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27 November 2019

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NEW - Art. 46 assessment report for Enstilar (calcipotriol/betamethasone dipropionate);

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## HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

## EUROPEAN MEDICINES AGENCY (EMA)

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| 02/12/2019 | Human medicines European public assessment report (EPAR): Translarna, Ataluren, Muscular Dystrophy, Duchenne, 31/07/2014, 13, Authorised (updated) |
| 02/12/2019 | Orphan designation: S-acetyl-(S)-4'-phosphopantetheine, calcium salt for the: Treatment of pantothenate-kinase-associated neurodegeneration, 28/04/2016, Positive (updated) |

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| 02/12/2019 | Periodic safety update single assessment: Nefopam: List of nationally authorised medicinal products - PSUSA/00002131/201903 |
| 02/12/2019 | Human medicines European public assessment report (EPAR): Odefsey, emtricitabine, rilpivirine hydrochloride, tenofovir alafenamide, HIV Infections, 21/06/2016, 15, Authorised (updated) |
| 29/11/2019 | Periodic safety update single assessment: Triamcinolone (intraocular formulations): List of nationally authorised medicinal products - PSUSA/00010292/201903 |
| 29/11/2019 | Other: PDCO meeting dates for 2019, 2020 and 2021 (updated) |
| 29/11/2019 | Human medicines European public assessment report (EPAR): Dupixent, dupilumab, Dermatitis, Atopic, 27/09/2017, 6, Authorised (updated) |
| 29/11/2019 | Human medicines European public assessment report (EPAR): Tysabri, natalizumab, Multiple Sclerosis, 27/06/2006, 28, Authorised (updated) |
| 29/11/2019 | Human medicines European public assessment report (EPAR): Udenyca, pegfilgrastim, Neutropenia, 21/09/2018, 3, Authorised (updated) |
| 29/11/2019 | Human medicines European public assessment report (EPAR): Kanjinti, trastuzumab, Stomach Neoplasms, Breast Neoplasms, 16/05/2018, 6, Authorised (updated) |
| 29/11/2019 | Human medicines European public assessment report (EPAR): DuoPlavin, clopidogrel, acetylsalicylic acid, Acute Coronary Syndrome, Myocardial Infarction, 14/03/2010, 20, Authorised (updated) |
| 29/11/2019 | Human medicines European public assessment report (EPAR): Vyndaqel, tafamidis, Amyloidosis, 16/11/2011, 15, Authorised (updated) |
| 29/11/2019 | Human medicines European public assessment report (EPAR): Senstend, lidocaine, prilocaine, Premature Ejaculation, 14/11/2019, Authorised |
| 29/11/2019 | Leaflet: World AIDS Day – Communities make the difference |
| 29/11/2019 | Other: Timetable: Periodic safety update report (PSUR) and PSUR single assessment (PSUSA) (updated) |
| 29/11/2019 | Other: Timetable: Periodic safety update report (PSUR) and PSUR single assessment (PSUSA) - Advanced therapy medicinal products (ATMPs) (updated) |
| 29/11/2019 | News and press releases: Meeting highlights from the Pharmacovigilance Risk Assessment Committee (PRAC) 25-28 Novemver 2019 |
| 29/11/2019 | Paediatric Committee (PDCO): 25-28 June 2019 , European Medicines Agency, Amsterdam, The Netherlands, from 25/06/2019 to 28/06/2019 (updated) |
| 29/11/2019 | Minutes: Minutes - PDCO minutes of the 25-28 June 2019 meeting |
| 29/11/2019 | Minutes: Minutes - PDCO minutes of the 27-29 May 2019 meeting |
| 29/11/2019 | Other: Organisation chart: Veterinary Medicines (updated) |
| 29/11/2019 | Human medicines European public assessment report (EPAR): Neulasta, pegfilgrastim, Neutropenia, Cancer, 22/08/2002, 34, Authorised (updated) |
| 29/11/2019 | Committee meeting report: CAT monthly report of application procedures, guidelines and related documents on advanced therapies: November 2019 |
| 29/11/2019 | Committee for Advanced Therapies (CAT): 06-08 November 2019 , European Medicines Agency, Amsterdam, The Netherlands, from 06/11/2019 to 08/11/2019 (updated) |
| 28/11/2019 | Human medicines European public assessment report (EPAR): Pelgraz, pegfilgrastim, Neutropenia, 21/09/2018, 4, Authorised (updated) |
| 28/11/2019 | News and press releases: ‘Regulatory science to 2025’: live broadcast of post-consultation workshop on veterinary medicines |
| 28/11/2019 | Agenda: Agenda - Multi-stakeholder workshop on draft 'Regulatory Science to 2025' strategy (stakeholders for veterinary medicines) |
| 28/11/2019 | Leaflet: EMA Regulatory Science to 2025 - Four goals for veterinary medicines regulation |
| 28/11/2019 | 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) |

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| 28/11/2019 | Periodic safety update single assessment: Cabergoline: CMDh Scientific conclusions and grounds for variation, amendments to the Product Information and timetable for the implementation - PSUSA/00000477/20190 |
| 28/11/2019 | Periodic safety update single assessment: Cabergoline: List of nationally authorised medicinal products - PSUSA/00000477/201903 |
| 28/11/2019 | Human medicines European public assessment report (EPAR): Cyramza, Ramucirumab, Stomach Neoplasms, 19/12/2014, 10, Authorised (updated) |
| 28/11/2019 | Human medicines European public assessment report (EPAR): Fotivda, tivozanib, Carcinoma, Renal Cell, 24/08/2017, 4, Authorised (updated) |
| 28/11/2019 | Human medicines European public assessment report (EPAR): Zeffix, lamivudine, Hepatitis B, Chronic, 28/07/1999, 24, Authorised (updated) |
| 28/11/2019 | Human medicines European public assessment report (EPAR): Toviaz, fesoterodine fumarate, Urinary Bladder, Overactive, 20/04/2007, 23, Authorised (updated) |
| 28/11/2019 | Human medicines European public assessment report (EPAR): Rixathon, rituximab, Lymphoma, Non-Hodgkin, Arthritis, Rheumatoid, Leukemia, Lymphocytic, Chronic, B-Cell, Wegener Granulomatosis, Microscopic Polyangiitis, Pemphigus, 15/06/2017, 3, Authorised (updated) |
| 28/11/2019 | Human medicines European public assessment report (EPAR): Somavert, Pegvisomant, Acromegaly, 12/11/2002, 21, Authorised (updated) |
| 28/11/2019 | Human medicines European public assessment report (EPAR): Dynastat, parecoxib sodium, Pain, Postoperative, 22/03/2002, 29, Authorised (updated) |
| 27/11/2019 | Human medicines European public assessment report (EPAR): Crysvita, Burosumab, Hypophosphatemia, Familial, Hypophosphatemic Rickets, X-Linked Dominant, 19/02/2018, 2, Authorised (updated) |
| 27/11/2019 | Veterinary medicines European public assessment report (EPAR): Nexgard Spectra, afoxolaner, milbemycin oxime, 14/01/2015, 6, Authorised (updated) |
| 27/11/2019 | Human medicines European public assessment report (EPAR): Champix, varenicline, Tobacco Use Cessation, 25/09/2006, 36, Authorised (updated) |
| 27/11/2019 | Human medicines European public assessment report (EPAR): Atriance, nelarabine, Precursor T-Cell Lymphoblastic Leukemia-Lymphoma, 22/08/2007, 21, Authorised (updated) |
| 27/11/2019 | Orphan designation: trabectedin for the: Treatment of ovarian cancer, 17/10/2003, Expired (updated) |
| 27/11/2019 | Human medicines European public assessment report (EPAR): Repatha, Evolocumab, Dyslipidemias, Hypercholesterolemia, 17/07/2015, 12, Authorised (updated) |
| 27/11/2019 | Human medicines European public assessment report (EPAR): Vaborem, meropenem trihydrate, vaborbactam, Urinary Tract Infections, Bacteremia, Bacterial Infections, Respiratory Tract Infections, Pneumonia, Pneumonia, Ventilator-Associated, 20/11/2018, 3, Authorised (updated) |
| 27/11/2019 | Big data (updated) |
| 27/11/2019 | Report: Dashboard created for visual representation of the scoring of the included data sources |
| 27/11/2019 | Report: Inventory of registries |
| 27/11/2019 | Report: Bioanalytical Omics - Subgroup report |
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| 27/11/2019 | Human medicines European public assessment report (EPAR): Ifirmasta (previously Irbesartan Krka), irbesartan hydrochloride, Hypertension, 01/12/2008, 11, Authorised (updated) |

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| 27/11/2019 | Human medicines European public assessment report (EPAR): Ritonavir Mylan, ritonavir, HIV Infections, 09/11/2017, 5, Authorised (updated) |
| 27/11/2019 | Maximum Residue Limits - Report: Toltrazuril: Summary Report (1) – Committee for Veterinary Medicinal Products (updated) |
| 27/11/2019 | Veterinary medicines European public assessment report (EPAR): Suvaxyn CSF Marker, live Recombinant E2 gene deleted Bovine Viral Diarrhoea Virus containing Classical Swine Fever E2 (CP7_E2alf), 10/02/2015, 3, Authorised (updated) |
| 27/11/2019 | Veterinary medicines European public assessment report (EPAR): Bovela, modified live bovine viral diarrhoea virus type 1, non-cytopathic parent strain KE-9 and modified live bovine viral diarrhoea virus type 2, non-cytopathic parent strain NY-93, 22/12/2014, 4, Authorised (updated) |
| 27/11/2019 | Human medicines European public assessment report (EPAR): Xalkori, crizotinib, Carcinoma, Non-Small-Cell Lung, 23/10/2012, 26, Authorised (updated) |
| 27/11/2019 | Human medicines European public assessment report (EPAR): Apealea, paclitaxel, Ovarian Neoplasms, 20/11/2018, 2, Authorised (updated) |
| 27/11/2019 | Leaflet: Ebola vaccine development 2014-2019 (updated) |
| 27/11/2019 | Human medicines European public assessment report (EPAR): Elaprase, idursulfase, Mucopolysaccharidosis II, 08/01/2007, 19, Authorised (updated) |
| 27/11/2019 | Other: HMPC: overview of assessment work - priority list (updated) |
| 27/11/2019 | Template or form: EudraVigilance user declaration for qualified person for pharmacovigilance/responsible person for EudraVigilance and trusted deputy (updated) |
| 27/11/2019 | Human medicines European public assessment report (EPAR): CoAprovel, irbesartan, hydrochlorothiazide, Hypertension, 14/10/1998, 37, Authorised (updated) |
| 27/11/2019 | Annex to CHMP highlights: Scientific advice and protocol assistance adopted during the CHMP meeting 11-14 November 2019 |
| 27/11/2019 | Human medicines European public assessment report (EPAR): Revatio, sildenafil, Hypertension, Pulmonary, 28/10/2005, 38, Authorised (updated) |
| 27/11/2019 | Veterinary medicines European public assessment report (EPAR): Broadline, eprinomectin, fipronil, praziquantel, (S)-methoprene, 04/12/2013, 8, Authorised (updated) |
| 27/11/2019 | Human medicines European public assessment report (EPAR): Sutent, sunitinib, Gastrointestinal Stromal Tumors, Carcinoma, Renal Cell, Neuroendocrine Tumors, 19/07/2006, 38, Authorised (updated) |
| 27/11/2019 | List of medicines under additional monitoring (updated) |
| 27/11/2019 | Medicines under additional monitoring: Annex XII - List of Dexamed and associated names (dexamfetamine sulphate-containing medicinal products) in the European Union (updated) |
| 27/11/2019 | Medicines under additional monitoring: Annex VII - List of Targocid and associated names (teicoplanin-containing medicinal products in the EU) (updated) |
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| 26/11/2019 | Human medicines European public assessment report (EPAR): Deferiprone Lipomed, Deferiprone, Iron Overload, beta-Thalassemia, 19/09/2018, 1, Authorised (updated) |
| 26/11/2019 | Periodic safety update single assessment: Levothyroxine : List of nationally authorised medicinal products - PSUSA/00001860/201901 |
| 26/11/2019 | Periodic safety update single assessment: Levothyroxine : CMDh Scientific conclusions and grounds for variation, amendments to the product information and timetable for the implementation - PSUSA/00001860/201901 |
| 26/11/2019 | Human medicines European public assessment report (EPAR): Enbrel, etanercept, Spondylitis, Ankylosing, Arthritis, Juvenile Rheumatoid, Arthritis, Psoriatic, Psoriasis, Arthritis, Rheumatoid, 02/02/2000, 60, Authorised (updated) |
| 26/11/2019 | Human medicines European public assessment report (EPAR): Capecitabine Medac, capecitabine, Colorectal Neoplasms, 19/11/2012, 9, Authorised (updated) |
| 26/11/2019 | Human medicines European public assessment report (EPAR): Tandemact, pioglitazone, glimepiride, Diabetes Mellitus, Type 2, 08/01/2007, 17, Authorised (updated) |
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| 26/11/2019 | Human medicines European public assessment report (EPAR): Arsenic trioxide Accord, Arsenic trioxide, Leukemia, Promyelocytic, Acute, 14/11/2019, Authorised |
| 26/11/2019 | Human medicines European public assessment report (EPAR): Ebymect, dapagliflozin propanediol monohydrate, metformin hydrochloride, Diabetes Mellitus, Type 2, 15/11/2015, 12, Authorised (updated) |
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| 26/11/2019 | Human medicines European public assessment report (EPAR): Segluromet, ertugliflozin l-pyroglutamic acid / metformin hydrochloride, Diabetes Mellitus, Type 2, 23/03/2018, 3, Authorised (updated) |
| 26/11/2019 | Human medicines European public assessment report (EPAR): Trisenox, Arsenic trioxide, Leukemia, Promyelocytic, Acute, 05/03/2002, 27, Authorised (updated) |
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| 26/11/2019 | Human medicines European public assessment report (EPAR): Xigduo, metformin hydrochloride, dapagliflozin propanediol monohydrate, Diabetes Mellitus, Type 2, 16/01/2014, 15, Authorised (updated) |
| 26/11/2019 | Human medicines European public assessment report (EPAR): Forxiga, dapagliflozin propanediol monohydrate, Diabetes Mellitus, Type 2, Diabetes Mellitus, Type 1, 11/11/2012, 16, Authorised (updated) |
| 26/11/2019 | Multi-stakeholder workshop on draft 'Regulatory Science to 2025' strategy (stakeholders for human medicines) , European Medicines Agency, Amsterdam, the Netherlands, from 18/11/2019 to 19/11/2019 (updated) |
| 26/11/2019 | Annual Patients and Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) meeting with all eligible organisations , European Medicines Agency, Amsterdam, the Netherlands, from 20/11/2019 to 20/11/2019 (updated) |
| 26/11/2019 | Other: European Medicines Agency second response to European Ombudsman regarding pre-submission activities |
| 26/11/2019 | Pre-authorisation guidance (updated) |
| 26/11/2019 | Regulatory and procedural guideline: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure (updated) |

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| 26/11/2019 | Regulatory and procedural guideline: European Medicines Agency pre-authorisation procedural advice for users of the centralised procedure: document with tracked changes (updated) |
| 26/11/2019 | Agenda: Agenda - Annual Patients and Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) meeting with all eligible organisations (updated) |
| 26/11/2019 | Other: List of participants - Annual Patients and Consumers Working Party (PCWP) and Healthcare Professionals Working Party (HCPWP) meeting with all eligible organisations |
| 26/11/2019 | Human medicines European public assessment report (EPAR): Elonva, corifollitropin alfa, Reproductive Techniques, Assisted, Ovulation Induction, 25/01/2010, 15, Authorised (updated) |
| 26/11/2019 | Implementation of the new Veterinary Medicines Regulation (updated) |
| 25/11/2019 | Human medicines European public assessment report (EPAR): Votrient, pazopanib, Carcinoma, Renal Cell, 14/06/2010, 22, Authorised (updated) |
| 25/11/2019 | Veterinary medicines European public assessment report (EPAR): Cepedex, dexmedetomidine hydrochloride, 13/12/2016, 3, Authorised (updated) |
| 25/11/2019 | Orphan designation: (S)-3-(1-(9H-purin-6-ylamino)ethyl)-8-chloro-2-phenylisoquinolin-1(2H)-one for the: Treatment of follicular lymphoma, 17/07/2013, Positive (updated) |
| 25/11/2019 | Orphan designation: (S)-3-(1-(9H-purin-6-ylamino)ethyl)-8-chloro-2-phenylisoquinolin-1(2H)-one (duvelisib) for the: Treatment of chronic lymphocytic leukaemia / small lymphocytic lymphoma, 26/04/2013, Positive (updated) |
| 25/11/2019 | Human medicines European public assessment report (EPAR): Pifeltro, Doravirine, HIV Infections, 22/11/2018, 3, Authorised (updated) |
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| 25/11/2019 | Human medicines European public assessment report (EPAR): Steglatro, ertugliflozin l-pyroglutamic acid, Diabetes Mellitus, Type 2, 21/03/2018, 5, Authorised (updated) |
| 25/11/2019 | Human medicines European public assessment report (EPAR): Oncaspar, pegaspargase, Precursor Cell Lymphoblastic Leukemia-Lymphoma, 14/01/2016, , 9, Authorised (updated) |
| 25/11/2019 | Human medicines European public assessment report (EPAR): Exjade, deferasirox, beta-Thalassemia, Iron Overload, 28/08/2006, 43, Authorised (updated) |
| 25/11/2019 | Human medicines European public assessment report (EPAR): Viagra, sildenafil, Erectile Dysfunction, 13/09/1998, 34, Authorised (updated) |
| 25/11/2019 | Human medicines European public assessment report (EPAR): Ifirmacombi, irbesartan, hydrochlorothiazide, Hypertension, 04/03/2011, 10, Authorised (updated) |
| 25/11/2019 | Human medicines European public assessment report (EPAR): Duloxetine Zentiva, duloxetine, Anxiety Disorders, Depressive Disorder, Major, Neuralgia, Diabetes Mellitus, 20/08/2015, 4, Authorised (updated) |
| 25/11/2019 | Human medicines European public assessment report (EPAR): Steglujan, ertugliflozin l-pyroglutamic acid, sitagliptin phosphate monohydrate, Diabetes Mellitus, Type 2, 23/03/2018, 6, Authorised (updated) |
| 25/11/2019 | Human medicines European public assessment report (EPAR): Dexdor, dexmedetomidine hydrochloride, Conscious Sedation, 15/09/2011, 11, Authorised (updated) |
| 25/11/2019 | Human medicines European public assessment report (EPAR): Besponsa, inotuzumab ozogamicin, Precursor Cell Lymphoblastic Leukemia-Lymphoma, 28/06/2017, 5, Authorised (updated) |
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| 25/11/2019 | Human medicines European public assessment report (EPAR): Bortezomib Fresenius Kabi, bortezomib, Multiple Myeloma, 14/11/2019, Authorised |
| 25/11/2019 | Periodic safety update single assessment: Dorzolamide: List of nationally authorised medicinal products - PSUSA/00003168/201902 |
| 25/11/2019 | Periodic safety update single assessment: Dorzolamide: CMDh Scientific conclusions and grounds for variation, amendments to the product information and timetable for the implementation - PSUSA/00003168/201902 |
| 25/11/2019 | Regulatory and procedural guideline: Advice on implementing measures under Article 37(4) of Regulation (EU) 2019/6 on veterinary medicinal products – Criteria for the designation of antimicrobials to be reserved for treatment of certain infections in humans |

**NOTICE TO APPLICANTS**

28 November 2019

Informed consent and patient recruitment procedure template (Eudralex Volume 10 - Clinical trials guidelines - Set of documents applicable to clinical trials under Regulation EU No 536/2014)

Draft Questions and Answers Document (Version 2.3) (Eudralex Volume 10 - Clinical trials guidelines - Set of documents applicable to clinical trials under Regulation EU No 536/2014)

**BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)**

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| 02.12.2019 | Rote-Hand-Brief zu ▼Increlex® (Mecasermin): Risiko für gutartige und bösartige Neoplasien<br><br>Wirkstoff Mecasermin<br><br>Die Firma Ipsen Pharma informiert über Fälle von gutartigen und bösartigen Neoplasien bei Kindern und Jugendlichen, die nach Markteinführung von Mecasermin mit Increlex® behandelt wurden. |
| 25.11.2019 | Methotrexat: Dosierungsfehler<br><br>Wirkstoff Methotrexat<br><br>Neue Maßnahmen zur Vermeidung potenziell tödlicher Dosierungsfehler mit Methotrexat bei entzündlichen Erkrankungen. |
| 25.11.2019 | Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/410149/2019 vom 25.07.2019 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Eisenpräparate parenteral (außer Eisen(III)-hydroxid-Dextran-Komplex (Eisen-Dextran))<br><br>Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Eisenpräparate parenteral (außer Eisen(III)-hydroxid-Dextran-Komplex (Eisen-Dextran)) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG. |
| 25.11.2019 | Umsetzung des einstimmigen Beschlusses der Koordinierungsgruppe EMA/CMDh/489617/2018 vom 20.08.2018 betreffend die Zulassungen für Humanarzneimittel mit dem Wirkstoff Eisenpräparate parenteral (einschließlich Eisen(III)-hydroxid-Dextran-Komplex (Eisen-Dextran))<br>Das BfArM veröffentlicht den Umsetzungsbescheid für den Wirkstoff Eisenpräparate parenteral (einschließlich Eisen(III)-hydroxid-Dextran-Komplex |

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| | (Eisen-Dextran)) infolge des Europäischen PSUR Single Assessment Verfahrens nach Artikel 107d) bis g) der Richtlinie 2001/83/EG. |
| 25.11.2019 | Rote-Hand-Brief zu Methotrexat: Neue Maßnahmen zur Vermeidung von Dosierungsfehlern mit potenziell tödlichen Folgen bei der Anwendung von Methotrexat bei Autoimmunerkrankungen<br><br>Wirkstoff Methotrexat<br><br>Die Zulassungsinhaber methotrexathaltiger Arzneimittel informieren über neue Maßnahmen zur Vermeidung von Dosierungsfehlern mit potenziell tödlichen Folgen. |

## BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since October 15th 2019.

## PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since November 15 th 2019.

## PHARMEUROPA TEXTS FOR COMMENT

No updates since October 7th 2019.