TABLE OF CONTENTS

HEADS OF AGENCIES – CMDh

13 September

NEW - 13-14 September CMDh Agenda

HEADS OF AGENCIES – PAEDIATRIC REGULATION

Article 45 work-sharing: *click here*

EUROPEAN MEDICINES AGENCY (EMA)

19/09/2022	Agenda: Agenda - HMPC agenda of the 19-21 September 2022 meeting
19/09/2022	Human medicines European public assessment report (EPAR): Dupixent, dupilumab, Dermatitis, Atopic, 26/09/2017, 17, Authorised (updated)
19/09/2022	Human medicines European public assessment report (EPAR): Benepali, etanercept, Arthritis, Psoriatic; Arthritis, Rheumatoid; Psoriasis, 13/01/2016, 16, Authorised (updated)
19/09/2022	Minutes: Minutes - PDCO minutes of the 22-25 March 2022 meeting (updated)
19/09/2022	Agenda: Agenda - PDCO agenda of the 19-22 April 2022 meeting (updated)
19/09/2022	Minutes: Minutes - PDCO minutes of the 22-25 February 2022 meeting (updated)
19/09/2022	Human medicines European public assessment report (EPAR): Nepexto, etanercept, Arthritis, Rheumatoid; Arthritis, Juvenile Rheumatoid; Arthritis, Psoriatic; Spondylarthropathies; Spondylitis, Ankylosing; Psoriasis, 20/05/2020, 7, Authorised (updated)
19/09/2022	Human medicines European public assessment report (EPAR): Spikevax (previously COVID-19 Vaccine Moderna), CX-024414 (single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2), COVID-19 virus infection, 06/01/2021, 29, Authorised (updated)
16/09/2022	Orphan designation: allogenic cytomegalovirus-specific cytotoxic T lymphocytes (adimlecleucel) for the: Treatment of cytomegalovirus infection in patients with impaired cell-mediated immunity, 18/11/2016, Withdrawn (updated)
16/09/2022	Scientific publications (updated)

16/09/2022	Orphan designation: Allogeneic CD34+ cells expanded ex vivo with an aryl hydrocarbon receptor antagonist (spanlecortemlocel) for the: Treatment of acute lymphoblastic leukaemia, 16/12/2014, Withdrawn (updated)
16/09/2022	Orphan designation: Autologous CD34+ cells transduced ex vivo with a lentiviral vector containing a modified gamma-globin gene for the: Treatment of sickle cell disease, 13/11/2020, Withdrawn (updated)
16/09/2022	Human medicines European public assessment report (EPAR): Intelence, Etravirine, HIV Infections, 28/08/2008, 29, Authorised (updated)
16/09/2022	Organisation Management System (OMS) Trouble Shooting Session for CTIS users - September 2022 , from 22/09/2022 to 22/09/2022 (updated)
16/09/2022	Other: Questions and answers on labelling flexibilities for COVID-19 vaccines (updated)
16/09/2022	Procurement (updated)
16/09/2022	Orphan designation: Self-complementary adeno-associated viral vector serotype 9 containing the SGSH gene for the: Treatment of mucopolysaccharidosis, type IIIA (Sanfilippo A syndrome), 20/09/2016, Positive (updated)
16/09/2022	Human medicines European public assessment report (EPAR): Instanyl, Fentanyl citrate, Pain; Cancer, 20/07/2009, 33, Authorised (updated)
16/09/2022	News and press releases: Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 12-15 September 2022
16/09/2022	Summary of opinion: Enjaymo, sutimlimab, 15/09/2022, Positive
16/09/2022	Summary of opinion: Pyrukynd, mitapivat, 15/09/2022, Positive
16/09/2022	Summary of opinion: Melatonin Neurim, melatonin, 15/09/2022, Positive
16/09/2022	CHMP opinions on consultation procedures (updated)
16/09/2022	Other: Floseal haemostatic matrix (Floseal VH S/D) - Procedural steps and scientific information after initial consultation (updated)
16/09/2022	Summary of opinion: Xalkori, crizotinib, 15/09/2022, Positive
16/09/2022	Summary of opinion: Adtralza, tralokinumab, 15/09/2022, Positive
16/09/2022	Summary of opinion: Zynlonta , loncastuximab tesirine, 15/09/2022, Positive
16/09/2022	Summary of opinion: Exparel liposomal, bupivacaine, 15/09/2022, Positive
16/09/2022	Summary of opinion: Teriflunomide Accord, teriflunomide, 15/09/2022, Positive
16/09/2022	Summary of opinion: Livtencity, maribavir, 15/09/2022, Positive
16/09/2022	Summary of opinion: Teriparatide Sun, teriparatide, 15/09/2022, Positive
16/09/2022	Summary of opinion: Vaxneuvance, pneumococcal polysaccharide conjugate vaccine (adsorbed), 15/09/2022, Positive
16/09/2022	Summary of opinion: Yescarta, axicabtagene ciloleucel, 15/09/2022, Positive
16/09/2022	Summary of opinion: Skyrizi, risankizumab, 15/09/2022, Positive
16/09/2022	News and press releases: New medicine to protect babies and infants from respiratory syncytial virus (RSV) infection
16/09/2022	Referral: Synchron , Article 31 referrals, Opinion provided by Committee for Medicinal Products for Human Use, 19/05/2022, 16/09/2022 (updated)
16/09/2022	Summary of opinion: Ximluci, ranibizumab, 15/09/2022, Positive
16/09/2022	Summary of opinion: Mycapssa, octreotide, 15/09/2022, Positive
16/09/2022	Summary of opinion: Sorafenib Accord , sorafenib, 15/09/2022, Positive
16/09/2022	Summary of opinion: Biktarvy, bictegravir, emtricitabine, tenofovir alafenamide, 15/09/2022, Positive
16/09/2022	Summary of opinion: Brukinsa, zanubrutinib, 15/09/2022, Positive
16/09/2022	Summary of opinion: Teriflunomide Mylan, teriflunomide, 15/09/2022, Positive
16/09/2022	Summary of opinion: Revolade, eltrombopag, 15/09/2022, Positive
16/09/2022	Summary of opinion: Beyfortus, nirsevimab, 15/09/2022, Positive
16/09/2022	Summary of opinion: Evusheld, tixagevimab, cilgavimab, 15/09/2022, Positive

16/09/2022	Summary of opinion: Veklury, remdesivir, 15/09/2022, Positive
16/09/2022	Human medicines European public assessment report (EPAR): Vpriv, velaglucerase alfa, Gaucher Disease, 26/08/2010, 18, Authorised (updated)
16/09/2022	Other: Decision of the Management Board on amending budget No. 01, amending appropriations in budget 2022
16/09/2022	Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) , Online, 10:00 - 11:00 Amsterdam time (CEST), from 02/09/2022 to 02/09/2022 (updated)
16/09/2022	Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) , Online, 15:00 - 16:00 Amsterdam time (CEST), from 25/07/2022 to 25/07/2022 (updated)
16/09/2022	News and press releases: EMA recommends standard marketing authorisations for Comirnaty and Spikevax COVID-19 vaccines
16/09/2022	Ad-hoc meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) , Online, 10:30-12:30 Amsterdam time (CEST), from 07/07/2022 to 07/07/2022 (updated)
16/09/2022	Clinical Trials Information System (CTIS) Webinar - 9 months on and going forward , Online, 13:30 - 17:30 Amsterdam time (CET), from 16/11/2022 to 16/11/2022 (updated)
16/09/2022	Regulatory and procedural guideline: Substances considered as not falling within the scope of Regulation (EC) No. 470/2009, with regard to residues of veterinary medicinal products in foodstuffs of animal origin (updated)
16/09/2022	Antimicrobial-resistance surveillance as post-marketing authorisation commitment (updated)
16/09/2022	Scientific guideline: Concept paper on a guideline on data requirements for post-authorisation studies for antimicrobial veterinary medicinal products under Article 36(2) of Regulation (EU) 2019/6
16/09/2022	Minutes: Minutes of the CVMP meeting of 12-14 July 2022
16/09/2022	Human medicines European public assessment report (EPAR): Kaletra, lopinavir, ritonavir, HIV Infections, 19/03/2001, 59, Authorised (updated)
15/09/2022	Human medicines European public assessment report (EPAR): Tenofovir disoproxil Zentiva, tenofovir disoproxil phosphate, HIV Infections, 15/09/2016, 12, Authorised (updated)
15/09/2022	European Medicines Agency (EMA) Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) Working Parties joint meeting , European Medicines Agency, Amsterdam, the Netherlands, from 22/09/2022 to 22/09/2022 (updated)
15/09/2022	Human medicines European public assessment report (EPAR): Sialanar, glycopyrronium bromide, Sialorrhea, 15/09/2016, 9, Authorised (updated)
15/09/2022	Regulatory and procedural guideline: Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) dataload friendly file including deprecated terms (updated)
15/09/2022	Regulatory and procedural guideline: List of changes to combined Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) list of clinical terms for reporting suspected adverse reactions in animal and humans to veterinary medicinal products (updated)
15/09/2022	Regulatory and procedural guideline: Combined Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (updated)
15/09/2022	Regulatory and procedural guideline: Combined Veterinary Dictionary for Drug Regulatory Activities (VeDDRA) list of clinical terms for reporting suspected adverse reactions in animals and humans to veterinary medicinal products (Excel) (updated)

15/09/2022	Quarterly system demo - Q3 2022 , Online, 09:00 - 12:30 Amsterdam time (CEST), from 28/09/2022 to 28/09/2022 (updated)
15/09/2022	Orphan designation: Sodium (4Z,7Z,10R,11E,13E,15Z,17S,19Z)10,17-dihydroxy-docosa-4,7,11,13,15,19-hexaenoate for the: Prevention of retinopathy of prematurity, 21/06/2022, Positive
15/09/2022	Orphan designation: Pirfenidone for the: Treatment of idiopathic pulmonary fibrosis, 24/06/2022, Positive
15/09/2022	Orphan designation: 4-[[(3S)-1-benzylpyrrolidin-3-yl]-methylamino]-2-fluoro-5-methyl-N-(1,3-thiazol-4-yl)benzenesulfonamide for the: Treatment of SCN8A developmental and epileptic encephalopathy, 21/06/2022, Positive
15/09/2022	Webinar on requesting access to and using EMA's substance, product, organisation and referential (SPOR) application programming interface (API) , Online, 14:00 - 16:00 Amsterdam time (CEST), from 11/10/2022 to 11/10/2022 (updated)
15/09/2022	Orphan designation: 3-(1-(2',3'-dimethoxy-[1,1'-biphenyl]-4-yl)-1H-1,2,3-triazol-4-yl)benzoic acid for the: Treatment of gain-of-function mutations of STIM1 and ORAI1 related diseases, 21/06/2022, Positive
15/09/2022	Orphan designation: ropeginterferon alfa-2b for the: Treatment of chronic myeloid leukaemia, 21/06/2022, Positive
15/09/2022	Orphan designation: amitriptyline for the: Treatment of erythromelalgia, 21/06/2022, Positive
15/09/2022	Human medicines European public assessment report (EPAR): Yellox, bromfenac sodium sesquihydrate, Pain, Postoperative; Ophthalmologic Surgical Procedures, 18/05/2011, 11, Authorised (updated)
15/09/2022	Orphan designation: Allogeneic human dendritic cells derived from a CD34+ progenitor cell line for the: Treatment of acute myeloid leukaemia, 22/05/2012, Positive (updated)
15/09/2022	Orphan designation: Allogeneic faecal microbiota, pooled for the: Treatment of graft-versus-host disease, 19/11/2018, Positive (updated)
15/09/2022	Orphan designation: Sebetralstat for the: Treatment of hereditary angioedema, 21/06/2022, Positive
15/09/2022	Orphan designation: Doxorubicin for the: Treatment of soft tissue sarcoma, 21/06/2022, Positive
15/09/2022	Orphan designation: losartan for the: Treatment of osteogenesis imperfecta, 21/06/2022, Positive
15/09/2022	Multi-stakeholder workshop: Patient experience data in medicines development and regulatory decision-making , European Medicines Agency, Amsterdam, the Netherlands, from 21/09/2022 to 21/09/2022 (updated)
15/09/2022	Orphan designation: Escherichia coli, strain Nissle 1917, expressing high affinity phenylalanine transporter, phenylalanine ammonia lyase and L-amino acid deaminase for the: Treatment of hyperphenylalaninaemia, 21/06/2022, Positive
15/09/2022	Opinion on medicine for use outside EU: Dapivirine Vaginal Ring 25 mg, dapivirine, Anti-HIV Agents, 23/07/2020, Positive opinion (updated)
15/09/2022	Human medicines European public assessment report (EPAR): Juluca, dolutegravir sodium, rilpivirine hydrochloride, HIV Infections, 16/05/2018, 12, Authorised (updated)
14/09/2022	Human medicines European public assessment report (EPAR): Symtuza, darunavir, cobicistat, emtricitabine, tenofovir alafenamide, HIV Infections, 21/09/2017, 15, Authorised (updated)
14/09/2022	Human medicines European public assessment report (EPAR): Tivicay, dolutegravir, HIV Infections, 16/01/2014, 31, Authorised (updated)

14/09/2022	Human medicines European public assessment report (EPAR): Triumeq, dolutegravir sodium, lamivudine, abacavir (as sulfate), HIV Infections, 31/08/2014, 29, Authorised (updated)
14/09/2022	COVID-19 vaccines: key facts (updated)
14/09/2022	Human medicines European public assessment report (EPAR): Efavirenz/Emtricitabine/Tenofovir disoproxil Mylan, efavirenz, emtricitabine, tenofovir disoproxil maleate, HIV Infections, 05/09/2017, 13, Authorised (updated)
14/09/2022	Orphan designation: budesonide for the: Treatment of primary IgA nephropathy, 18/11/2016, Positive (updated)
14/09/2022	EMA regular press briefing on COVID-19 and monkeypox , Online, 14:00 - 14:30 Amsterdam time (CEST), from 20/09/2022 to 20/09/2022
14/09/2022	Orphan designation: 17α,21-Dihydroxy-16α-methyl-pregna-1,4,9(11)-triene-3,20-dione (vamorolone) for the: Treatment of Duchenne muscular dystrophy, 22/08/2014, Positive (updated)
14/09/2022	Orphan designation: Modified mRNA encoding the UGT1A1 protein for the: Treatment of Crigler-Najjar syndrome, 27/06/2016, Positive (updated)
14/09/2022	Referral: Veterinary medicinal products containing N-methyl pyrrolidone as an excipient , Article 82, Under evaluation, 11/05/2022, 14/09/2022 (updated)
14/09/2022	Orphan designation: Radio-iodinated (131I) anti-CD45 murine monoclonal antibody for the: Treatment in haematopoietic stem cell transplantation, 14/10/2016, Positive (updated)
14/09/2022	Opinion/decision on a Paediatric investigation plan (PIP): abelacimab, P: decision agreeing on a investigation plan, with or without partial waiver(s) and or deferral(s), P/0127/2022
14/09/2022	Opinion/decision on a Paediatric investigation plan (PIP): Giroctocogene fitelparvovec, P: decision agreeing on a investigation plan, with or without partial waiver(s) and or deferral(s), P/0332/2021 (updated)
14/09/2022	Opinion/decision on a Paediatric investigation plan (PIP): cenobamate, P: decision agreeing on a investigation plan, with or without partial waiver(s) and or deferral(s), P/0300/2021 (updated)
14/09/2022	Opinion/decision on a Paediatric investigation plan (PIP): Lebrikizumab, P: decision agreeing on a investigation plan, with or without partial waiver(s) and or deferral(s), P/0286/2021 (updated)
14/09/2022	Opinion/decision on a Paediatric investigation plan (PIP): Phenobarbital, P: decision agreeing on a investigation plan, with or without partial waiver(s) and or deferral(s), P/0301/2021 (updated)
14/09/2022	Opinion/decision on a Paediatric investigation plan (PIP): PEGylated-fibroblast growth factor 21 (BMS-986036), PM: decision on the application for modification of an agreed PIP, P/0346/2021 (updated)
14/09/2022	Human medicines European public assessment report (EPAR): PritorPlus, telmisartan, hydrochlorothiazide, Hypertension, 22/04/2002, 37, Authorised (updated)
14/09/2022	Human medicines European public assessment report (EPAR): MicardisPlus, telmisartan, hydrochlorothiazide, Hypertension, 19/04/2002, 32, Authorised (updated)
14/09/2022	Human medicines European public assessment report (EPAR): Kinzalkomb, telmisartan, hydrochlorothiazide, Hypertension, 19/04/2002, 39, Authorised (updated)
13/09/2022	Human medicines European public assessment report (EPAR): Lynparza, Olaparib, Ovarian Neoplasms, 16/12/2014, 18, Authorised (updated)
13/09/2022	Human medicines European public assessment report (EPAR): Jyseleca, filgotinib maleate, Arthritis, Rheumatoid, 24/09/2020, 7, Authorised (updated)

13/09/2022	Human medicines European public assessment report (EPAR): Tysabri, natalizumab, Multiple Sclerosis, 27/06/2006, 40, Authorised (updated)
13/09/2022	Fifth European Medicines Agency - Medicines for Europe bilateral meeting , Virtual meeting, from 15/09/2022 to 15/09/2022
13/09/2022	Agenda: Agenda - Fifth EMA-Medicines for Europe bilateral meeting
13/09/2022	Clinical Trials Information System (CTIS) bitesize talk: Notifications - Part 2 , Online, 14:30 - 16:00 Amsterdam time (CEST), from 23/11/2022 to 23/11/2022 (updated)
13/09/2022	Other: Clinical Trials Information System (CTIS) common features - CTIS Training Programme - Module 02 (updated)
13/09/2022	Other: CTIS Training materials - Latest updates (updated)
13/09/2022	Human medicines European public assessment report (EPAR): Nuvaxovid, SARS-CoV-2 recombinant spike protein, COVID-19 virus infection, 20/12/2021, 4, Authorised (updated)
13/09/2022	Human medicines European public assessment report (EPAR): Quviviq, daridorexant hydrochloride, Sleep Initiation and Maintenance Disorders, 29/04/2022, 2, Authorised (updated)
13/09/2022	Human medicines European public assessment report (EPAR): Pregabalin Mylan, pregabalin, Anxiety Disorders; Epilepsy, 24/06/2015, 14, Authorised (updated)
13/09/2022	Human medicines European public assessment report (EPAR): Comirnaty, Single-stranded, 5'-capped messenger RNA produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2, COVID-19 virus infection, 21/12/2020, 29, Authorised (updated)
13/09/2022	Opinion/decision on a Paediatric investigation plan (PIP): Sivopixant, W: decision granting a waiver in all age groups for all conditions or indications, P/0326/2021
13/09/2022	Opinion/decision on a Paediatric investigation plan (PIP): Gemcitabine (hydrochloride), W: decision granting a waiver in all age groups for all conditions or indications, P/0288/2021
13/09/2022	Opinion/decision on a Paediatric investigation plan (PIP): Cetrelimab, W: decision granting a waiver in all age groups for all conditions or indications, P/0289/2021
13/09/2022	Eight industry stakeholder platform on research and development support , Online, from 11/07/2022 to 11/07/2022 (updated)
13/09/2022	Human medicines European public assessment report (EPAR): COVID-19 Vaccine (inactivated, adjuvanted) Valneva, SARS-CoV-2 virus (inactivated) Wuhan strain hCoV-19 / Italy / INMI1-isl / 2020, COVID-19 virus infection, 24/06/2022, 2, Authorised (updated)
13/09/2022	Human medicines European public assessment report (EPAR): Aripiprazole Mylan Pharma (previously Aripiprazole Pharmathen), aripiprazole, Schizophrenia; Bipolar Disorder, 30/06/2015, 14, Authorised (updated)
12/09/2022	Human medicines European public assessment report (EPAR): Cinacalcet Mylan, cinacalcet hydrochloride, Hyperparathyroidism, Secondary; Hypercalcemia, 19/11/2015, 14, Authorised (updated)
12/09/2022	Protection of personal data and commercially confidential information (CCI) for documents uploaded and published in the Clinical Trials Information System (CTIS): Workshop on draft guidance , Online, 10:00-17:00 Amsterdam time (CEST), from 14/07/2022 to 14/07/2022 (updated)
12/09/2022	Opinion/decision on a Paediatric investigation plan (PIP): Ramipril,amlodipine,hydrochlorothiazide, W: decision granting a waiver in all age groups for all conditions or indications, P/0297/2021

12/09/2022	Human medicines European public assessment report (EPAR): Libmeldy, atidarsagene autotemcel, Leukodystrophy, Metachromatic, 17/12/2020, 5, Authorised (updated)
12/09/2022	Annex to the European Commission guideline on 'Excipients in the labelling and package leaflet of medicinal products for human use' (updated)
12/09/2022	Opinion/decision on a Paediatric investigation plan (PIP): Immunoglobulin G1 anti-SORT1 human monoclonal antibody, W: decision granting a waiver in all age groups for all conditions or indications, P/0299/2021
12/09/2022	News and press releases: Adapted vaccine targeting BA.4 and BA.5 Omicron variants and original SARS-CoV-2 recommended for approval
12/09/2022	Meeting of the Executive Steering Group on Shortages and Safety of Medicinal Products (MSSG) , Online, 09:00 - 11:15 Amsterdam time (CEST), from 14/09/2022 to 14/09/2022
12/09/2022	Union Product Database: release notes (updated)
12/09/2022	Other: Example files - production release version 1.6.8 September 2022 - Veterinary Medicinal Products Regulation: Union Product Database
12/09/2022	Other: Release notes - production release version 1.6.8 September 2022 - Veterinary Medicinal Products Regulation: Union Product Database
12/09/2022	Orphan designation: Efgartigimod alfa for the: Treatment of myasthenia gravis, 10/08/2022, Positive (updated)
12/09/2022	Opinion/decision on a Paediatric investigation plan (PIP): gabapentin, W: decision granting a waiver in all age groups for all conditions or indications, P/0335/2021
12/09/2022	Opinion/decision on a Paediatric investigation plan (PIP): Insulin icodec,semaglutide, W: decision granting a waiver in all age groups for all conditions or indications, P/0312/2021
12/09/2022	PIP decision: P/0344/2021 : EMA decision of 12 August 2021 on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for epcoritamab (EMEA-002907-PIP01-20)
12/09/2022	Opinion/decision on a Paediatric investigation plan (PIP): Epcoritamab, P: decision agreeing on a investigation plan, with or without partial waiver(s) and or deferral(s), P/0344/2021
12/09/2022	PIP decision: P/0330/2021 : EMA decision of 11 August 2021 on the agreement of a paediatric investigation plan and on the granting of a deferral for cefepime / zidebactam (EMEA-002892-PIP01-20)
12/09/2022	Opinion/decision on a Paediatric investigation plan (PIP): cefepime,zidebactam, P: decision agreeing on a investigation plan, with or without partial waiver(s) and or deferral(s), P/0330/2021
12/09/2022	Opinion/decision on a Paediatric investigation plan (PIP): Human, recombinant, non-fucosylated IgG1k monoclonal antibody targeting OX-40 receptor on activated T cells (KHK4083), P: decision agreeing on a investigation plan, with or without partial waiver(s) and or deferral(s), P/0320/2021 (updated)
12/09/2022	Human medicines European public assessment report (EPAR): Vyvgart, Efgartigimod alfa, Myasthenia Gravis, 10/08/2022, Authorised (updated)
12/09/2022	Human medicines European public assessment report (EPAR): Tavlesse, Fostamatinib disodium, Thrombocytopenia, 09/01/2020, 5, Authorised (updated)

NOTICE TO APPLICANTS

No updates since February 20th 2022.

BFARM - PHARMAKOVIGILANZ (SPECIFIC FOR GERMANY)

14.09.2022	Sartane: Verunreinigungen der Wirkstoffe Wirkstoffe: Valsartan | Candesartan | Irbesartan | Losartan | OlmesartanDas Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM) hat mit dem Bescheid vom 02.09.2022 das Ruhen einiger Zulassungen der Firma axcount aufgehoben.

BFARM – MEDIZINPRODUKTE (SPECIFIC FOR GERMANY)

No updates since September 9th 2022.

PEI - VIGILANZ (SPECIFIC FOR GERMANY)

No updates since June 3rd 2022.

PHARMEUROPA TEXTS FOR COMMENT

Information on Pharmeuropa updates will be presented quarterly.