



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 April 2023
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Human Medicines Division

Paediatric Committee (PDCO)

Draft Agenda for the meeting on 24-26 April 2023

Chair: Brian Aylward – Vice-Chair: Sylvie Benchetrit

24 April 2023, 08:30 - 19:00, Virtual meeting

25 April 2023, 08:30 - 19:00, Virtual meeting

26 April 2023, 08:30 - 19:00, 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 24-26 April 2023. See April 2023 PDCO minutes (to be published post May 2023 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 24-26 April 2023.

1.3. Adoption of the minutes

PDCO minutes for 28-31 March 2023.

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. Insulin human (rDNA) - EMEA-003194-PIP02-22

Treatment of type 2 diabetes mellitus

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

Note: Withdrawal request received on 17 April 2023

2.1.2. Crofelemer - Orphan - EMEA-003296-PIP01-22

Napo Therapeutics S.p.A.; Treatment of short bowel syndrome

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.3. Efgartigimod alfa - EMEA-002597-PIP08-22

Treatment of dermatomyositis / Treatment of polymyositis (including antisynthetase syndrome) / Treatment of immune-mediated necrotising myopathy

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.4. Asunercept - Orphan - EMEA-003201-PIP01-22

Apogenix AG; Treatment of coronavirus disease 2019 (COVID-19)

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.5. Fosmanogepix - Orphan - EMEA-003280-PIP01-22

Pfizer Europe MA EEIG; Treatment of invasive fungal infections

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.6. RNA replicase inhibitor - EMEA-003306-PIP01-22

Treatment of coronavirus disease 2019 (COVID-19)

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.7. Humanised VHH-type bispecific antibody against complement component 5 and serum albumin - EMEA-003302-PIP01-22

Treatment of acetylcholine receptor-antibody positive generalised myasthenia gravis

Day 120 opinion

Action: For adoption

Neurology

2.1.8. Adult differentiated autologous T-cells from peripheral blood, expanded and transduced with a lentivirus to express a chimeric antigen receptor with anti-CD19

specificity (A3B1) conjugated with the co-stimulatory regions 4-1BB and CD3z -
EMEA-003264-PIP01-22

Treatment of B-lymphoblastic leukaemia/lymphoma

Day 120 opinion

Action: For adoption

Oncology

2.1.9. Live attenuated respiratory syncytial virus (RSV) - EMEA-003277-PIP01-22

Prevention of respiratory syncytial virus (RSV) diseases

Day 120 opinion

Action: For adoption

Vaccines

2.1.10. Single-stranded 5' capped mRNA encoding the Respiratory syncytial virus glycoprotein F stabilized in the prefusion conformation - EMEA-003309-PIP01-22

Prevention of lower respiratory tract illness (LRTI) caused by respiratory syncytial virus (RSV)

Day 120 opinion

Action: For adoption

Vaccines

2.1.11. Iodine (131I) apamistamab - Orphan - EMEA-003395-PIP01-23

Immedica Pharma AB; Conditioning treatment prior to haematopoietic stem cell transplantation (HSCT) in malignant neoplasms of haematopoietic and lymphoid tissue

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Oncology

2.1.12. Amphotericin B - Orphan - EMEA-003391-PIP01-23

Matinas BioPharma Holdings Inc.; Treatment of cryptococcosis

Day 60 opinion

Action: For adoption

Infectious Diseases

2.1.13. Carbidopa / levodopa - EMEA-003384-PIP02-23

Treatment of Parkinson's disease

Day 60 opinion

Action: For adoption

Neurology

2.1.14. Deutetrabenazine - EMEA-002052-PIP02-23

Treatment of tardive dyskinesia

Day 60 opinion

Action: For adoption

Neurology

2.1.15. Inhibitor of receptor-interacting serine/threonine-protein kinase 1 (RIPK1) - EMEA-003383-PIP02-23

Treatment of amyotrophic lateral sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.1.16. Belzutifan - Orphan - EMEA-002619-PIP02-23

Merck, Sharp & Dohme (Europe) Inc; Treatment of von Hippel-Lindau disease (except von Hippel-Lindau disease associated renal cell carcinoma) / Treatment of neuroendocrine tumours

Day 60 opinion

Action: For adoption

Oncology

2.1.17. EMEA-003260-PIP02-23

Treatment of biliary tract cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.18. (S)-lactic acid - EMEA-003247-PIP02-23

Treatment of degenerative disc disease

Day 60 opinion

Action: For adoption

Other

2.2. Opinions on Compliance Check

2.2.1. Dry aqueous extract of *Paullinia cupana* seed / liquid ethanolic extract 30 per cent (w/w) of *Allium cepa* fresh bulb and citrus limon fresh fruit / dry hydroethanolic extract of *Theobroma cacao* seed - EMEA-C-001835-PIP01-15-M05

LEGACY HEALTHCARE (FRANCE)SAS; Treatment of alopecia

Day 60 opinion

Action: For adoption

Dermatology

2.2.2. Efanesoctocog alfa - EMEA-C-002501-PIP01-18-M03

Swedish Orphan Biovitrium; Treatment of haemophilia A

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. 3,4-Dimethoxy-N-methylbenzohydroxamic acid / deferoxamine mesylate / alpha-ketoglutaric acid / arginine / alanine / glycine / aspartic acid / tryptophan / N-acetyl-histidine (monohydrate) / histidine / calcium chloride (dihydrate) / magnesium chloride (hexahydrate) / potassium chloride / sodium chloride - EMEA-002735-PIP01-19-M01

Dr. Franz Köhler Chemie GmbH; Cardioplegia

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. 3,4-Dimethoxy-N-methylbenzohydroxamic acid / deferoxamine mesylate / alpha-ketoglutaric acid / arginine / alanine / glycine / aspartic acid / tryptophan / N-acetyl-histidine (monohydrate) / histidine / calcium chloride (dihydrate) /

magnesium chloride (hexahydrate) / potassium chloride / sodium chloride - EMEA-002735-PIP03-20-M02

Dr. Franz Köhler Chemie GmbH; Heart transplantation

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.3. Landiolol (hydrochloride) - EMEA-001150-PIP02-13-M05

AOP Orphan Pharmaceuticals GmbH; Treatment of supraventricular arrhythmias

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.4. Treprostinil - EMEA-000207-PIP01-08-M08

Ferrer Internacional, S.A.; Other secondary hypertension / Primary pulmonary hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.5. Brodalumab - EMEA-001089-PIP02-13-M04

LEO Pharma A/S; Treatment of psoriasis

Day 60 opinion

Action: For adoption

Dermatology

2.3.6. Ethinyl estradiol / dienogest - EMEA-002229-PIP02-21-M01

Chemo Research; Treatment of polycystic ovary syndrome

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.7. Denecimig - EMEA-002762-PIP02-20-M01

Novo Nordisk A/S; Treatment of haemophilia A

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.8. [Lamivudine \(3TC\) / abacavir \(ABC\) / dolutegravir \(DTG\) - EMEA-001219-PIP01-11-M07](#)

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

Day 60 opinion

Action: For adoption

Infectious Diseases

Note: Withdrawal request received on 13 April 2023

2.3.9. [Posaconazole - EMEA-000468-PIP02-12-M08](#)

Merck Sharp & Dohme (Europe), Inc.; Prevention of invasive fungal infections / Treatment of invasive fungal infections

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.10. [Regdanvimab - EMEA-002961-PIP01-21-M02](#)

Celltrion Healthcare Hungary Kft.; Treatment of coronavirus disease 2019 (COVID-19)

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.11. [Sotrovimab - EMEA-002899-PIP01-20-M02](#)

GlaxoSmithKline Trading Services Ltd; Treatment of coronavirus disease 2019 (COVID-19)

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.12. [Tenofovir alafenamide / rilpivirine / emtricitabine - EMEA-001679-PIP01-14-M03](#)

Gilead Sciences International Ltd.; Treatment of human immunodeficiency virus (HIV-1) infection

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.13. Efinaconazole - EMEA-001627-PIP01-14-M03

Almirall, S.A.; Treatment of onychomycosis (tinea unguium)

Day 60 opinion

Action: For adoption

Infectious Diseases / Dermatology

2.3.14. Ataluren - Orphan - EMEA-000115-PIP01-07-M13

PTC Therapeutics International, Limited; Treatment of dystrophinopathy

Day 60 opinion

Action: For adoption

Neurology

2.3.15. Cenobamate - EMEA-002563-PIP02-19-M02

Angelini Pharma S.p.A; Treatment of focal onset seizures / Treatment of primary generalised tonic clonic seizures

Day 60 opinion

Action: For adoption

Neurology

2.3.16. Odronextamab - Orphan - EMEA-003149-PIP01-21-M01

Regeneron Ireland DAC; Treatment of mature B cell malignancies

Day 60 opinion

Action: For adoption

Oncology

2.3.17. Bilastine - EMEA-000347-PIP02-16-M05

Faes Farma S.A.; Treatment of allergic conjunctivitis

Day 60 opinion

Action: For adoption

Ophthalmology

2.3.18. Ponesimod - EMEA-000798-PIP01-09-M04

Janssen-Cilag International NV; Treatment of multiple sclerosis

Day 60 opinion

Action: For adoption

Other / Neurology

2.3.19. Adsorbed modified allergen extract of a mixture of 50% *Dermatophagoides pteronyssinus* and 50% *Dermatophagoides farinae* - EMEA-000902-PIP01-10-M01

HAL Allergy BV; Treatment of allergic rhinitis/rhino-conjunctivitis

Day 60 opinion

Action: For adoption

Pneumology - Allergology

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. Perflubutane - EMEA-C1-003037-PIP02-22

GE Healthcare AS; Diagnostic evaluation of focal hepatic lesions

Day 30 letter

Action: For information

Diagnostic / Oncology

2.7.2. Crovalimab - EMEA-C1-002709-PIP01-19-M01

F.Hoffmann La Roche GmbH; Treatment of atypical haemolytic uremic syndrome

Day 30 letter

Action: For information

Haematology-Hemostaseology

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. [Adapalene, micronised / benzoyl peroxide, hydrous / clindamycin - EMEA-003263-PIP01-22](#)

Treatment of acne vulgaris

Day 90 discussion

Action: For discussion

Dermatology

3.1.2. [Spesolimab - EMEA-002475-PIP03-22](#)

Treatment of Netherton syndrome

Day 90 discussion

Action: For discussion

Dermatology

3.1.3. [EMEA-003019-PIP01-21](#)

Treatment of inborn errors of amino acid metabolism

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.4. [Izokibep - EMEA-003325-PIP01-22](#)

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis, and juvenile idiopathic arthritis)

Day 90 discussion

Action: For discussion

3.1.5. [Lenacapavir / bictegravir - EMEA-003324-PIP01-22](#)

Treatment of human immunodeficiency virus (HIV-1) infection

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.6. [Posoleucel - Orphan - EMEA-002908-PIP02-22](#)

AlloVir International DAC; Prevention of viral disease in haematopoietic stem cell transplantation (HCT)

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.7. [1-\(4-\(6-chloropyridazin-3-yl\)piperazin-1-yl\)-2-\(4-cyclopropyl-3-fluorophenyl\)ethan-1-one - Orphan - EMEA-003268-PIP01-22](#)

Bridge Bio Europe B.V.; Treatment of pantothenate kinase-associated neurodegeneration

Day 90 discussion

Action: For discussion

Other

3.1.8. [Immunoglobulin G4 \[228-proline\], anti-\(*Betula alleghaniensis* allergen Bet v 1\) \(human monoclonal \$\gamma\$ 4-chain\), disulphide with human monoclonal \$\kappa\$ -chain, dimer / immunoglobulin G4 \[227-proline\], anti-\(*Betula alleghaniensis* allergen Bet v 1\) \(human monoclonal \$\gamma\$ 4-chain\), disulphide with human monoclonal \$\kappa\$ -chain, dimer / immunoglobulin G4 \[224-proline\], anti-\(*Betula alleghaniensis* allergen Bet v 1\) \(human monoclonal \$\gamma\$ 4-chain\), disulphide with human monoclonal \$\kappa\$ -chain, dimer - EMEA-003270-PIP01-22](#)

Treatment of allergic rhinitis with or without conjunctivitis in birch tree pollen allergic patients

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.9. [EMEA-003276-PIP01-22](#)

Treatment of post-traumatic stress disorder

Day 90 discussion

Action: For discussion

Psychiatry

3.1.10. [Phuket modRNA / Darwin modRNA / Austria modRNA / Wisconsin modRNA - EMEA-003318-PIP01-22](#)

Prevention of influenza disease

Day 90 discussion

Action: For discussion

Vaccines

3.1.11. [Recombinant human monoclonal antibody to insulin receptor - Orphan - EMEA-002813-PIP01-23](#)

Rezolute (Bio) Ireland Limited; Treatment of hyperinsulinaemic hypoglycaemia

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.12. [Inebilizumab - EMEA-001911-PIP03-23](#)

Treatment of immunoglobulin G4-related disease (IgG4-RD)

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.13. [Upadacitinib - EMEA-001741-PIP09-23](#)

Treatment of systemic lupus erythematosus

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.14. [Haematopoietic stem cells and blood progenitors umbilical cord-derived expanded with \(1R,4R\)-N1-\(2-benzyl-7-\(2-methyl-2H-tetrazol-5-yl\)-9H-pyrimido\[4,5-b\]indol-4-yl\)cyclohexane-1,4-diamine dihydrobromide dihydrate \(ECT-001-CB\) - Orphan - EMEA-003025-PIP03-23](#)

ExCellThera; Treatment in allogeneic haematopoietic stem cell transplantation

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Oncology / Haematology-Hemostaseology

3.1.15. [Broadly neutralising anti-HIV human monoclonal antibody - EMEA-003392-PIP01-23](#)

Treatment of human immunodeficiency virus (HIV-1) infection

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.16. [Dordaviprone - Orphan - EMEA-003389-PIP01-23](#)

Chimerix IRL Limited; Treatment of high-grade glioma

Day 60 discussion

Action: For discussion

Oncology

3.1.17. [ALM \(Almonds\), CAS \(Cashews\), COD \(Codfish\), EGG \(Egg\), HAZ \(Hazelnuts\), MIL \(Milk\), PEA \(Peanuts\), PEC \(Pecans\), PIS \(Pistachios\), SAL \(Salmon\), SES \(Sesame Seed\), SHR \(Shrimp\), SOY \(Soybeans\), WAL \(Walnuts\), WHE \(Wheat\) - EMEA-003397-PIP01-23](#)

Treatment of food allergy

Day 60 discussion

Action: For discussion

Other

3.1.18. [EMEA-003394-PIP01-23](#)

Treatment of Duchenne/Becker muscular dystrophy

Day 60 discussion

Action: For discussion

Other / Neurology

3.1.19. [Sodium hyaluronate / xylometazoline - EMEA-003387-PIP01-22](#)

Treatment of acute viral rhinosinusitis

Day 60 discussion

Action: For discussion

Oto-rhino-laryngology

3.1.20. Salbutamol - EMEA-003398-PIP01-23

Treatment of asthma

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.21. Tanimilast - EMEA-003393-PIP01-23

Treatment of asthma

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.22. Complement factor B antisense oligonucleotide - EMEA-003396-PIP01-23

Treatment of glomerulonephritis and nephrotic syndrome / Treatment of primary IgAN

Day 60 discussion

Action: For discussion

Uro-nephrology

3.1.23. Influenza virus type B, whole virion, inactivated / influenza virus type A H3N2, whole virion, inactivated / influenza virus Type A H1N1, whole virion, inactivated - EMEA-003267-PIP02-23

Prevention of influenza disease

Day 30 discussion

Action: For discussion

3.1.24. Acetylsalicylic acid / rosuvastatin - EMEA-003410-PIP01-23

Prevention of cardiovascular events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.25. Indapamide / candesartan (cilexetil) - EMEA-003401-PIP01-23

I10 Essential primary hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.26. Rivaroxaban / amlodipine - EMEA-003412-PIP01-23

Treatment of hypertension / Prevention of thromboembolic events / Prevention of stroke and systemic embolism

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.27. Semaglutide - EMEA-003402-PIP01-23

Treatment of non-alcoholic steatohepatitis (NASH)

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.28. Tetrahydrouridine / decitabine - Orphan - EMEA-003404-PIP01-23

Novo Nordisk A/S; Treatment of sickle cell disease (SCD)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.29. EMEA-003350-PIP01-23

Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.30. Belimumab - EMEA-000520-PIP03-23

Treatment of systemic sclerosis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

[3.1.31. Daxdilimab - EMEA-003411-PIP01-23](#)

Treatment of systemic lupus erythematosus

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

[3.1.32. Deucravacitinib - EMEA-002350-PIP05-23](#)

Treatment of Sjögren's syndrome

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

[3.1.33. Efozofitmod - Orphan - EMEA-003352-PIP02-23](#)

FGK Representative Service GmbH; Treatment of systemic sclerosis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

[3.1.34. Nipocalimab - Orphan - EMEA-002559-PIP08-23](#)

Janssen-Cilag International NV; Treatment of idiopathic inflammatory myopathies

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

[3.1.35. Secukinumab - EMEA-000380-PIP10-23](#)

Treatment of polymyalgia rheumatica

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.36. Secukinumab - EMEA-000380-PIP11-23

Treatment of rotator cuff tendinopathy

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.37. Niclosamide ethanolamine - EMEA-003407-PIP01-23

Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.38. Povidone-iodine - EMEA-003413-PIP01-23

Treatment of common cold

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.39. Reparixin - Orphan - EMEA-001693-PIP05-23

Dompé farmaceutici S.p.A.; Treatment of acute respiratory distress syndrome (ARDS)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.40. Bidridistrogene xeboparvovec - Orphan - EMEA-003400-PIP01-23

Sarepta Therapeutics Ireland; Treatment of limb-girdle muscular dystrophy type 2E/R4

Day 30 discussion

Action: For discussion

Neurology

3.1.41. Opicapone - EMEA-003406-PIP01-23

Treatment of Parkinson's disease

Day 30 discussion

Action: For discussion

Neurology

3.1.42. [Vemircopan - Orphan - EMEA-002863-PIP02-23](#)

Alexion Europe SAS; Treatment of generalised myasthenia gravis

Day 30 discussion

Action: For discussion

Neurology

3.1.43. [EMEA-003409-PIP01-23](#)

Treatment of solid malignancies

Day 30 discussion

Action: For discussion

Oncology

3.1.44. [Therapeutic DNA plasmid vaccine targeting HPV16 E6 and E7 proteins - EMEA-003403-PIP01-23](#)

Treatment of head and neck cancer / Treatment of cervical cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.45. [Gallium \(68Ga\) boclatixafortide - EMEA-003408-PIP01-23](#)

Staging of adult patients with confirmed marginal zone lymphoma

Day 30 discussion

Action: For discussion

Other

3.1.46. [mRNA encoding CMV gB / mRNA encoding the gH protein in the CMV glycoprotein complex pentamer / mRNA encoding the UL131A protein in the CMV glycoprotein complex pentamer / mRNA encoding the UL130 protein in the CMV glycoprotein complex pentamer / mRNA encoding the gL protein in the CMV glycoprotein complex pentamer / mRNA encoding the UL128 protein in the CMV glycoprotein complex pentamer - EMEA-003405-PIP01-23](#)

Prevention of cytomegalovirus infection

Day 30 discussion

Action: For discussion

Vaccines

3.1.47. [Zapomeran - EMEA-003349-PIP01-22](#)

Prevention of coronavirus disease 2019 (COVID-19)

Day D60 discussion

Action: For discussion

Vaccines

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. [Sotatercept - EMEA-C1-002756-PIP01-19-M01](#)

Merck Sharp & Dohme B.V.; Treatment of pulmonary arterial hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.2.2. [Apremilast - EMEA-C2-000715-PIP03-11-M06](#)

Amgen Europe B.V.; Treatment of psoriasis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Dermatology

3.2.3. [Avibactam / aztreonam - EMEA-C1-002283-PIP01-17-M04](#)

Pfizer Europe MA EEIG; Treatment of infections caused by aerobic gram-negative bacteria

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.4. [Baloxavir marboxil - EMEA-C3-002440-PIP01-18-M04](#)

Roche Registration GmbH; Treatment of influenza

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.5. Lenvatinib - EMEA-C-001119-PIP02-12-M08

Eisai GmbH; Treatment of osteosarcoma

Day 30 discussion

Action: For discussion

Oncology

3.2.6. Human thrombin (component 2) / human fibrinogen (component 1) - EMEA-C-001598-PIP01-13-M03

Instituto Grifols, S.A.; Treatment of haemorrhage resulting from a surgical procedure

Day 30 discussion

Action: For discussion

Other

3.2.7. Dermatophagoides pteronyssinus / dermatophagoides farinae - EMEA-C3-001258-PIP01-11-M08

ALK-Abelló A/S; Treatment of allergic rhinitis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Azilsartan medoxomil - EMEA-000237-PIP01-08-M11

Takeda Development Centre Europe Ltd; Treatment of hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. Macitentan - Orphan - EMEA-001032-PIP01-10-M06

Janssen-Cilag International NV; Treatment of pulmonary arterial hypertension / Treatment of idiopathic pulmonary fibrosis / Treatment of systemic sclerosis

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.3. [Mavacamten - EMEA-002231-PIP01-17-M01](#)

Bristol-Myers Squibb Pharma EEIG; Treatment of hypertrophic cardiomyopathy

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.4. [Nemolizumab - EMEA-001624-PIP01-14-M06](#)

Galderma International S.A.S; Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.3.5. [Rocatinlimab - EMEA-002886-PIP01-20-M03](#)

Amgen Europe B.V; Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.3.6. [Recombinant parathyroid hormone: rhPTH \(1-84\) - Orphan - EMEA-001526-PIP01-13-M06](#)

Takeda Pharmaceuticals International AG Ireland Branch; Hypoparathyroidism

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.7. [Potassium chloride / sodium chloride / ascorbic acid / sodium sulfate / sodium ascorbate / polyethylene glycol 3350 - EMEA-001705-PIP02-15-M04](#)

Norgine Limited; Bowel cleansing prior to clinical procedures

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.8. Efgartigimod alfa - Orphan - EMEA-002597-PIP04-21-M01

argenx BV; Treatment of immune thrombocytopenia

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.9. Baricitinib - EMEA-001220-PIP01-11-M08

Eli Lilly and Company Limited; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondyloarthritis, psoriatic arthritis and juvenile idiopathic arthritis)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.10. Ixekizumab - EMEA-001050-PIP02-18-M02

Eli Lilly and Company (Ireland) Limited; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondyloarthritis and juvenile idiopathic arthritis)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.11. Upadacitinib - EMEA-001741-PIP01-14-M06

AbbVie Ltd; Treatment of chronic idiopathic arthritis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.12. Tenofovir alafenamide / emtricitabine / bictegravir - EMEA-001766-PIP01-15-M05

Gilead Sciences International Ltd.; Treatment of human immunodeficiency virus (HIV) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.13. Soticlestat - Orphan - EMEA-002572-PIP02-19-M03

Takeda Pharma A/S; Dravet syndrome / Lennox-Gastaut syndrome

Day 30 discussion

Action: For discussion

Neurology

3.3.14. (4S,7aR,9aR,10S,11E,14S,15R)-6'-chloro-10-methoxy-14,15-dimethyl-3',4',7a,8,9,9a,10,13,14,15-decahydro-2'H,7H-spiro[1,19-ethenocyclobuta[i][1,4]oxazepino[3,4f][1,2,7]thiadiazacyclohexadecine-4,1'-naphthalen]-18(17H)-one 16,16-dioxide (AMG 176) - EMEA-002631-PIP01-19-M02

Amgen Europe BV; Treatment of acute myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.3.15. Magrolimab - Orphan - EMEA-002819-PIP01-20-M01

Gilead Sciences International Ltd; Treatment of myelodysplastic syndromes (including juvenile myelomonocytic leukaemia) / Treatment of acute myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.3.16. Talimogene laherparepvec - EMEA-001251-PIP01-11-M06

Amgen Europe B.V.; Treatment of melanoma

Day 30 discussion

Action: For discussion

Oncology

3.3.17. Gilteritinib (as fumarate) - Orphan - EMEA-002064-PIP01-16-M05

Astellas Pharma Europe B.V.; Treatment of acute myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.3.18. Ivacaftor / tezacaftor / elexacaftor - Orphan - EMEA-002324-PIP01-17-M04

Vertex Pharmaceuticals (Ireland) Limited; Treatment of cystic fibrosis

Day 30 discussion

Action: For discussion

Other / Pneumology - Allergology

3.3.19. Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA-002330-PIP01-18-M03

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

Day 30 discussion

Action: For discussion

Vaccines

3.3.20. Modified vaccinia Ankara - Bavarian Nordic virus (smallpox) - EMEA-001161-PIP02-11-M03

Bavarian Nordic A/S; Prevention of smallpox, mpox and related orthopoxvirus infection

Day 30 discussion

Action: For discussion

Vaccines

3.3.21. NVX-CoV2373 - EMEA-002941-PIP01-20-M03

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

Day 30 discussion

Action: For discussion

Vaccines

3.3.22. Recombinant COVID-19 subunit nanoparticle (adjuvanted with AS03) (GBP510) - EMEA-003115-PIP01-21-M01

SK Chemicals GmbH; Prevention 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 24 April 2023 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. Strategic Review and Learning Meeting (SRLM)

No item

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 Party: D30 Products identified

PDCO member: Karen van Malderen

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward (*ad interim*)

Action: For information

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

No item

9.4. Cooperation within the EU regulatory network

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

No item

9.5. Cooperation with International Regulators

9.5.1. Paediatric Cluster Teleconference

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

9.8.1. EMA Business Pipeline activity and Horizon scanning

No item

10. Any other business

10.1. ACT EU multi-stakeholder platform

Action: For information

10.2. Concept paper on the need to update the inflammatory bowel disease (IBD) guideline

Action: For information

10.3. COVID-19 update

Action: For information

10.4. EU Network Training Centre: Paediatric curriculum and rollout of Learning & Development toolkit

Action: For information

10.5. New Experts Management tool

Action: For information

10.6. Prerequisites for PIP modification of an approved PIP

Action: For discussion

10.7. Revision of EMA policy 0044 on handling of competing interests of scientific committees' members and experts

Action: For information

10.8. Upcoming Innovation Task Force (ITF) meetings

Action: For information

11. Breakout sessions

11.1. Neonatology

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

11.2. Vaccines

Action: For discussion on Wednesday, 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/