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### HEADS OF AGENCIES – CMDh

9 March 2020

[NEW - Art. 45 assessment reports for econazole nitrate & triamcinolone acetonide and oxcarbazepine;](#)

[NEW - Art. 46 assessment reports for Ismigen/PMBL tablet \(polyvalent mechanical bacterial lysate\), Valtrex \(valaciclovir\), Palexia, Yantil, Tapentadol Grünenthal \(tapentadol \(as hydrochloride\) \(DE/W/123+124/pdWS/01\)\);](#)

[UPDATE - CMDh Standard Operating Procedure - Disagreement in procedures -Referral to CMDh;](#)

[UPDATE - Decentralised Procedure Members States' Standard Operating Procedure;](#)

6 March 2020

[UPDATE - CMDh practical guidance for Marketing Authorisation Holders of nationally authorised products \(incl. MRP/DCP\) in relation to the Art. 5\(3\) Referral on Nitrosamines](#)

5 March 2020

[NEW - January 2020 CMDh Minutes](#)

[NEW - 2019 - Statistics for New Applications \(MRP/DCP\), Variations, Referrals and Paediatric Worksharing procedures](#)

4 March 2020

[NEW - Report from the meeting held on 25-27 February 2020](#)

### HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: [click here2](#)

## EUROPEAN MEDICINES AGENCY (EMA)

06/03/2020	Veterinary medicines European public assessment report (EPAR): <a href="#">Letifend</a> , recombinant protein Q from Leishmania infantum MON-1, 20/04/2016, 6, Authorised (updated)
06/03/2020	<a href="#">Pharmacovigilance Risk Assessment Committee (PRAC): 9-12 March 2020</a> , from 09/03/2020 to 12/03/2020 (updated)
06/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Mirapexin</a> , pramipexole dihydrochloride monohydrate, Restless Legs Syndrome, Parkinson Disease, 23/02/1998, 35, Authorised (updated)
06/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Ibrance</a> , palbociclib, Breast Neoplasms, 09/11/2016, 10, Authorised (updated)
06/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Xeljanz</a> , tofacitinib citrate, Arthritis, Rheumatoid, 21/03/2017, 25/04/2013, 9, Authorised (updated)
06/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Atazanavir Mylan</a> , atazanavir sulfate, HIV Infections, 22/08/2016, 7, Authorised (updated)
06/03/2020	Referral: <a href="#">Xeljanz</a> , tofacitinib , Article 20 procedures, European Commission final decision, 14/11/2019, 31/01/2020, 06/03/2020 (updated)
06/03/2020	Withdrawn application: <a href="#">Ekesivy</a> , diclofenamide, Date of withdrawal: 02/10/2019, Initial authorisation (updated)
06/03/2020	Orphan designation: <a href="#">Yttrium (90Y)-DOTA-radiolabelled humanized monoclonal antibody against mucin 1</a> for the: Treatment of pancreatic cancer, 06/02/2009, Withdrawn (updated)
06/03/2020	Orphan designation: <a href="#">Veltuzumab</a> for the: Treatment of chronic lymphocytic leukaemia, 29/01/2010, Withdrawn (updated)
06/03/2020	News and press releases: <a href="#">Regulatory information – adjusted fees for applications to EMA from 1 April 2020</a> (updated)
06/03/2020	<a href="#">European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties Joint meeting</a> , European Medicines Agency, Amsterdam, the Netherlands, from 03/03/2020 to 04/03/2020 (updated)
06/03/2020	Agenda: <a href="#">Agenda - PCWP/HCPWP joint meeting on 3-4 March 2020</a> (updated)
06/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Mysimba</a> , bupropion hydrochloride, naltrexone hydrochloride, Obesity, Overweight, 26/03/2015, 15, Authorised (updated)
06/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Ivabradine Zentiva</a> , ivabradine hydrochloride, Angina Pectoris, Heart Failure, 11/11/2016, 2, Authorised (updated)
06/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Vyxeos liposomal (previously known as Vyxeos)</a> , daunorubicin hydrochloride / cytarabine, Leukemia, Myeloid, Acute, 23/08/2018, 3, Authorised (updated)
06/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Obizur</a> , susoctocog alfa, Hemophilia A, 11/11/2015, 4, Authorised (updated)
06/03/2020	Human medicines European public assessment report (EPAR): <a href="#">DuoPlavin</a> , clopidogrel, acetylsalicylic acid, Acute Coronary Syndrome, Myocardial Infarction, 14/03/2010, 21, Authorised (updated)
06/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Crysvita</a> , Burosumab, Hypophosphatemia, Familial, Hypophosphatemic Rickets, X-Linked Dominant, 19/02/2018, 5, Authorised (updated)
06/03/2020	Veterinary medicines European public assessment report (EPAR): <a href="#">Aftovaxpur DOE</a> , Maximum three of the following purified, inactivated foot-and-mouth disease virus strains: O1 Manisa $\geq 6$ PD50*; O1 BFS $\geq 6$ PD50*; O Taiwan 3/97 $\geq 6$ PD50*; A22 Iraq $\geq 6$ PD50*; A24 Cruzeiro $\geq 6$ PD50*; A Turkey 14/98 $\geq 6$ PD50*; Asia 1 Shamir $\geq 6$ PD50*; SAT2 Saudi Arabia $\geq 6$ PD50*; * PD50 – 50%

	protective dose in cattle as described in Ph. Eur. monograph 0063., 15/07/2013, 16/05/2013, 7, Authorised (updated)
06/03/2020	<a href="#">Third international awareness session on science and regulation for animal health and welfare, public health and the environment</a> , European Medicines Agency, Amsterdam, the Netherlands, from 02/04/2020 to 03/04/2020 (updated)
06/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Aerius</a> , desloratadine, Rhinitis, Allergic, Perennial, Urticaria, Rhinitis, Allergic, Seasonal, 15/01/2001, 42, Authorised (updated)
06/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Sirturo</a> , bedaquiline fumarate, Tuberculosis, Multidrug-Resistant, 05/03/2014, 17, Authorised (updated)
05/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Rinvoq</a> , Upadacitinib, Arthritis, Rheumatoid, 16/12/2019, Authorised (updated)
05/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Caspofungin Accord</a> , caspofungin acetate, Candidiasis, Aspergillosis, 11/02/2016, 6, Authorised (updated)
05/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Praxbind</a> , idarucizumab, Hemorrhage, 20/11/2015, 6, Authorised (updated)
05/03/2020	<a href="#">Joint European Medicines Agency (EMA) / European Organisation for Research and Treatment of Cancer (EORTC) workshop on novel patient-reported outcomes (PRO) and quality of life (QoL) approaches in cancer clinical research</a> , European Medicines Agency, Amsterdam, the Netherlands, from 12/03/2020 to 13/03/2020 (updated)
05/03/2020	<a href="#">Management Board meeting: 18-19 December 2019</a> , European Medicines Agency, Amsterdam, the Netherlands, from 18/12/2019 to 19/12/2019 (updated)
05/03/2020	Minutes: <a href="#">Minutes of the 106th meeting of the Management Board: 18-19 December 2019</a> (new)
05/03/2020	Minutes: <a href="#">Minutes of the CVMP meeting of 21-23 January 2020</a> (new)
05/03/2020	Referral: <a href="#">Panexcell</a> , Article 31 referrals, Procedure started, 27/02/2020, 05/03/2020 (updated)
05/03/2020	Report: <a href="#">List of products granted eligibility to PRIME</a> (updated)
05/03/2020	Veterinary medicines European public assessment report (EPAR): <a href="#">Nasym</a> , live attenuated bovine respiratory syncytial virus (BRSV), strain Lym-56, 29/07/2019, 1, Authorised (updated)
05/03/2020	Annex to CHMP highlights: <a href="#">Recommendations on eligibility to PRIME scheme - Adopted at the CHMP meeting of 24-27 February 2020</a> (new)
05/03/2020	Veterinary medicines European public assessment report (EPAR): <a href="#">Cerenia</a> , maropitant citrate, 28/09/2006, 20, Authorised (updated)
05/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Trimbow</a> , Beclometasone dipropionate, formoterol fumarate dihydrate, Glycopyrronium bromide, Pulmonary Disease, Chronic Obstructive, 17/07/2017, 1, Authorised (updated)
05/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Cholib</a> , fenofibrate, simvastatin, Dyslipidemias, 26/08/2013, 10, Authorised (updated)
05/03/2020	Orphan designation: <a href="#">Triheptanoïn</a> for the: Treatment of carnitine palmitoyltransferase II deficiency, 28/07/2015, Positive (updated)
05/03/2020	Orphan designation: <a href="#">Triheptanoïn</a> for the: Treatment of mitochondrial trifunctional protein deficiency, 28/07/2015, Positive (updated)
05/03/2020	Orphan designation: <a href="#">Triheptanoïn</a> for the: Treatment of long-chain 3-hydroxyacyl-coA dehydrogenase deficiency, 28/07/2015, Positive (updated)
05/03/2020	Orphan designation: <a href="#">Triheptanoïn</a> for the: Treatment of very long-chain acyl-CoA dehydrogenase deficiency, 19/06/2015, Positive (updated)
05/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Galvus</a> , vildagliptin, Diabetes Mellitus, Type 2, 25/09/2007, 17, Authorised (updated)

05/03/2020	Orphan designation: <a href="#">Adeno-associated viral vector serotype 8 containing the human factor-VII gene</a> for the: Treatment of congenital factor VII deficiency, 15/01/2015, Positive (updated)
05/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Zostavax</a> , varicella-zoster virus (live, attenuated), Herpes Zoster, Immunization, 19/05/2006, 28, Authorised (updated)
05/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Byetta</a> , exenatide, Diabetes Mellitus, Type 2, 20/11/2006, 23, Authorised (updated)
04/03/2020	Referrals document: <a href="#">Picato Article-20 referral - Assessment report on provisional measures</a> (updated)
04/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Picato</a> , Ingenol mebutate, Keratosis, Actinic, 15/11/2012, 9, Withdrawn (updated)
04/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Kuvan</a> , Sapropterin dihydrochloride, Phenylketonurias, 02/12/2008, 20, Authorised (updated)
04/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Hycamtin</a> , topotecan, Ovarian Neoplasms, Uterine Cervical Neoplasms, Small Cell Lung Carcinoma, 12/11/1996, 30, Authorised (updated)
04/03/2020	Other: <a href="#">Involvement of patient representatives in scientific advice procedures at the European Medicines Agency</a> (updated)
04/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Cimzia</a> , Certolizumab pegol, Arthritis, Rheumatoid, 01/10/2009, 26, Authorised (updated)
04/03/2020	Other: <a href="#">Orientation guide for patient representatives and healthcare professionals - EMA building</a> (new)
04/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Mavenclad</a> , Cladribine, Multiple Sclerosis, 22/08/2017, 3, Authorised (updated)
04/03/2020	Regulatory and procedural guideline: <a href="#">EudraVigilance registration manual</a> (updated)
04/03/2020	Other: <a href="#">List of European Union reference dates and frequency of submission of periodic safety update reports</a> (updated)
04/03/2020	News and press releases: <a href="#">Emiel van Galen elected as chair of the Committee for Herbal Medicinal Products</a>
04/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Inhixa</a> , enoxaparin sodium, Venous Thromboembolism, 15/09/2016, 13, Authorised (updated)
04/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Deferasirox Accord</a> , deferasirox, Iron Overload, beta-Thalassemia, 09/01/2020, Authorised
04/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Cufence</a> , trientine dihydrochloride, Hepatolenticular Degeneration, 25/07/2019, 2, Authorised (updated)
04/03/2020	Orphan designation: <a href="#">3,4-diaminopyridine phosphate (amifampridine)</a> for the: Treatment of Lambert-Eaton myasthenic syndrome, 19/12/2002, Withdrawn (updated)
04/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Clopidogrel Apotex (previously Clopidogrel Mylan Pharma)</a> , clopidogrel besilate, Peripheral Vascular Diseases, Stroke, Myocardial Infarction, 16/10/2009, 18, Authorised (updated)
04/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Apealea</a> , paclitaxel, Ovarian Neoplasms, 20/11/2018, 3, Authorised (updated)
04/03/2020	Veterinary medicines European public assessment report (EPAR): <a href="#">Clomicalm</a> , clomipramine, 01/04/1998, 16, Authorised (updated)
04/03/2020	<a href="#">Aluvia H-W-764</a> (updated)
04/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Daxas</a> , roflumilast, Pulmonary Disease, Chronic Obstructive, 05/07/2010, 13, Authorised (updated)
04/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Neoclarityn</a> , desloratadine, Rhinitis, Allergic, Perennial, Urticaria, Rhinitis, Allergic, Seasonal, 15/01/2001, 38, Authorised (updated)

04/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Arava</a> , leflunomide, Arthritis, Rheumatoid, Arthritis, Psoriatic, 02/09/1999, 35, Authorised (updated)
04/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Verzenio</a> , abemaciclib, Breast Neoplasms, 26/09/2018, 5, Authorised (updated)
04/03/2020	Veterinary medicines European public assessment report (EPAR): <a href="#">Emdocam</a> , meloxicam, 18/08/2011, 7, Authorised (updated)
04/03/2020	Scientific guideline: <a href="#">Guideline on good pharmacovigilance practices (GVP): Module VII – Periodic safety update report - Explanatory note</a> (updated)
04/03/2020	Other: <a href="#">Orphan medicines figures 2000-2019</a> (updated)
04/03/2020	Scientific guideline: <a href="#">ICH guideline Q12 on technical and regulatory considerations for pharmaceutical product lifecycle management - Step 5</a> (new)
04/03/2020	<a href="#">ICH Q12 Technical and regulatory considerations for pharmaceutical product lifecycle management</a> (updated)
04/03/2020	Other: <a href="#">Note on EU implementation of ICH Q12 (guideline on technical and regulatory considerations for pharmaceutical product lifecycle management)</a> (new)
04/03/2020	Scientific guideline: <a href="#">ICH guideline Q12 on technical and regulatory considerations for pharmaceutical product lifecycle management - Step 5 - Annexes</a> (new)
03/03/2020	Veterinary medicines European public assessment report (EPAR): <a href="#">Nexgard Spectra</a> , afoxolaner, milbemycin oxime, 15/01/2015, 7, Authorised (updated)
03/03/2020	Veterinary medicines European public assessment report (EPAR): <a href="#">NexGard</a> , afoxolaner, 11/02/2014, 10, Authorised (updated)
03/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Nimenrix</a> , Neisseria meningitidis serogroup A polysaccharide conjugated to tetanus toxoid, Neisseria meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / Neisseria meningitidis serogroup W-135 polysaccharide conjugated to tetanus toxoid, Neisseria meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid, Meningitis, Meningococcal, 20/04/2012, 29, Authorised (updated)
03/03/2020	<a href="#">Nitrosamine impurities</a> (updated)
03/03/2020	News and press releases: <a href="#">Update on nitrosamines in EU medicines</a>
03/03/2020	Minutes: <a href="#">Minutes of the CHMP meeting 9-12 December 2019</a> (new)
03/03/2020	Human medicines European public assessment report (EPAR): <a href="#">Briviact (in Italy: Nubriveo)</a> , Brivaracetam, Epilepsy, 13/01/2016, 7, Authorised (updated)

## NOTICE TO APPLICANTS

No updates since November 28<sup>th</sup> 2019.

## BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

04.03.2020	<a href="#">Aktuelle Informationen zu Nitrosaminen in Humanarzneimitteln</a>  Wirkstoff Metformin und weitere Aktuelle Informationen zu Nitrosaminen in metforminhaltigen und weiteren Humanarzneimitteln.
02.03.2020	<a href="#">Sartane: Verunreinigungen der Wirkstoffe</a>  Wirkstoff Valsartan; Candesartan; Irbesartan; Losartan; Olmesartan Das BfArM hat nach Anhörung das Ruhen der Zulassungen bis zur vollständigen Umsetzung angeordnet.
02.03.2020	<a href="#">82. Sitzung (23. Januar 2020) – Ergebnisprotokoll</a>  Sachverständigen-Ausschuss für Verschreibungspflicht nach § 53 Absatz 2 AMG

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**BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)**

No updates since January 9<sup>th</sup> 2020.

**PEI - VIGILANZ (SPECIFIC FOR GERMANY)**

No updates since January 24<sup>th</sup> 2020.

**PHARMEUROPA TEXTS FOR COMMENT**

Information on Pharmeuropa updates will be presented quarterly.