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### HEADS OF AGENCIES – CMDh

13 June 2019

[UPDATE - Q&As on Variations](#)

### HEADS OF AGENCIES – PAEDIATRIC REGULATION

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

### EUROPEAN MEDICINES AGENCY (EMA)

|            |   |
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| 17/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Afstyla</a> , lonococog alfa, Hemophilia A, 04/01/2017, 4, Authorised (updated)   |
| 14/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Wilzin</a> , zinc, Hepatolenticular Degeneration, 12/10/2004, 11, Authorised (updated)  |
| 14/06/2019 | Orphan designation: <a href="#">Diacerein</a> for the: Treatment of epidermolysis bullosa, 08/11/2018, Negative   |
| 14/06/2019 | Orphan designation: <a href="#">Eculizumab</a> for the: Treatment of neuromyelitis optica spectrum disorders, 05/08/2013, Positive (updated)  |
| 14/06/2019 | Orphan designation: <a href="#">Sodium benzoate, Sodium phenylacetate</a> for the: Treatment of ornithine transcarbamylase deficiency, 24/04/2019, Positive   |
| 14/06/2019 | Orphan designation: <a href="#">Human culture expanded autologous mesenchymal stromal cells</a> for the: Treatment of amyotrophic lateral sclerosis, 24/04/2019, Positive   |
| 14/06/2019 | Referral: <a href="#">Leuprorelin-containing depot medicinal products</a> , leuprorelin, See "List of the medicines affected by the referral (Annex I)", Article 31 referrals, Procedure started                                      |
| 14/06/2019 | News and press releases: <a href="#">Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 11-14 June 2019</a>   |
| 14/06/2019 | Orphan designation: <a href="#">Balipodect</a> for the: Treatment of fragile X syndrome, 14/04/2019, Positive   |
| 14/06/2019 | Orphan designation: <a href="#">Autologous human bone marrow-derived haematopoietic and mesenchymal stem cells depleted of erythrocytes, monocytes and lymphocytes</a> for the: Treatment of spinal cord injury, 24/04/2019, Positive |
| 14/06/2019 | Orphan designation: <a href="#">3-(3-(3,5-bis(trifluoromethyl)phenyl)-1h-pyrazol-1-yl)propanoic acid</a> for the: Treatment of Stargardt's disease, 24/04/2019, Positive  |
| 14/06/2019 | Report: <a href="#">Applications for new human medicines under evaluation by the CHMP: June 2019</a>  |

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| 14/06/2019 | <a href="#">Procurement</a> (updated)  |
| 14/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Grepid</a> , clopidogrel besilate, Peripheral Vascular Diseases, Stroke, Myocardial Infarction, 27/07/2009, 18, Authorised (updated)   |
| 14/06/2019 | <a href="#">Management Board meeting: 12-13 June 2019</a> , European Medicines Agency, Amsterdam, the Netherlands, from 12/06/2019 to 13/06/2019 (updated)   |
| 14/06/2019 | Agenda: <a href="#">Agenda for the 104th meeting of the Management Board</a> (updated)   |
| 14/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Docetaxel Kabi</a> , docetaxel, Head and Neck Neoplasms, Carcinoma, Non-Small-Cell Lung, Adenocarcinoma, Prostatic Neoplasms, Breast Neoplasms, 22/05/2012, 12, Authorised (updated)   |
| 14/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Olanzapine Teva</a> , olanzapine, Schizophrenia, Bipolar Disorder, 12/12/2007, 24, Authorised (updated)  |
| 14/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Cystadrops</a> , mercaptamine hydrochloride, Cystinosis, 18/01/2017, 5, Authorised (updated)   |
| 14/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Velmetia</a> , sitagliptin, metformin hydrochloride, Diabetes Mellitus, Type 2, 16/07/2008, 26, Authorised (updated)   |
| 14/06/2019 | <a href="#">Mosquirix H-W-2300</a> (updated)   |
| 14/06/2019 | Minutes: <a href="#">Minutes of the 103rd meeting of the Management Board: 21 March 2019</a>   |
| 14/06/2019 | <a href="#">Management Board meeting: 21 March 2019</a> , European Medicines Agency, Amsterdam, the Netherlands, from 21/03/2019 to 21/03/2019 (updated)   |
| 14/06/2019 | Orphan designation: <a href="#">Modified messenger ribonucleic acid encoding human propionyl-coenzyme A carboxylase alpha and beta subunits encapsulated into lipid nanoparticle</a> for the: Treatment of propionic acidaemia, 24/04/2019, Positive   |
| 13/06/2019 | Referral: <a href="#">Omega-3 acid ethyl esters - containing medicinal products for oral in use in secondary prevention after myocardial infarction</a> , Omega-3 fatty acid ethyl esters , Article 31 referrals, European Commission final decision, 13/12/2018, 06/06/2019, 13/06/2019 (updated) |
| 13/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Sancuso</a> , granisetron, Vomiting, Cancer, 20/04/2012, 12, Authorised (updated)  |
| 13/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Clopidogrel Mylan</a> , clopidogrel hydrochloride, Peripheral Vascular Diseases, Stroke, Myocardial Infarction, 21/09/2009, 13, Authorised (updated)   |
| 13/06/2019 | Veterinary medicines European public assessment report (EPAR): <a href="#">Bravecto</a> , fluralaner, 11/02/2014, 8, Authorised (updated)  |
| 13/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Latuda</a> , lurasidone, Schizophrenia, 20/03/2014, 16, Authorised (updated)   |
| 13/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Accofil</a> , filgrastim, Neutropenia, 17/09/2014, 10, Authorised (updated)  |
| 13/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Leflunomide Zentiva (previously Leflunomide Winthrop)</a> , leflunomide, Arthritis, Rheumatoid, Arthritis, Psoriatic, 08/01/2010, 15, Authorised (updated)   |
| 13/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Cystadane</a> , Betaine anhydrous, Homocystinuria, 14/02/2007, 13, Authorised (updated)  |
| 13/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Pemetrexed Hospira</a> , pemetrexed, Carcinoma, Non-Small-Cell Lung, Mesothelioma, 19/11/2015, 7, Authorised (updated)   |
| 13/06/2019 | Veterinary medicines European public assessment report (EPAR): <a href="#">Leucogen</a> , purified p45 FeLV-envelope antigen, 17/06/2009, 7, Authorised (updated)  |
| 13/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Onivyde</a> , irinotecan hydrochloride trihydrate, Pancreatic Neoplasms, 14/10/2016, 3, Authorised (updated)   |

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| 13/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Mvasi</a> , bevacizumab, Carcinoma, Renal Cell, Peritoneal Neoplasms, Ovarian Neoplasms, Breast Neoplasms, Carcinoma, Non-Small-Cell Lung, Fallopian Tube Neoplasms, 14/01/2018, 4, Authorised (updated)   |
| 13/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Truxima</a> , rituximab, Lymphoma, Non-Hodgkin, Arthritis, Rheumatoid, Wegener Granulomatosis, Leukemia, Lymphocytic, Chronic, B-Cell, Microscopic Polyangiitis, 17/02/2017, 8, Authorised (updated)   |
| 13/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Translarna</a> , Ataluren, Muscular Dystrophy, Duchenne, 31/07/2014, 11, Authorised (updated)  |
| 13/06/2019 | Veterinary medicines European public assessment report (EPAR): <a href="#">Leucofeligen FeLV/RCP</a> , live feline calicivirus (strain F9) / live feline viral rhinotracheitis virus (strain F2) / live feline panleucopenia virus, purified p45 feline leukaemia virus envelope antigen, 24/06/2009, 7, Authorised (updated)                                      |
| 12/06/2019 | Veterinary medicines European public assessment report (EPAR): <a href="#">Nobivac LeuFel</a> , purified Rp-45 FeLV-envelope antigen, 06/11/2017, 2, Authorised (updated)  |
| 12/06/2019 | Veterinary medicines European public assessment report (EPAR): <a href="#">Suvaxyn PCV</a> , porcine circovirus recombinant virus (CPCV) 1-2, inactivated, 24/07/2009, 13, Authorised (updated)  |
| 12/06/2019 | Other: <a href="#">Article 57 product data</a> (updated)   |
| 12/06/2019 | Veterinary medicines European public assessment report (EPAR): <a href="#">Baycox Iron</a> , Iron(iii) ion / toltrazuril, 20/05/2019, Authorised   |
| 12/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Zessly</a> , infliximab, Arthritis, Psoriatic, Psoriasis, Crohn Disease, Arthritis, Rheumatoid, Colitis, Ulcerative, Spondylitis, Ankylosing, 18/05/2018, 3, Authorised (updated)  |
| 12/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Irbesartan/Hydrochlorothiazide Teva</a> , irbesartan, hydrochlorothiazide, Hypertension, 26/11/2009, 16, Authorised (updated)  |
| 12/06/2019 | Referral: <a href="#">Fenspiride containing medicinal products</a> , fenspiride, Article 107i procedures, Position provided by CMDh, 29/05/2019, 12/06/2019 (updated)  |
| 12/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Alpivab</a> , Peramivir, Influenza, Human, 13/04/2018, 1, Authorised (updated)   |
| 12/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Irbesartan Teva</a> , irbesartan, Hypertension, 30/10/2009, 11, Authorised (updated)   |
| 11/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Revlimid</a> , lenalidomide, Multiple Myeloma, Lymphoma, Mantle-Cell, Myelodysplastic Syndromes, 14/06/2007, 38, Authorised (updated)  |
| 11/06/2019 | <a href="#">European Medicines Agency (EMA) and European Union (EU) payer community meeting</a> , Zorginstituut Nederland, Diemen, The Netherlands, from 18/06/2019 to 18/06/2019  |
| 11/06/2019 | Annex to CHMP highlights: <a href="#">Scientific advice and protocol assistance adopted during the CHMP meeting 27 – 29 May 2019</a>   |
| 11/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Glivec</a> , imatinib, Precursor Cell Lymphoblastic Leukemia-Lymphoma, Gastrointestinal Stromal Tumors, Dermatofibrosarcoma, Myelodysplastic-Myeloproliferative Diseases, Leukemia, Myelogenous, Chronic, BCR-ABL Positive, Hypereosinophilic Syndrome, 07/11/2001, 35, Authorised (updated) |
| 11/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Tesavel</a> , sitagliptin, Diabetes Mellitus, Type 2, 10/01/2008, 21, Authorised (updated)   |
| 11/06/2019 | Human medicines European public assessment report (EPAR): <a href="#">Modigraf</a> , tacrolimus, Graft Rejection, 15/05/2009, 12, Authorised (updated)   |
| 11/06/2019 | Agenda: <a href="#">Agenda - PRAC draft agenda of meeting 11-14 June 2019</a>  |
| 11/06/2019 | <a href="#">Mutual recognition agreements (MRA)</a> (updated)  |

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| 11/06/2019 | Other: <a href="#">Questions and answers on the impact of mutual recognition agreement between the European Union and the United States as of 10 June 2019</a> (updated) |
| 11/06/2019 | News and press releases: <a href="#">Two additional countries to benefit from EU-US mutual recognition agreement for inspections</a>                                     |

## NOTICE TO APPLICANTS

No updates since December 15<sup>th</sup> 2017.

## BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

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| 17.06.2019 | <p><a href="#">Leuprorelinhaltige Arzneimittel: Medikationsfehler bei Depotzubereitungen</a></p> <p>Wirkstoff Leuprorelin</p> <p>Die Europäische Arzneimittel-Agentur (EMA) hat ein Bewertungsverfahren zur Überprüfung von Medikationsfehlern bei Depotzubereitungen eingeleitet.</p> |
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## BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

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| 13.06.2019 | <p><a href="#">Empfehlung für die Verwendung von Paclitaxel-beschichteten Stents (DES) und Ballons (DCB) in der Behandlung der peripheren arteriellen Verschlusskrankheit (pAVK)</a></p> <p>Im Dezember 2018 wurde von Katsamos et al. im Journal of American Heart Association eine Meta-Analyse randomisierter kontrollierter Studien veröffentlicht. Die Analyse konzentrierte sich auf Paclitaxel-beschichtete Ballons und Stents, die in Oberschenkel- und Kniekehlenarterien bei Patientinnen und Patienten mit intermittierender Claudicatio eingesetzt wurden. Die Autoren kamen zu dem Ergebnis, dass Patientinnen / Patienten, bei denen diese Produkte eingesetzt wurden, 2 bis 5 Jahre nach deren Anwendung eine statistisch signifikant erhöhte Sterbewahrscheinlichkeit (Gesamtmortalität) im Vergleich zu Patientinnen / Patienten aufwiesen, die mit unbeschichteten Ballons oder Bare-Metal-Stents behandelt wurden.</p> |
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## PEI - VIGILANZ (SPECIFIC FOR GERMANY)

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| 17.06.2019 | Rote-Hand-Brief: Darzalex (Daratumumab) | <a href="#">zum Beitrag</a> |
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## PHARMEUROPA TEXTS FOR COMMENT

| Text  | Monograph number | Group | Issue   | Deadline   |
|---|------------------|-------|---------|------------|
| Preparations for inhalation                       | 671              | INH   | 31. Mrz | 30.09.2019 |
| Lovastatin  | 1538             | 10A   | 31. Mrz | 30.09.2019 |
| Semi-solid preparations for cutaneous application | 132              | 12    | 31. Mrz | 30.09.2019 |
| Plasters, medicated                               | 3032             | 12    | 31. Mrz | 30.09.2019 |
| Norfloxacin                                       | 1248             | 10A   | 31. Mrz | 30.09.2019 |

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| <b>Text</b>                         | <b>Monograph number</b> | <b>Group</b> | <b>Issue</b> | <b>Deadline</b> |
|-------------------------------------|-------------------------|--------------|--------------|-----------------|
| Intravesical preparations           | 2811                    | 12           | 31. Mrz      | 30.09.2019      |
| 2.9.4. Dissolution test for patches | 20904                   | 12           | 31. Mrz      | 30.09.2019      |