



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

17 May 2022
EMA/PDCO/233334/2022
Human Medicines Division

Paediatric Committee (PDCO)

Agenda for the meeting on 17-20 May 2022

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

17 May 2022, 14:00 - 19:00, Virtual meeting

18 May 2022, 08:30 - 19:00, Virtual meeting

19 May 2022, 08:30 - 19:00, Virtual meeting

20 May 2022, 08:30 - 13:00, Virtual meeting

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the PDCO Committee meeting reports (after the PDCO Opinion is adopted), and on the Opinions and decisions on paediatric investigation plans webpage (after the EMA Decision is issued).

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).



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1. Introductions

1.1. Welcome and declarations of interest of members, alternates and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PDCO plenary session to be held 17-20 May 2022. See May 2022 PDCO minutes (to be published post June 2022 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 17-20 May 2022.

1.3. Adoption of the minutes

PDCO minutes for 19-22 April 2022.

2. Opinions

Some information related to this section cannot be disclosed at the present time as it is deemed to contain commercially confidential information.

2.1. Opinions on Products

2.1.1. Semaglutide / cagrilintide - EMEA-003059-PIP01-21

Treatment of obesity

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.2. EMEA-003090-PIP01-21

Treatment of hereditary angioedema

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.3. Bepirovirsen - EMEA-003082-PIP01-21

Treatment of chronic hepatitis B infection

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.4. [Lonafarnib - Orphan - EMEA-002516-PIP02-21](#)

EigerBio Europe Limited; Treatment of hepatitis D virus infection

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.5. [Mixture of 2 synthetic double-stranded N-Acetyl-galactosamine conjugated siRNA oligonucleotides that are directed against hepatitis B virus - EMEA-002694-PIP02-21](#)

Treatment of chronic hepatitis D infection

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.6. [Alprazolam - EMEA-003043-PIP01-21](#)

Treatment of epileptic seizures

Day 120 opinion

Action: For adoption

Neurology

2.1.7. [Cannabidiol - EMEA-001964-PIP03-21](#)

Treatment of epilepsy with myoclonic atonic seizures

Day 120 opinion

Action: For adoption

Neurology

2.1.8. [Autologous tumour-infiltrating lymphocytes \(TILs\) isolated from a patient's cancer tissue and expanded ex vivo - EMEA-003072-PIP01-21](#)

Treatment of advanced melanoma

Day 120 opinion

Action: For adoption

Oncology

2.1.9. [Rituximab / CD3+CD4+CD25+CD127-FoxP3+ regulatory T cells - EMEA-002737-PIP01-19](#)

Treatment of type 1 diabetes mellitus (T1DM)

Day 120 opinion

Action: For adoption

Other / Endocrinology-Gynaecology-Fertility-Metabolism

2.1.10. [Benralizumab - EMEA-001214-PIP09-21](#)

Treatment of eosinophilic granulomatosis with polyangiitis (EGPA)

Day 120 opinion

Action: For adoption

Pneumology - Allergology

2.1.11. [Sibeprenlimab - Orphan - EMEA-003085-PIP01-21](#)

Otsuka Pharmaceutical Netherlands B.V.; Treatment of primary IgA nephropathy

Day 120 opinion

Action: For adoption

Uro-nephrology

2.1.12. [Respiratory syncytial virus stabilised prefusion F subunit vaccine \(RSVpreF\) - EMEA-002795-PIP02-21](#)

Prevention of lower respiratory tract disease caused by respiratory syncytial virus /
Prevention of RSV-associated lower respiratory tract illness

Day 120 opinion

Action: For adoption

Vaccines

2.1.13. [Autologous bone marrow-derived mononuclear cell enriched white blood cells - EMEA-003193-PIP01-22](#)

Treatment of chronic limb-threatening ischemia

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.14. Botulinum toxin type E - EMEA-003190-PIP01-22

Treatment of muscle-induced wrinkles

Day 60 opinion

Action: For adoption

Dermatology

2.1.15. Derivative of 6-[2-(pyridin-2-yl)phenoxy]methyl}-1,2,3,4-tetrahydroisoquinoline - EMEA-003002-PIP02-22

Treatment of clinically significant portal hypertension (CSPH)

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.16. Lurbinectedin - Orphan - EMEA-002846-PIP02-22

Pharma Mar, S.A.; Treatment of malignant mesothelioma

Day 60 opinion

Action: For adoption

Oncology

2.1.17. Parsaclisib (as hydrochloride) - Orphan - EMEA-002696-PIP03-22

Incyte Biosciences Distribution B.V.; Treatment of primary myelofibrosis (ICD-11: XH7GG7)
/ Treatment of myelofibrosis

Day 60 opinion

Action: For adoption

Oncology

2.1.18. Peptide KLBPVQLWV / Peptide SMPPPGRV / Peptide YLQLVFGIEV / Peptide RLLQETELV / Peptide YLSGADLNL / Peptide LLTFWNPPV / Peptide IMIGHLVGV / Peptide KVAEIVHFL / Peptide KVFGSLAFV / Pan HLA DR-binding epitope D-Ala-Lys-Cha-Val-Ala-Ala-Trp-Thr-Leu-Lys-Ala-Ala-D-Ala - EMEA-003181-PIP01-22

Treatment of lung cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.19. Radium-224 adsorbed in calcium carbonate microparticles - EMEA-003199-PIP01-22

Treatment of peritoneal carcinomatosis

Day 60 opinion

Action: For adoption

Oncology

2.1.20. Trabectedin - Orphan - EMEA-000610-PIP02-22

Pharma Mar, S.A.; Treatment of leiomyosarcoma

Day 60 opinion

Action: For adoption

Oncology

2.1.21. Botulinum toxin type A - EMEA-003202-PIP01-22

Treatment of upper facial wrinkles

Day 60 opinion

Action: For adoption

Other

2.2. Opinions on Compliance Check

2.2.1. Ritlecitinib - EMEA-C1-002451-PIP01-18

Pfizer Europe MA EEIG; Treatment of alopecia areata

Day 60 letter

Action: For adoption

Dermatology

2.2.2. Pitolisant - EMEA-C-001176-PIP01-11-M06

BIOPROJET PHARMA; Treatment of narcolepsy

Day 60 opinion

Action: For adoption

Neurology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Lebrikizumab - EMEA-002536-PIP01-18-M02

Eli Lilly and Company Limited; Treatment of atopic dermatitis

Day 60 opinion

Action: For adoption

Dermatology

2.3.2. Garadacimab - Orphan - EMEA-002726-PIP01-19-M02

CSL Behring GmbH; Treatment of hereditary angioedema attacks (HAE)

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.3. Vadadustat - EMEA-001944-PIP01-16-M04

Otsuka Pharmaceutical Development & Commercialisation Europe GmbH; Treatment of anaemia due to chronic disorders

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.4. Avacopan - Orphan - EMEA-002023-PIP01-16-M06

ChemoCentryx Ireland Ltd.; Treatment of anti-neutrophil cytoplasmic auto-antibody (ANCA)-associated vasculitis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.5. Liposomal ciclosporin A (L-CsA) - Orphan - EMEA-002344-PIP02-18-M01

Zambon S.p.A.; Treatment of bronchiolitis obliterans syndrome (BOS)

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.6. Oritavancin (diphosphate) - EMEA-001270-PIP01-12-M05

Menarini International Operations Luxembourg S.A.; Treatment of acute bacterial skin and skin structure infections

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.7. Remdesivir - EMEA-002826-PIP01-20-M03

Gilead Sciences International Ltd.; Treatment of coronavirus disease 2019 (COVID-19)

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.8. Cannabidiol - Orphan - EMEA-001964-PIP01-16-M04

GW Pharma (International) B.V.; Treatment of Lennox Gastaut syndrome / Dravet syndrome / tuberous sclerosis complex / infantile spasms

Day 60 opinion

Action: For adoption

Neurology

2.3.9. Delandistrogene moxeparvovec - Orphan - EMEA-002677-PIP01-19-M02

Roche Registration GmbH; Treatment of Duchenne muscular dystrophy

Day 60 opinion

Action: For adoption

Neurology

2.3.10. Lacosamide - EMEA-000402-PIP03-17-M06

UCB Pharma S.A.; Treatment of generalized epilepsy and epilepsy syndromes

Day 60 opinion

Action: For adoption

Neurology

2.3.11. Daratumumab - Orphan - EMEA-002152-PIP01-17-M03

Janssen-Cilag International NV; Treatment of lymphoid malignancies (except mature B cell

neoplasms)

Day 60 opinion

Action: For adoption

Oncology

2.3.12. Ixazomib - Orphan - EMEA-001410-PIP02-17-M04

Takeda Pharma A/S; Treatment of lymphoid malignancies (excluding multiple myeloma) / Treatment of multiple myeloma

Day 60 opinion

Action: For adoption

Oncology

2.3.13. Mometasone (furoate) / indacaterol (acetate) - EMEA-001217-PIP01-11-M08

Novartis Europharm Limited; Treatment of asthma

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.14. Dexmedetomidine (hydrochloride) - EMEA-002758-PIP01-19-M02

BioXcel Therapeutics, Inc.; Treatment of bipolar disorder / Treatment of schizophrenia

Day 60 opinion

Action: For adoption

Psychiatry

2.3.15. Daprodustat - EMEA-001452-PIP01-13-M04

GlaxoSmithKline Trading Services Limited; Treatment of anaemia associated with chronic kidney disease

Day 60 opinion

Action: For adoption

Uro-nephrology / Haematology-Hemostaseology

2.3.16. Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA-002330-PIP01-18-M02

Pfizer Europe MA EEIG; Prevention of disease caused by *Streptococcus pneumoniae*

Day 60 opinion

Action: For adoption

Vaccines

2.3.17. Hepatitis B (rDNA) surface antigen adjuvanted - EMEA-001127-PIP02-11-M02

Dynavax GmbH; Prevention of hepatitis B virus infection

Day 60 opinion

Action: For adoption

Vaccines

2.3.18. *Neisseria meningitidis* serogroup W polysaccharide conjugated to tetanus toxoid / *Neisseria meningitidis* serogroup Y polysaccharide conjugated to tetanus toxoid / *Neisseria meningitidis* serogroup C polysaccharide conjugated to tetanus toxoid / *Neisseria meningitidis* serogroup A polysaccharide conjugated to tetanus toxoid - EMEA-001930-PIP01-16-M04

Sanofi Pasteur; Prevention of invasive meningococcal disease

Day 60 opinion

Action: For adoption

Vaccines

2.3.19. Nirsevimab - EMEA-001784-PIP01-15-M04

AstraZeneca AB; Prevention of respiratory syncytial viral infections

Day 60 opinion

Action: For adoption

Vaccines

2.3.20. NVX-CoV2373 - EMEA-002941-PIP01-20-M02

Novavax CZ, a.s.; Prevention of coronavirus disease 2019 (COVID-19)

Day 60 opinion

Action: For adoption

Vaccines

2.3.21. Split influenza virus, inactivated containing antigens equivalent to the B-like strain (*Yamagata lineage*) / Split influenza virus, inactivated containing antigens equivalent to the B-like strain (*Victoria lineage*) / Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain / Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain - EMEA-002359-PIP01-18-M05

Sanofi Pasteur; Prevention of influenza infection

Day 60 opinion

Action: For adoption

Vaccines

2.3.22. Upadacitinib - EMEA-001741-PIP03-16-M02

AbbVie Ltd; Treatment of Crohn's disease

Day 30 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.4. Opinions on Re-examinations

No item

2.5. Opinions on Review of Granted Waivers

No item

2.6. Finalisation and adoption of Opinions

No item

2.7. Partial Compliance Checks completed by EMA

The following partial compliance checks have been identified by the PME coordinator and PDCO rapporteur as not needing to be referred to the PDCO for discussion. The PDCO has been informed in writing.

2.7.1. Dupilumab - EMEA-C2-001501-PIP04-19-M01

Regeneron Ireland DAC; Treatment of eosinophilic esophagitis

Day 30 letter

Action: For information

Gastroenterology-Hepatology

2.7.2. Chloroprocaine hydrochloride - EMEA-C1-000639-PIP03-16-M01

Sintetica GmbH; Peripheral nerve block (local anaesthesia by perineural injection)

Day 30 letter

Action: For information

Anaesthesiology

2.7.3. Formoterol fumarate dihydrate / glycopyrronium bromide / budesonide - EMEA-C1-002063-PIP01-16-M01

AstraZeneca AB; Treatment of asthma

Day 30 letter

Action: For information

Pneumology – Allergology

2.7.4. PEGylated-fibroblast growth factor 21 (BMS-986036) - EMEA-C2-002448-PIP01-18-M02

Bristol-Myers Squibb International Corporation; Treatment of non-alcoholic steatohepatitis (NASH)

Day 30 letter

Action: For information

Gastroenterology-Hepatology

2.7.5. Ivacaftor N-(2,4-di-tert-butyl-5-hydroxyphenyl)-4-oxo-1,4-dihydroquinoline-3-carboxamide / lumacaftor 3 [6 ({[1 (2,2-difluoro 1,3-benzodioxol-5-yl)cyclopropyl]carbonyl}amino)-3 methylpyridin-2-yl]benzoic acid - EMEA-C7-001582-PIP01-13-M10

Vertex Pharmaceuticals (Ireland) Limited; Treatment of cystic fibrosis

Day 30 letter

Action: For information

Other

3. Discussion of applications

Some information related to this section cannot be disclosed at the present time as it is deemed to contain commercially confidential information.

3.1. Discussions on Products D90-D60-D30

3.1.1. Oxytocin - Orphan - EMEA-003148-PIP01-21

OT4B; Treatment of Prader-Willi syndrome

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.2. Venglustat - Orphan - EMEA-001716-PIP06-21

Genzyme Europe B.V.; Treatment of Fabry disease

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.3. Efruxifermin - EMEA-003114-PIP01-21

Treatment of non-alcoholic fatty liver disease including non-alcoholic steatohepatitis

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.4. Etrasimod L-arginine - EMEA-002713-PIP02-21

Treatment of Crohn's disease

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.5. Ritlecitinib - EMEA-002451-PIP02-21

Treatment of ulcerative colitis

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.6. Deucravacitinib - EMEA-002350-PIP04-21

Treatment of ulcerative colitis

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.7. [Gliadin protease - EMEA-003116-PIP01-21](#)

Treatment of coeliac disease / Treatment of celiac disease

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Gastroenterology-Hepatology

3.1.8. [Remibrutinib - EMEA-002582-PIP02-21](#)

Treatment of multiple sclerosis

Day 90 discussion

Action: For discussion

Neurology

3.1.9. [\(R\)-tetrahydrofuran-3-yl 4-\(6-\(5-\(4-ethoxy-1-isopropylpiperidin-4-yl\) pyridin-2-yl\)pyrrolo\[1,2-b\]pyridazin-4-yl\)piperazine-1-carboxylate sesquisuccinate - Orphan - EMEA-003133-PIP01-21](#)

Ipsen Pharma; Treatment of fibrodysplasia ossificans progressiva

Day 90 discussion

Action: For discussion

Other

3.1.10. [Azelastine hydrochloride / mometasone furoate - EMEA-003122-PIP01-21](#)

Treatment of seasonal allergic rhinitis

Day 90 discussion

Action: For discussion

Oto-rhino-laryngology

3.1.11. [A 2'-O-\(2'-methoxyethyl\) modified antisense oligonucleotide targeting prekallikrein \(PKK\) mRNA - EMEA-003112-PIP01-21](#)

Treatment of hereditary angioedema / Prevention of hereditary angioedema

Day 90 discussion

Action: For discussion

3.1.12. EMEA-003098-PIP01-21

Treatment of proteinuric chronic kidney disease

Day 90 discussion

Action: For discussion

Uro-nephrology

3.1.13. Lademirsen - Orphan - EMEA-003064-PIP01-21

Genzyme Europe B.V.; Treatment of Alport syndrome

Day 90 discussion

Action: For discussion

Uro-nephrology

3.1.14. Pegcetacoplan - Orphan - EMEA-002600-PIP03-21

Apellis Ireland Limited; Treatment of glomerulonephritis and nephrotic syndrome

Day 90 discussion

Action: For discussion

Uro-nephrology

3.1.15. Vibegron - EMEA-001415-PIP02-21

Treatment of myoneurogenic bladder disorders

Day 90 discussion

Action: For discussion

Uro-nephrology

3.1.16. RSV F protein - EMEA-003094-PIP02-21

Prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV)

Day 90 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.1.17. EMEA-003196-PIP01-22

Treatment of ulcerative colitis / Treatment of Crohn's disease

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.18. 6-[(3S,4S)-4-methyl-1-(pyrimidin-2-ylmethyl)pyrrolidin-3-yl]-3-tetrahydropyran-4-yl-7H-imidazo[1,5-a]pyrazin-8-one - Orphan - EMEA-002991-PIP02-22

Imara Inc.; Treatment of sickle cell disease

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

Note: *Withdrawal request received on 26 April 2022*

3.1.19. Depemokimab - EMEA-003051-PIP05-22

Treatment of hypereosinophilic syndrome (HES)

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.20. Vidofludimus - EMEA-003195-PIP01-22

Treatment of multiple sclerosis

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Neurology

3.1.21. Exenatide acetate - Orphan - EMEA-003183-PIP02-22

Invex Therapeutics Ltd; Treatment of idiopathic intracranial hypertension

Day 60 discussion

Action: For discussion

Neurology

3.1.22. Troriluzole - Orphan - EMEA-003084-PIP03-22

Biohaven Pharmaceutical Ireland DAC; Treatment of hereditary spinocerebellar ataxia

Day 60 discussion

Action: For discussion

Neurology

3.1.23. [Infigratinib - Orphan - EMEA-002594-PIP04-22](#)

Helsinn Birex Pharmaceuticals Ltd.; Treatment of paediatric low-grade gliomas (LGG)

Day 60 discussion

Action: For discussion

Oncology

3.1.24. [Efavaleukin alfa - EMEA-003156-PIP02-22](#)

Treatment of ulcerative colitis

Day 60 discussion

Action: For discussion

Other

3.1.25. [Depemokimab - EMEA-003051-PIP04-22](#)

Treatment of eosinophilic granulomatosis with polyangiitis (EGPA)

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.26. [Stiripentol - Orphan - EMEA-003200-PIP01-22](#)

Biocodex SA; Treatment of primary hyperoxaluria

Day 60 discussion

Action: For discussion

Uro-nephrology

3.1.27. [COVID-19 vaccine \(recombinant, adjuvanted\) - EMEA-003191-PIP01-22](#)

Prevention of coronavirus disease 2019 (COVID-19)

Day 60 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.1.28. Acetylsalicylic acid / rosuvastatin - EMEA-003206-PIP01-22

Prevention of cardiovascular events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.29. Ezetimibe / atorvastatin - EMEA-003205-PIP01-22

Treatment of hypercholesterolaemia / Prevention of cardiovascular events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.30. Milvexian - EMEA-003220-PIP01-22

Prevention of thromboembolism

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.31. Zilebesiran - EMEA-003218-PIP01-22

Treatment of hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.32. EMEA-003223-PIP01-22

Treatment of palmoplantar pustulosis

Day 30 discussion

Action: For discussion

Dermatology

3.1.33. Nipocalimab - Orphan - EMEA-002559-PIP05-22

Janssen-Cilag International NV; Treatment of bullous pemphigoid

Day 30 discussion

Action: For discussion

Dermatology

3.1.34. [Perflubutane - EMEA-003037-PIP02-22](#)

Diagnostic evaluation of focal hepatic lesions

Day 30 discussion

Action: For discussion

Diagnostic / Oncology

3.1.35. [Danuglipron - EMEA-002944-PIP02-22](#)

Treatment of obesity / Treatment of chronic weight management

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.36. [Doxribtimine / doxecitine - Orphan - EMEA-003210-PIP01-22](#)

Zogenix ROI Limited; Treatment of thymidine kinase 2 deficiency

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.37. [Insulin human \(RDNA\) - EMEA-003194-PIP02-22](#)

Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.38. [Inclacumab - EMEA-003219-PIP01-22](#)

Treatment of sickle cell disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.39. Synthetic peptide of 20 amino acids comprising a T cell epitope from pro-insulin - EMEA-002379-PIP01-22

Treatment of type 1 diabetes

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Endocrinology-Gynaecology-Fertility-Metabolism / Vaccines

3.1.40. EMEA-003222-PIP01-22

Treatment of SCN8A developmental and epileptic encephalopathy

Day 30 discussion

Action: For discussion

Neurology

3.1.41. Gold (Au) - EMEA-003211-PIP01-22

Treatment of amyotrophic lateral sclerosis (ALS)

Day 30 discussion

Action: For discussion

Neurology

3.1.42. Satralizumab - Orphan - EMEA-001625-PIP04-22

Roche Registration GmbH; Treatment of autoimmune encephalitis

Day 30 discussion

Action: For discussion

Neurology

3.1.43. Autologous CD4+ and CD8+ T cells transduced with lentiviral vector encoding a chimeric antigen receptor (CAR) directed against CD19 and preserving the T cell phenotype of the leukapheresis starting material - EMEA-003212-PIP01-22

Treatment of mature B cell neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.1.44. Fianlimab - EMEA-003207-PIP01-22

Treatment of melanoma

Day 30 discussion

Action: For discussion

Oncology

3.1.45. Modakafusp alfa - EMEA-003217-PIP01-22

Treatment of multiple myeloma

Day 30 discussion

Action: For discussion

Oncology

3.1.46. Humanised IgG2 monoclonal antibody against interleukin-6 - EMEA-003215-PIP01-22

Treatment of macular oedema

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.47. Humanized monoclonal antibody of IgG1 subtype targeting NRP1 - EMEA-003214-PIP01-22

Treatment of diabetic retinopathy

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.48. Magnesium lactate dihydrate / tramadol - EMEA-003216-PIP01-22

Management of chronic pain in adults with osteoarthritis of the hip and/or knee

Day 30 discussion

Action: For discussion

Other

3.1.49. Pregabalin - EMEA-003221-PIP01-22

Treatment of neuropathic pain associated with diabetic peripheral neuropathy / Treatment of postherpetic neuralgia

Day 30 discussion

Action: For discussion

Pain / Neurology

3.1.50. Benzylamine derivative of benzofuran - EMEA-002974-PIP02-22

Treatment of C3 glomerulopathy

Day 30 discussion

Action: For discussion

Uro-nephrology

3.2. Discussions on Compliance Check

The following compliance checks have been identified for discussion and the members of the PDCO have been invited to comment on issues of possible non-compliance.

3.2.1. Apixaban - EMEA-C-000183-PIP01-08-M08

Bristol-Myers Squibb / Pfizer EEIG; Prevention of arterial thromboembolism

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.2.2. Sacubitril / valsartan - EMEA-C-000316-PIP02-11-M05

Novartis Europharm Ltd; Treatment of heart failure

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.2.3. Pegzilarginase - EMEA-C1-001925-PIP02-19

Immedica Pharma AB; Treatment of hyperargininaemia

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.4. Giroctocogene fitelparovvec - EMEA-C1-002724-PIP01-19-M02

Pfizer Europe MA EEIG; Treatment of haemophilia A

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.2.5. Methoxy polyethylene glycol-epoetin beta - EMEA-C-000172-PIP01-07-M03

Roche Registration GmbH; Treatment of symptomatic anaemia associated with chronic kidney disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.2.6. Cabotegravir - EMEA-C-001418-PIP02-15-M03

ViiV Healthcare UK Limited; Prevention of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.7. Lisdexamfetamine dimesylate - EMEA-C-000553-PIP01-09-M05

Shire Pharmaceutical Contracts Ltd; Treatment of attention deficit hyperactivity disorder

Day 30 discussion

Action: For discussion

Psychiatry

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Obinutuzumab - Orphan - EMEA-001207-PIP02-19-M01

Roche Registration GmbH; Treatment of systemic lupus erythematosus

Day 30 discussion

Action: For discussion

Antineoplastic and immunomodulating agents

3.3.2. Chlorprocaine hydrochloride - EMEA-000639-PIP03-16-M02

Sintetica GmbH; Peripheral nerve block (local anaesthesia by perineural injection)

Day 30 discussion

Action: For discussion

Anaesthesiology

3.3.3. [Bempedoic acid - EMEA-001872-PIP01-15-M02](#)

Esperion Therapeutics, Inc.; Treatment of elevated cholesterol

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.4. [Etripamil - EMEA-002303-PIP01-17-M03](#)

Milestone Pharmaceuticals, Inc.; Treatment of supraventricular tachycardia

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.5. [Omecamtiv mecarbil - EMEA-001696-PIP01-14-M02](#)

Cytokinetics, Inc.; Treatment of heart failure

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.6. [Bimekizumab - EMEA-002189-PIP01-17-M03](#)

UCB Biopharma SRL; Treatment of psoriasis

Day 30 discussion

Action: For discussion

Dermatology

3.3.7. [Deucravacitinib - EMEA-002350-PIP01-18-M02](#)

Bristol-Myers Squibb International Corporation; Treatment of psoriasis

Day 30 discussion

Action: For discussion

Dermatology

3.3.8. [Fluciclovine \(18F\) - Orphan - EMEA-001644-PIP02-14-M03](#)

Blue Earth Diagnostics Ireland Ltd; Diagnosis of amino acid metabolism in solid malignant

tumours

Day 30 discussion

Action: For discussion

Diagnostic / Oncology

3.3.9. Pegunigalsidase alfa - Orphan - EMEA-001828-PIP01-15-M03

Chiesi Farmaceutici S.p.A; Treatment of Fabry disease

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.10. Cilofexor - Orphan - EMEA-002554-PIP02-19-M01

Gilead Sciences International Ltd.; Treatment of primary sclerosing cholangitis (DB96.2)

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.11. Maralixibat chloride - Orphan - EMEA-001475-PIP02-13-M02

Mirum Pharmaceuticals; Treatment of Alagille syndrome

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.12. Fidanacogene elaparvovec - Orphan - EMEA-002362-PIP02-19-M02

Pfizer Europe MA EEIG; Treatment of congenital factor IX deficiency (haemophilia B)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.13. Rilzabrutinib - Orphan - EMEA-002438-PIP02-19-M02

Principia Biopharma, Inc.; Treatment of immune thrombocytopenia

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.14. Avibactam / ceftazidime - EMEA-001313-PIP01-12-M12

Pfizer Europe MA EEIG; Treatment of intra-abdominal infections / Treatment of pneumonia / Treatment of urinary tract infections / Treatment of infections due to aerobic Gram-negative organisms

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.15. Bulevirtide - Orphan - EMEA-002399-PIP01-18-M01

Gilead Sciences International Ltd.; Treatment of chronic hepatitis D infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.16. Casirivimab - EMEA-002964-PIP01-21-M02

Roche Registration GmbH; Treatment of coronavirus disease 2019 (COVID-19) in hospitalised patients / Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.17. Enmetazobactam - EMEA-002240-PIP02-17-M01

Allegra Therapeutics GmbH; Treatment of urinary tract infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.18. Imdevimab - EMEA-002965-PIP01-21-M02

Roche Registration GmbH; Treatment of coronavirus disease 2019 (COVID-19) / Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.19. Pretomanid - Orphan - EMEA-002115-PIP01-17-M05

Global Alliance for TB Drug Development; Treatment of multi-drug-resistant tuberculosis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.20. Rezafungin acetate - Orphan - EMEA-002319-PIP01-17-M02

Mundipharma Corporation (Ireland) Limited; Treatment of invasive candidiasis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.21. Ritonavir / (1R,2S,5S)-N-{(1S)-1-cyano-2-[(3S)-2-oxopyrrolidin-3-yl]ethyl}-6,6-dimethyl-3-[3-methyl-N-(trifluoroacetyl)-L-valyl]-3-azabicyclo[3.1.0]hexane-2-carboxamide - EMEA-003081-PIP01-21-M01

Pfizer Europe MA EEIG; Treatment of coronavirus disease 2019 (COVID-19) / Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.22. Eptinezumab - EMEA-002243-PIP01-17-M03

H. Lundbeck A/S; Prevention of migraine headaches

Day 30 discussion

Action: For discussion

Neurology

3.3.23. Lasmiditan - EMEA-002166-PIP01-17-M06

Eli Lilly and Company Limited; Treatment of migraine with and without aura

Day 30 discussion

Action: For discussion

Neurology

3.3.24. Ravulizumab - EMEA-001943-PIP03-20-M01

Alexion Europe SAS; Treatment of generalized myasthenia gravis

Day 30 discussion

Action: For discussion

Neurology

3.3.25. [Rimegepant - EMEA-002812-PIP02-20-M01](#)

Biohaven Pharmaceutical Ireland DAC; Treatment of migraine headaches

Day 30 discussion

Action: For discussion

Neurology

3.3.26. [Setmelanotide - Orphan - EMEA-002209-PIP01-17-M03](#)

Rhythm Pharmaceuticals, Inc; Treatment of appetite and general nutrition disorders

Day 30 discussion

Action: For discussion

Nutrition

3.3.27. [Bosutinib - EMEA-000727-PIP01-09-M06](#)

Pfizer Europe MA EEIG; Treatment of chronic myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.3.28. [Larotrectinib - EMEA-001971-PIP03-18-M02](#)

Bayer AG; Treatment of malignant neoplasms of the central nervous system

Day 30 discussion

Action: For discussion

Oncology

3.3.29. [Lenvatinib - EMEA-001119-PIP02-12-M08](#)

Eisai GmbH; Treatment of follicular carcinoma / Treatment of osteosarcoma / Treatment of papillary thyroid carcinoma

Day 30 discussion

Action: For discussion

Oncology

3.3.30. Andexanet alfa - EMEA-001902-PIP01-15-M06

AstraZeneca AB; Treatment of factor Xa inhibitor associated haemorrhage / Prevention of factor Xa inhibitor associated haemorrhage

Day 30 discussion

Action: For discussion

Other

3.3.31. Setrusumab - Orphan - EMEA-002169-PIP01-17-M01

Mereo Biopharma 3 Ltd; Treatment of osteogenesis imperfecta

Day 30 discussion

Action: For discussion

Other

3.3.32. Vamorolone - Orphan - EMEA-001794-PIP02-16-M05

ReveraGen BioPharma Ltd; Treatment of Duchenne muscular dystrophy

Day 30 discussion

Action: For discussion

Other

3.3.33. Ivacaftor / tezacaftor / elexacaftor - Orphan - EMEA-002324-PIP01-17-M03

Vertex Pharmaceuticals (Ireland) Limited; Treatment of cystic fibrosis

Day 30 discussion

Action: For discussion

Other / Pneumology - Allergology

3.3.34. Dermatophagoides farinae / dermatophagoides pteronyssinus - EMEA-001258-PIP01-11-M08

ALK-Abelló A/S; Treatment of asthma / Treatment of allergic rhinitis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.35. Brexpiprazole - EMEA-001185-PIP01-11-M08

Otsuka Pharmaceutical Development & Commercialisation Europe GmbH; Treatment of schizophrenia

Day 30 discussion

Action: For discussion

Psychiatry

3.3.36. Vortioxetine - EMEA-000455-PIP02-10-M09

H. Lundbeck A/S; Treatment of major depressive disorder

Day 30 discussion

Action: For discussion

Psychiatry

3.3.37. COVID-19 vaccine (ChAdOx1-S [recombinant]) - EMEA-002862-PIP01-20-M03

AstraZeneca AB; Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Vaccines

4. Nominations

Information related to this section cannot be disclosed at the present time as it is deemed to contain commercially confidential information.

4.1. List of submissions of applications with start of procedure 23 May 2022 for Nomination of Rapporteur and Peer reviewer

Action: For adoption

4.2. Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver

Action: For adoption

4.3. Nominations for other activities

Action: For adoption

5. Scientific Advice Working Party (SAWP) and Paediatric Committee (PDCO) Interaction

Information related to this section cannot be disclosed at the present time as it is deemed to contain commercially confidential information.

6. Discussion on the applicability of class waivers

Some information related to this section cannot be disclosed at the present time as it is deemed to contain commercially confidential information.

6.1. Discussions on the applicability of class waiver for products

No item

7. Discussion on the inclusion of an indication within a condition in an agreed PIP/waiver

7.1. Discussion on the possibility to include an indication within a condition in an agreed PIP/waiver

No item

8. Annual reports on deferrals

Note: The annual reports on deferrals to be noted by the members of the PDCO are flagged in the Annex B.

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. PDCO membership

Action: For information

9.1.2. Vote by Proxy

Action: For information

9.1.3. Mandate of PDCO Chairperson - call for nominations

Action: For information

9.2. Coordination with EMA Scientific Committees or CMDh-v

9.2.1. Committee for Medicinal Products for Human Use (CHMP)

Action: For information

9.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

9.3.1. Non-clinical Working Group: D30 Products identified

PDCO member: Karen van Malderen

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.3.3. Patients and Consumers Working Party (PCWP)/Healthcare Professionals Working Party (HCPWP)

Meeting Summary PCWP-HCPWP meeting 2-3 March 2022

Draft Agenda - PCWP-HCPWP Joint meeting - June 2022

Action: For information

Draft PCWP-HCPWP Work plan 2022-2025

Action: For adoption

9.4. Cooperation within the EU regulatory network

9.4.1. European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA)

Action: For information

9.5. Cooperation with International Regulators

9.5.1. Paediatric cluster conference

Action: For information

9.6. Contacts of the PDCO with external parties and interaction with the Interested Parties to the Committee

No item

9.7. PDCO work plan

No item

9.8. Planning and reporting

No item

10. Any other business

10.1. ALADDIN - Educational program on regulatory science in paediatric oncology

Action: For information

10.2. COVID-19 update

Action: For information

10.3. Exparel liposomal - EMEA/H/C/004586/II/0005 PDCO consultation from CHMP

Action: For discussion

10.4. Feedback from FDA paediatric oncology subcommittee of Oncologic Drugs Advisory Committee (ODAC)

PDCO member: Siri Wang, Karen Van Malderen

Action: For information

10.5. New EMA Online Booking Tool

Action: for information

11. Breakout sessions

11.1. Internal PDCO Operations

Action: For discussion on Tuesday, 11:00 - 12:00

11.2. Paediatric oncology

Action: For discussion on Tuesday, 13:00 - 14:00

11.3. Neonatology

Action: For discussion on Wednesday, 13:00 - 14:00

11.4. Vaccines

Action: For discussion on Thursday, 13:00 - 14:00

12. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

Paediatric investigation plan (PIP) (section 2.1 Opinion on PIPs and section 3.1 Discussions on PIPs)

A paediatric investigation plan (PIP) is a development plan aimed at ensuring that the necessary data are obtained through studies in children, when it is safe to do so, to support the authorisation of a medicine for children. Pharmaceutical companies submit proposals for PIPs to the European Medicines Agency's Paediatric Committee (PDCO). This Committee is responsible for agreeing or refusing the plan.

Compliance checks (section 2.2 Opinions on Compliance check, section 3.2 Discussions on Compliance check)

A compliance check may be necessary before any application for marketing authorisation (even for an adult indication) can be considered valid, if there was no deferral for at least one of the studies agreed in the PIP, or after the due date of initiation or completion of a study/measure. The same applies to some regulatory applications for authorised products, as described above.

Modification of an Agreed Paediatric Investigation Plan (section 2.3 Opinions on Modification of an agreed PIP, section 3.3 Discussions on Modification of an agreed PIP)

The development plan for a medicine can be modified at a later stage as knowledge increases.

Modifications can also be made if the applicant encounters such difficulties with the implementation of a PIP, which render it unworkable or no longer appropriate.

In some cases, studies can be deferred until after the studies in adults have been conducted. This ensures that research in children is done only when it is safe and ethical to do so. Even when studies are deferred, the PIP will include details of the paediatric studies and their timelines.

Class waiver (section 6 Discussion on the applicability of class waiver)

As some diseases do not affect children (for example Parkinson's disease), the development of medicines for these diseases should not be performed in children. In these cases, a PIP is not required and it will be waived. For more information on the classes of diseases subject to waivers, see [class waivers](#).

Annual reports on deferrals (section 8)

If the medicinal product is approved in the EU, annual reports on the deferred measures in the PIP must be submitted to the Agency.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/