
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10/09/2019	Veterinary medicines European public assessment report (EPAR): HorStem, equine umbilical cord mesenchymal stem cells, 19/06/2019, Authorised
10/09/2019	Periodic safety update single assessment: Bezafibrate: List of nationally authorised products - PSUSA/00000405/201901
10/09/2019	Periodic safety update single assessment: Biotin: List of nationally authorised medicinal products - PSUSA/00000414/201901
10/09/2019	Periodic safety update single assessment: Niflumic acid: List of nationally authorised products - PSUSA/00002157/201812
10/09/2019	Report: Applications for new human medicines under evaluation by the CHMP: August 2019 (updated)
10/09/2019	Committee for Orphan Medicinal Products (COMP): 10-12 September 2019 , European Medicines Agency, Amsterdam, the Netherlands, from 10/09/2019 to 12/09/2019 (updated)
10/09/2019	Other: Organisation chart: Inspections, Human Medicines Pharmacovigilance and Committees Division (updated)
10/09/2019	Agenda: Agenda - CVMP agenda of the 10-12 September 2019 meeting
10/09/2019	Human medicines European public assessment report (EPAR): Mycamine, micafungin, Candidiasis, 25/04/2008, 14, Authorised (updated)
10/09/2019	Report: Medicinal products for human use: monthly figures - August 2019
10/09/2019	Agenda: Agenda - COMP agenda of the 10-12 September 2019 meeting
10/09/2019	Human medicines European public assessment report (EPAR): Cosentyx, Secukinumab, Arthritis, Psoriatic, Psoriasis, Spondylitis, Ankylosing, 14/01/2015, 12, Authorised (updated)
10/09/2019	Periodic safety update single assessment: Benzydamine / cetylpyridine: List of nationally authorised medicinal products - PSUSA/00000378/201901
09/09/2019	Human medicines European public assessment report (EPAR): Otezla, apremilast, Arthritis, Psoriatic, Psoriasis, 15/01/2015, 9, Authorised (updated)
09/09/2019	Human medicines European public assessment report (EPAR): Orencia, Abatacept, Arthritis, Psoriatic, Arthritis, Juvenile Rheumatoid, Arthritis, Rheumatoid, 21/05/2007, 30, Authorised (updated)

NOTICE TO APPLICANTS

No updates since December 15th 2017.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

10.09.2019	Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/283570/2019 vom 27.05.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Diclofenac (topische Formulierungen) Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Diclofenac (topische Formulierungen) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

12.09.2019	Empfehlung des BfArM zur Risikominimierung möglicher Fehlkonnektion von Beatmungsschläuchen in der Anästhesie Dem BfArM sind Risikomeldungen bekannt geworden, bei denen Patientinnen und Patienten im Rahmen einer Narkoseeinleitung zu Schaden gekommen sind. In einigen Fällen konnten Fehler im Bereich der Konnektion der Beatmungsschläuche als Ursache ermittelt werden, die nicht bzw. zu spät als solche erkannt wurden und eine Beatmung der Patientin / des Patienten verhindert haben.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since September 2nd 2019.

PHARMEUROPA TEXTS FOR COMMENT

Text	Monograph number	Group	Issue	Deadline
Liquid preparations for cutaneous application	927	12	31.4	31.12.2019
2.9.27. Uniformity of delivered doses from multidose containers	20927	12	31.4	31.12.2019
2.4.33. Tetrabutylammonium in radiopharmaceutical preparations	20433	14	31.4	31.12.2019
Eucalyptus oil	390	13A	31.4	31.12.2019
Ear preparations	652	12	31.4	31.12.2019
Alfacalcidol	1286	VIT	31.4	31.12.2019