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19 June 2019

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19/06/2019	Other: Qualification opinion - Treatment effect measures when using recurrent event endpoints - Applicant's submission
19/06/2019	Other: Qualification opinion - Treatment effect measures when using recurrent event endpoints - First list of issues
19/06/2019	Human medicines European public assessment report (EPAR): Clopidogrel ratiopharm GmbH, clopidogrel, Peripheral Vascular Diseases, Acute Coronary Syndrome, Myocardial Infarction, Stroke, 28/07/2009, 11, Authorised (updated)
18/06/2019	Periodic safety update single assessment: Clindamycin: List of nationally authorised medicinal products - PSUSA/00000795/201810
18/06/2019	Orphan designation: Recombinant adeno-associated viral vector containing human acid alfa-glucosidase-gene for the: Treatment of glycogen storage disease type II (Pompe's disease), 04/07/2012, Positive (updated)
18/06/2019	Orphan designation: Deferiprone for the: Treatment of sickle cell disease, 23/02/2011, Positive (updated)
18/06/2019	Minutes: CHMP ORGAM minutes for the meeting on 18 February 2019
18/06/2019	Minutes: CHMP ORGAM minutes for the meeting on 21 January 2019
18/06/2019	Human medicines European public assessment report (EPAR): Competact, pioglitazone, metformin hydrochloride, Diabetes Mellitus, Type 2, 28/07/2006, 17, Authorised (updated)
18/06/2019	Human medicines European public assessment report (EPAR): Pedea, Ibuprofen, Ductus Arteriosus, Patent, 28/07/2004, 14, Authorised (updated)
18/06/2019	Type-IA variations: questions and answers (updated)
18/06/2019	Q&A: Grouping of variations (updated)
18/06/2019	Veterinary post-authorisation Q&A: Introduction (updated)
18/06/2019	Q&A: Worksharing of variations (updated)
18/06/2019	Type-IB variations: questions and answers (updated)
18/06/2019	Q&A: Type II variations (updated)
18/06/2019	Q&A: Type II variations vs Extension applications (updated)
18/06/2019	Q&A: Extension applications (updated)
18/06/2019	Q&A: Mock-ups (updated)
18/06/2019	Q&A: Transparency (updated)
18/06/2019	Q&A: Application of the so-called 'sunset clause' to centrally authorised veterinary medicinal products (updated)
18/06/2019	Q&A: Other (updated)
18/06/2019	Human medicines European public assessment report (EPAR): Onpattro, patisiran sodium, Amyloidosis, Familial, 27/08/2018, 2, Authorised (updated)
18/06/2019	Herbal – European Union herbal monograph: Draft European Union herbal monograph on Aesculus hippocastanum L., semen - Revision 1
18/06/2019	Herbal medicinal product: Hippocastani semen, Hippocastani semen, F: Assessment finalised (updated)
18/06/2019	Human medicines European public assessment report (EPAR): Imnovid (previously Pomalidomide Celgene), Pomalidomide, Multiple Myeloma, 05/08/2013, 15, Authorised (updated)
18/06/2019	Orphan designation: Pomalidomide for the: Treatment of multiple myeloma, 08/10/2009, Positive (updated)

18/06/2019	Regulatory and procedural guideline: Recommendations for the implementation of the exemptions to the labelling and package-leaflet obligations in the centralised procedure (updated)
18/06/2019	Periodic safety update single assessment: Piretanide: List of nationally authorised medicinal products - PSUSA/00002433/201810
18/06/2019	Human medicines European public assessment report (EPAR): Jinarc, Tolvaptan, Polycystic Kidney, Autosomal Dominant, 27/05/2015, 12, Authorised (updated)
18/06/2019	Agenda: Agenda - COMP agenda of the 18-20 June 2019 meeting
18/06/2019	Herbal medicinal product: Menthae piperitae aetheroleum, Menthae piperitae aetheroleum, D: Draft under discussion (updated)
18/06/2019	Herbal – European Union herbal monograph: Draft European Union herbal monograph on Mentha x piperita L., aetheroleum - Revision 1
18/06/2019	Herbal – European Union list entry: Draft European Union list entry on Mentha x piperita L., aetheroleum - Revision 1
17/06/2019	Human medicines European public assessment report (EPAR): Rilutek, Riluzole, Amyotrophic Lateral Sclerosis, 10/06/1996, 26, Authorised (updated)
17/06/2019	Work programme: EMA activities, other than the highest priority activities (category 1 activities), that will continue in 2019 - Annex 1 (updated)
17/06/2019	Human medicines European public assessment report (EPAR): Tecentriq, atezolizumab, Carcinoma, Transitional Cell, Carcinoma, Non-Small-Cell Lung, 20/09/2017, 5, Authorised (updated)
17/06/2019	Human medicines European public assessment report (EPAR): Lorviqua, Lorlatinib, Carcinoma, Non-Small-Cell Lung, 06/05/2019, Authorised
17/06/2019	United Kingdom's withdrawal from the European Union ('Brexit') (updated)
17/06/2019	Brexit-related guidance for companies (updated)
17/06/2019	Clinical Trial Regulation (updated)
17/06/2019	News and press releases: Highlights of Management Board meeting: June 2019
17/06/2019	Orphan designation: 4-[2-(6-Methylpyridin-2-yl)-5,6-dihydro-4H-pyrrolo[1,2-b]pyrazol-3-yl]-quinoline-6-carboxamide monohydrate for the: Treatment of glioma, 26/04/2013, Positive (updated)
17/06/2019	Management Board meeting: 12-13 June 2019 , European Medicines Agency, Amsterdam, the Netherlands, from 12/06/2019 to 13/06/2019 (updated)
17/06/2019	Orphan designation: 4-[2-(6-Methylpyridin-2-yl)-5,6-dihydro-4H-pyrrolo[1,2-b]pyrazol-3-yl]-quinoline-6-carboxamide monohydrate for the: Treatment of hepatocellular carcinoma, 12/03/2013, Withdrawn (updated)
17/06/2019	Orphan designation: Human/murine chimeric monoclonal antibody against endoglin (carotuximab) for the: Treatment of soft tissue sarcoma, 28/04/2016, Withdrawn (updated)
17/06/2019	Other: Rules for reimbursement of expenses for delegates attending meetings with effect from 14 June 2019 (updated)
17/06/2019	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, 1, Authorised (updated)
17/06/2019	Human medicines European public assessment report (EPAR): Insulin lispro Sanofi, insulin lispro, Diabetes Mellitus, 18/07/2017, 4, Authorised (updated)
17/06/2019	Periodic safety update single assessment: Everolimus (indicated for rejection of transplanted organs) : CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - PSUSA/00010269/201807 (updated)

17/06/2019	Human medicines European public assessment report (EPAR): Voncento, Human coagulation factor VIII, human von willebrand factor, Hemophilia A, von Willebrand Diseases, 12/08/2013, 12, Authorised (updated)
17/06/2019	Human medicines European public assessment report (EPAR): Intrarosa, Prasterone, Menopause, 08/01/2018, 3, Authorised (updated)

NOTICE TO APPLICANTS

No updates since December 15th 2017.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

18.06.2019	Risiko der Übertragung von multiresistenten Erregern durch Fäkale Mikrobiota-Transplantation (FMT, Stuhltransplantation) Wirkstoff FMT Risiko der Übertragung von multiresistenten Erregern durch Fäkale Mikrobiota-Transplantation (FMT, Stuhltransplantation)
18.06.2019	Omega-3-Fettsäuren: EMA bewertet die Anwendung nach Herzinfarkt Wirkstoff Omega-3-Fettsäuren Das Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) setzt mit Bescheid vom 14. Juni 2019 den Durchführungsbeschluss der Europäischen Kommission um.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since June 13th 2019

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

NO updates since June 17th2019

PHARMEUROPA TEXTS FOR COMMENT

Text	Monograph number	Group	Issue	Deadline
Prednicarbate	1467	10B	31. Mrz	30.09.2019
Forsythia fruit	2720	TCM	31. Mrz	30.09.2019
myo-Inositol	1805	CRB	31. Mrz	30.09.2019
Sanguisorba root	2385	TCM	31. Mrz	30.09.2019
Piracetam	1733	10B	31. Mrz	30.09.2019
Florfenicol for veterinary use	2920	7	31. Mrz	30.09.2019
Disopyramide	1006	10A	31. Mrz	30.09.2019
Cyproheptadine hydrochloride sesquihydrate	817	10A	31. Mrz	30.09.2019
Aripiprazole	2617	10C	31. Mrz	30.09.2019

Text	Monograph number	Group	Issue	Deadline
Sodium cromoglicate	562	10A	31. Mrz	30.09.2019
Sodium aminosalicylate dihydrate	1993	10A	31. Mrz	30.09.2019
Flucloxacillin sodium monohydrate	668	7	31. Mrz	30.09.2019
Dihydrostreptomycin sulfate for veterinary use	485	7	31. Mrz	30.09.2019
Patches	1011	12	31. Mrz	30.09.2019
Codeine phosphate sesquihydrate	75	11	31. Mrz	30.09.2019
Tigecycline	2825	P4	31. Mrz	30.09.2019
Dapsone	77	11	31. Mrz	30.09.2019