



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

03 November 2023
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Human Medicines Division

Paediatric Committee (PDCO)

Draft Agenda for the meeting on 07-10 November 2023

Chair: Brian Aylward – Vice-Chair: Sylvie Benchetrit

07 November 2023, 14:00 - 19:45, room 2C

08 November 2023, 08:30 - 19:45, room 2C

09 November 2023, 08:30 - 19:45, room 2C

10 November 2023, 08:30 - 13:00, room 2C

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the 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 07-10 November 2023. See November PDCO minutes (to be published post December 2023 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 07-10 November 2023.

1.3. Adoption of the minutes

PDCO minutes for 10-13 October 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. EMEA-002674-PIP01-19

Treatment of acne vulgaris

Day 120 opinion

Action: For adoption

Dermatology

2.1.2. Modified messenger ribonucleic acid encoding human propionyl-coenzyme A carboxylase alpha and beta subunits encapsulated into lipid nanoparticles - Orphan - EMEA-003419-PIP01-23

Moderna Biotech Spain, S.L.; Treatment of propionic acidaemia

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.3. [Modified mRNA encoding human methylmalonyl-coenzyme A mutase containing a polymorphism at position 671 - Orphan - EMEA-003437-PIP01-23](#)

Moderna Biotech Spain, S.L.; Treatment of methylmalonic acidaemia

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.4. [EMEA-003350-PIP01-23](#)

Prevention of coronavirus disease 2019 (COVID-19)

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

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

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

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

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

Treatment of human immunodeficiency virus (HIV-1) infection

Day 120 opinion

Action: For adoption

Infectious Diseases

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

Alexion Europe SAS; Treatment of generalised myasthenia gravis

Day 120 opinion

Action: For adoption

Neurology

2.1.8. [Olutasidenib - Orphan - EMEA-003421-PIP01-23](#)

Rigel Pharmaceuticals B.V.; Treatment of acute myeloid leukaemia

Day 120 opinion

Action: For adoption

Oncology

2.1.9. Tamibarotene - Orphan - EMEA-003329-PIP02-22

Syros Pharmaceutical (Ireland) Limited; Treatment of acute myeloid leukaemia / Treatment of myelodysplastic syndromes

Day 120 opinion

Action: For adoption

Oncology

Note: withdrawal request received on 01 November 2023

2.1.10. Cedazuridine / decitabine – Orphan - EMEA-003071-PIP02-23

Otsuka Pharmaceutical Netherlands B.V.; Treatment of myelodysplastic syndromes

Day 120 opinion

Action: For adoption

Oncology / Haematology-Hemostaseology

2.1.11. Taldefgrobep alfa - Orphan - EMEA-003386-PIP01-22

Biohaven Bioscience Ireland Limited; Treatment of spinal muscular atrophy

Day 120 opinion

Action: For adoption

Other

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

Treatment of immunoglobulin A nephropathy (IgAN)

Day 120 opinion

Action: For adoption

Uro-nephrology

2.1.13. EMEA-003487-PIP01-23

Prevention of cardiovascular events

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

Note: withdrawal request received on 19 October 2023

2.1.14. Elinzanetant - EMEA-003500-PIP01-23

Treatment of vasomotor symptoms caused by endocrine therapy related to breast cancer

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.15. Humanised IgG1 kappa monoclonal antibody directed against IGF-1R - EMEA-003499-PIP01-23

Treatment of thyroid eye disease

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.16. Sitagliptin / dapagliflozin - EMEA-003486-PIP01-23

Treatment of type 2 diabetes mellitus

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.17. Diflunisal - Orphan - EMEA-003490-PIP01-23

AO Pharma AB; Treatment of transthyretin amyloidosis

Day 60 opinion

Action: For adoption

Neurology

2.1.18. EMEA-003495-PIP01-23

Treatment of tenosynovial giant cell tumours

Day 60 opinion

Action: For adoption

Oncology

2.1.19. [Oregovomab - EMEA-003497-PIP01-23](#)

Treatment of ovarian cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.20. [Rilvegostomig - EMEA-003501-PIP01-23](#)

Treatment of biliary tract cancer / Treatment of lung cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.21. [Lotilaner - EMEA-003488-PIP01-23](#)

Treatment of *Demodex* blepharitis

Day 60 opinion

Action: For adoption

Ophthalmology / Infectious Diseases

2.1.22. [DNA plasmid encoding HPV type 18 consensus E6 and E7 proteins / DNA plasmid encoding HPV type 16 consensus E6 and E7 proteins - EMEA-002022-PIP02-23](#)

Treatment of squamous intraepithelial lesions of the anus caused by HPV types 16 and 18

Day 60 opinion

Action: For adoption

Vaccines / Infectious Diseases

2.1.23. [Baxdrostat - EMEA-003507-PIP01-23](#)

Treatment of hypertension

Day 30 opinion

Action: For adoption

Cardiovascular Diseases

2.1.24. [Retifanlimab – Orphan – EMEA-002798-PIP04-23](#)

Incyte Biosciences Distribution B.V.; Treatment of lung cancer

Day 30 opinion

Action: For adoption

Oncology

2.2. Opinions on Compliance Check

2.2.1. Dupilumab - EMEA-C1-001501-PIP07-20-M01

Sanofi Winthrop Industrie; Treatment of chronic spontaneous urticaria

Day 60 letter

Action: For adoption

Dermatology

2.2.2. Doxribtimine / doxecitine - EMEA-C1-003210-PIP01-22

UCB Pharma S.A.; Treatment of thymidine kinase 2 deficiency

Day 60 letter

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.2.3. Avibactam / ceftazidime - EMEA-C-001313-PIP01-12-M13

Pfizer Europe MA EEIG; Treatment of intra-abdominal infections

Day 60 opinion

Action: For adoption

Infectious Diseases

2.2.4. Eliglustat - EMEA-C-000461-PIP02-11-M05

Sanofi B.V.; Treatment of Gaucher disease type 1 and type 3

Day 60 opinion

Action: For adoption

Other

2.2.5. Isoflurane – EMEA-C-002320-PIP01-17-M03

Sedana Medical AB; Sedation of mechanically ventilated patients

Day 30 opinion

Action: For adoption

Neonatology – Paediatric Intensive Care

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Birch bark extract - EMEA-001299-PIP01-12-M02

Amryt Pharmaceuticals DAC; Treatment of skin injuries

Day 60 opinion

Action: For adoption

Dermatology

2.3.2. Delgocitinib - EMEA-002329-PIP02-20-M03

LEO Pharma A/S; Treatment of chronic hand eczema

Day 60 opinion

Action: For adoption

Dermatology

2.3.3. Glycopyrronium bromide - EMEA-002383-PIP01-18-M03

Dr. August Wolff GmbH & Co. KG - Arzneimittel; Treatment of hyperhidrosis

Day 60 opinion

Action: For adoption

Dermatology

2.3.4. Interleukin-23 receptor antagonist peptide - EMEA-003301-PIP01-22-M01

Janssen-Cilag International NV; Treatment of psoriasis

Day 60 opinion

Action: For adoption

Dermatology

2.3.5. Ritlecitinib - EMEA-002451-PIP01-18-M02

Pfizer Europe MA EEIG; Treatment of alopecia areata

Day 60 opinion

Action: For adoption

Dermatology

2.3.6. Venglustat - Orphan - EMEA-001716-PIP04-19-M01

Sanofi B.V.; Treatment of GM2 gangliosidosis / Treatment of GM1 gangliosidosis / Treatment of galactosialidosis / Treatment of sialidosis

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.7. Filgotinib - EMEA-001619-PIP03-16-M02

Galapagos NV; Treatment of ulcerative colitis / Treatment of Crohn's disease

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.8. Mirikizumab - EMEA-002208-PIP01-17-M03

Eli Lilly and Company; Treatment of ulcerative colitis / Treatment of Crohn's disease

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.9. Potassium chloride / sodium chloride / ascorbic acid / sodium sulfate / sodium ascorbate / polyethylene glycol 3350 - EMEA-001705-PIP02-15-M05

Norgine Limited; Bowel cleansing prior to clinical procedures

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.10. Zinc gluconate / alisitol / retinyl palmitate - Orphan - EMEA-002198-PIP01-21-M01

Vanessa Research Spain S.L.; Treatment of microvillus inclusion disease

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.11. Iron as ferric maltol - EMEA-001195-PIP01-11-M07

Norgine BV; Treatment of iron deficiency

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.12. Baricitinib - EMEA-001220-PIP01-11-M09

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

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.13. Cendakimab - EMEA-002640-PIP01-19-M01

Bristol-Myers Squibb Pharma EEIG; Treatment of eosinophilic esophagitis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.14. Rilzabrutinib - Orphan - EMEA-002438-PIP02-19-M03

Sanofi B.V.; Treatment of immune thrombocytopenia

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.15. Fully human IgG1 RB-1 YTE anti-RSV F monoclonal antibody - EMEA-002755-PIP01-19-M02

Merck Sharp & Dohme (Europe), Inc.; Prevention of lower respiratory tract infection caused by respiratory syncytial virus

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.16. Vaborbactam / meropenem - EMEA-001731-PIP01-14-M04

Menarini International Operations Luxembourg S.A.; Treatment of gram-negative bacterial infections

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.17. Inebilizumab - EMEA-001911-PIP01-15-M05

Horizon Therapeutics Ireland DAC; Treatment of neuromyelitis optica spectrum disorders

Day 60 opinion

Action: For adoption

Neurology

2.3.18. Pridopidine (hydrochloride) - Orphan - EMEA-003174-PIP01-21-M01

Prilenia Therapeutics B.V.; Treatment of Huntington disease (HD)

Day 60 opinion

Action: For adoption

Neurology

2.3.19. Vamorolone - Orphan - EMEA-001794-PIP02-16-M06

Santhera Pharmaceuticals (Deutschland) GmbH; Treatment of Duchenne muscular dystrophy

Day 60 opinion

Action: For adoption

Other

2.3.20. Meloxicam / bupivacaine - EMEA-002246-PIP01-17-M04

Heron Therapeutics B.V.; Treatment of acute postoperative pain

Day 60 opinion

Action: For adoption

Pain

2.3.21. Mirabegron - EMEA-000597-PIP02-10-M10

Astellas Pharma Europe B.V.; Treatment of idiopathic overactive bladder

Day 60 opinion

Action: For adoption

Uro-nephrology

2.3.22. Pneumococcal polysaccharide serotype 35B – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 31 – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 24F – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 23B – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 23A – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 16F – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 15C – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 15A – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 20A – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 17F – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 12F – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 11A – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 10A – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 9N – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 8 – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 33F – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 22F – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 19A – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 7F – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 6A – diphtheria CRM197 conjugate /
Pneumococcal polysaccharide serotype 3 – diphtheria CRM197 conjugate - EMEA-
003155-PIP01-21-M01

Merck Sharp & Dohme (Europe), Inc.; Prevention of disease caused by *Streptococcus pneumoniae*

Day 60 opinion

Action: For adoption

Vaccines

2.3.23. Recombinant respiratory syncytial virus pre-fusion F protein, adjuvanted with AS01E - EMEA-002904-PIP01-20-M01

GlaxoSmithKline Biologicals S.A.; Prevention of lower respiratory tract disease caused by respiratory syncytial virus

Day 60 opinion

Action: For adoption

Vaccines

2.3.24. Etrasimod L-arginine - EMEA-002713-PIP02-21-M01

Pfizer Europe MA EEIG; Treatment of Crohn's disease

Day 30 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.25. Satralizumab - Orphan - EMEA-001625-PIP01-14-M07

Roche Registration GmbH; Treatment of neuromyelitis optica spectrum disorders

Day 30 opinion

Action: For adoption

Neurology

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. Tezacaftor / ivacaftor / elexacaftor – EMEA-C5-002324-PIP01-17-M05

Vertex Pharmaceuticals (Ireland) Limited; Treatment of cystic fibrosis

Day 30 letter

Action: For information

Other

2.7.2. Fidanacogene elaparvovec – EMEA-C2-002362-PIP02-19-M02

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

Day 30 letter

Action: For information

Haematology-Hemostaseology

2.7.3. Nirogacestat hydrobromide – EMEA-C1-002971-PIP01-21

SpringWorks Therapeutics Ireland Limited; Treatment of soft tissue sarcoma

Day 30 letter

Action: For information

Oncology

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. Obicetrapib - EMEA-003438-PIP02-23

Treatment of elevated cholesterol

Day 90 discussion

Action: For discussion

Cardiovascular Diseases

3.1.2. Remibrutinib - EMEA-002582-PIP03-23

Treatment of chronic inducible urticaria

Day 90 discussion

Action: For discussion

Dermatology

3.1.3. Frexalimab - EMEA-002945-PIP03-23

Treatment of type 1 diabetes mellitus

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.4. Semaglutide - EMEA-003402-PIP01-23

Treatment of non-alcoholic steatohepatitis (NASH)

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.5. Tarperprumig - Orphan - EMEA-003432-PIP01-23

Alexion Europe SAS; Treatment of sickle cell disease (SCD)

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.6. EMEA-003271-PIP02-22

Treatment of epilepsy syndromes / Treatment of primary generalised tonic-clonic seizures

Day 90 discussion

Action: For discussion

Neurology

3.1.7. Dordaviprone - Orphan - EMEA-003389-PIP01-23

Chimerix IRL Limited; Treatment of glioma

Day 90 discussion

Action: For discussion

Oncology

3.1.8. Trotabresib - EMEA-003361-PIP01-22

Treatment of malignant neoplasms of the central nervous system

Day 90 discussion

Action: For discussion

Oncology

3.1.9. Apitegromab - Orphan - EMEA-002951-PIP02-21

Scholar Rock, Inc.; Treatment of spinal muscular atrophy

Day 90 discussion

Action: For discussion

Other / Neurology

3.1.10. Ferric citrate coordination complex (FCCC) - EMEA-001213-PIP03-23

Treatment of anaemias due to chronic kidney disorders

Day 90 discussion

Action: For discussion

Uro-nephrology

3.1.11. [Zigakibart - Orphan - EMEA-003300-PIP01-22](#)

Chinook Therapeutics, Inc.; Treatment of primary IgA nephropathy

Day 90 discussion

Action: For discussion

Uro-nephrology

3.1.12. [MRNA encoding for the linked NTD and RBD domains of the spike glycoprotein of SARS-CoV-2 - EMEA-003426-PIP01-23](#)

Prevention of coronavirus disease 2019 (COVID-19)

Day 90 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.1.13. [Seralutinib - Orphan - EMEA-002972-PIP02-23](#)

Gossamer Bio 002 Limited; Treatment of pulmonary arterial hypertension

Day 60 discussion

Action: For discussion

Cardiovascular Diseases

3.1.14. [Govorestat - Orphan - EMEA-003365-PIP02-23](#)

Applied Therapeutics, Inc; Treatment of galactosaemia

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Neurology

3.1.15. [Mitapivat - Orphan - EMEA-002684-PIP03-23](#)

Agios Netherlands B.V.; Treatment of sickle cell disease

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.16. [Allogeneic cultured postnatal thymus-derived tissue - Orphan - EMEA-003496-PIP01-23](#)

Enzyvant Therapeutics Ireland Limited; Treatment of congenital athymia

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.17. [Belumosudil - Orphan - EMEA-003425-PIP02-23](#)

Sanofi Winthrop Industrie; Treatment of chronic lung allograft dysfunction

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.18. [Betula pendula pollen allergoid, mannan-conjugated, polymerised - EMEA-003492-PIP01-23](#)

Treatment of allergic rhinitis/rhino-conjunctivitis / Treatment of birch pollen allergic rhinitis/rhino-conjunctivitis

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.19. [Dermatophagoides pteronyssinus allergoid, mannan-conjugated, polymerised / Dermatophagoides farinae allergoid, mannan-conjugated, polymerised - EMEA-003493-PIP01-23](#)

Treatment of allergic rhinitis/rhino-conjunctivitis / Treatment of house dust mite allergic rhinitis/rhino-conjunctivitis

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.20. [Phleum pratense pollen allergoid, mannan-conjugated, polymerised / Dactylis glomerata pollen allergoid, mannan-conjugated, polymerised - EMEA-003491-PIP01-23](#)

Treatment of grass pollen allergic rhinitis/rhino-conjunctivitis / Treatment of allergic rhinitis/rhino-conjunctivitis

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.21. [Proline derivative - EMEA-003440-PIP01-23](#)

Treatment of type 1 interferonopathies

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.22. [EMEA-003489-PIP01-23](#)

Treatment of relapsed and refractory solid malignant tumours / Treatment of relapsed and refractory malignant neoplasms of the hematopoietic and lymphoid tissue / Treatment of malignant neoplasms of the hematopoietic and lymphoid tissue

Day 60 discussion

Action: For discussion

Oncology

3.1.23. [Live attenuated respiratory syncytial virus \(RSV\) - EMEA-003277-PIP02-23](#)

Prevention of respiratory syncytial virus (RSV) disease

Day 60 discussion

Action: For discussion

Vaccines

3.1.24. [Human papillomavirus type 58 L1 protein / human papillomavirus type 52 L1 protein / human papillomavirus type 45 L1 protein / human papillomavirus type 33 L1 protein / human papillomavirus type 31 L1 protein / human papillomavirus type 18 L1 protein / human papillomavirus type 16 L1 protein / human papillomavirus type 11 L1 protein / human papillomavirus type 6 L1 protein - EMEA-003209-PIP02-23](#)

Prevention of infection by human papillomavirus (HPV)

Day 60 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.1.25. [Ezetimibe / obicetrapib - EMEA-003514-PIP01-23](#)

Treatment of mixed dyslipidaemia

Day 30 discussion

Action: For discussion
Cardiovascular Diseases

3.1.26. Ezetimibe / obicetrapib - EMEA-003514-PIP02-23

Treatment of elevated cholesterol
Day 30 discussion
Action: For discussion
Cardiovascular Diseases

3.1.27. Ruxolitinib - EMEA-002618-PIP04-23

Treatment of *Prurigo nodularis*
Day 30 discussion
Action: For discussion
Dermatology

3.1.28. Venglustat – Orphan – EMEA-001716-PIP08-23

Sanofi B.V.; Treatment of Fabry disease
Day 30 discussion
Action: For discussion
Endocrinology-Gynaecology-Fertility-Metabolism

3.1.29. EMEA-003513-PIP01-23

Treatment of coeliac disease
Day 30 discussion
Action: For discussion
Gastroenterology-Hepatology

3.1.30. Mezagitamab – EMEA-003502-PIP01-23

Treatment of primary immune thrombocytopenia (ITP)
Day 30 discussion
Action: For discussion
Haematology-Hemostaseology

3.1.31. Recombinant humanised IgG1, kappa light chain, long-acting monoclonal antibody – EMEA-003510-PIP01-23

Prevention of hereditary angioedema attacks

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.32. EMEA-003503-PIP01-23

Treatment of eosinophilic granulomatosis with polyangiitis (EGPA)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.33. Nipocalimab – Orphan – EMEA-002559-PIP09-23

Janssen-Cilag International NV; Prevention of fetal and neonatal alloimmune thrombocytopenia

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.34. Zunsemetinib – EMEA-003511-PIP01-23

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

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.35. Humanised IgG1K monoclonal antibody against interferon beta – Orphan – EMEA-003089-PIP02-23

Pfizer Europe MA EEIG; Treatment of idiopathic inflammatory myopathy (ICD11 4A41)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Dermatology

3.1.36. Contezolid – EMEA-003508-PIP01-23

Acute bacterial skin and skin structure infection (ABSSSI) / Moderate to severe diabetic foot infection (DFI) without concomitant osteomyelitis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.37. Contezolid acefosamil – EMEA-003509-PIP01-23

Acute bacterial skin and skin structure infection (ABSSSI) / Moderate to severe diabetic foot infection (DFI) without concomitant osteomyelitis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.38. Cladribine – EMEA-000383-PIP04-23

Treatment of generalised myasthenia gravis (gMG)

Day 30 discussion

Action: For discussion

Neurology

3.1.39. Sonrotoclax – EMEA-003489-PIP02-23

Treatment of malignant solid tumours

Day 30 discussion

Action: For discussion

Oncology

3.1.40. Tifcemalimab – EMEA-003512-PIP01-23

Treatment of all conditions in the category of malignant neoplasms (except central nervous system, lymphoid and haematopoietic malignancies)

Day 30 discussion

Action: For discussion

Oncology

3.1.41. Tinengotinib – EMEA-003504-PIP01-23

Treatment of cholangiocarcinoma

Day 30 discussion

Action: For discussion

Oncology

3.1.42. Faricimab – EMEA-002817-PIP05-23

Treatment of choroidal neovascularisation secondary to pathologic myopia

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.43. Multivalent, recombinant, N-terminal surface protein vaccine, containing the alpha-like proteins Rib, AlpC, Alp1, Alp 2/3 antigens of *Streptococcus agalactiae* – EMEA-003505-PIP01-23

Prevention of group B streptococcal invasive disease in infants through maternal immunisation

Day 30 discussion

Action: For discussion

Vaccines

3.1.44. Doruxapapogenum ralaplasmidum (pGX3024) – Orphan – EMEA-003506-PIP01-23

Inovio, Inc.; Treatment of papilloma viral infections

Day 30 discussion

Action: For discussion

Vaccines / Infectious Diseases

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. Nemolizumab – EMEA-C1-001624-PIP01-14-M06

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

Day 30 discussion

Action: For discussion

Dermatology

3.2.2. Belimumab – EMEA-C-000520-PIP02-13-M04

Glaxo Group Limited; Treatment of systemic lupus erythematosus

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.3. Bimezikumab – EMEA-C1-002189-PIP03-19

Manuel Iniesta; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.4. Apremilast – EMEA-C-000715-PIP03-11-M06

Amgen Europe B.V.; Treatment of psoriasis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Dermatology

3.2.5. Bosutinib – EMEA-C-000727-PIP01-09-M07

Pfizer Europe MA EEIG; Treatment of chronic myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.2.6. Isatuximab – EMEA-C-002205-PIP01-17-M04

Sanofi Aventis Recherche & Développement; Treatment of malignant neoplasms of the haematopoietic and lymphoid tissue

Day 30 discussion

Action: For discussion

Oncology

3.2.7. Palovarotene – EMEA-C-001662-PIP01-14-M05

Ipsen Pharma; Treatment of fibrodysplasia ossificans progressiva

Day 30 discussion

Action: For discussion

Other

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Tocilizumab – EMEA-000309-PIP07-21-M01

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

Day 30 discussion

Action: For discussion

Immunology

3.3.2. Etripamil – EMEA-002303-PIP01-17-M04

Milestone Pharmaceuticals, Inc.; Treatment of supraventricular arrhythmia

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.3. Deucravacitinib – EMEA-002350-PIP01-18-M03

Bristol-Myers Squibb Pharma EEIG; Treatment of psoriasis

Day 30 discussion

Action: For discussion

Dermatology

3.3.4. Tralokinumab – EMEA-001900-PIP02-17-M08

LEO Pharma A/S; Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.3.5. Regadenoson – EMEA-000410-PIP01-08-M06

GE Healthcare AS; Diagnosis of myocardial perfusion disturbances

Day 30 discussion

Action: For discussion

Diagnostic / Cardiovascular Diseases

3.3.6. Adeno-associated viral vector serotype 8 containing the human glucose-6-phosphatase gene (DTX401, pariglasgene breccaparvovec) – Orphan – EMEA-002734-PIP01-19-M01

Ultragenyx Germany GmbH; Treatment of glycogen storage disease type Ia

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.7. Tolvaptan – EMEA-001231-PIP02-13-M11

Otsuka Pharmaceutical Netherlands B.V.; Treatment of polycystic kidney disease

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology

3.3.8. Crizanlizumab - Orphan - EMEA-002141-PIP01-17-M04

Novartis Europharm Limited; Treatment of sickle cell disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.9. Mozafancogene autotemcel - Orphan - EMEA-002578-PIP01-19-M01

Rocket Pharmaceuticals, Inc; Treatment of Fanconi anaemia subtype A

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.10. Apremilast - EMEA-000715-PIP02-11-M07

Amgen Europe B.V.; Treatment of juvenile psoriatic arthritis (JPsA) / Treatment of juvenile idiopathic arthritis (JIA)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.11. Upadacitinib - EMEA-001741-PIP01-14-M07

AbbVie Ltd; Treatment of chronic idiopathic arthritis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.12. Ceftobiprole medocaril sodium - EMEA-000205-PIP02-11-M06

Basilea Pharmaceutica Deutschland GmbH; Treatment of pneumonia

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.13. Ivosidenib - Orphan - EMEA-002247-PIP03-17-M01

Les Laboratoires Servier; Treatment of acute myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.3.14. Obecabtagene autoleucel - Orphan - EMEA-003171-PIP01-21-M01

Autolus GmbH; Treatment of acute lymphoblastic leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.3.15. Odronextamab - Orphan - EMEA-003149-PIP01-21-M02

Regeneron Ireland DAC; Treatment of mature B cell malignancies

Day 30 discussion

Action: For discussion

Oncology

3.3.16. Bupivacaine - EMEA-000877-PIP03-17-M05

Pacira Ireland Ltd; Postsurgical analgesia

Day 30 discussion

Action: For discussion

Pain

3.3.17. Pegcetacoplan - Orphan - EMEA-002600-PIP03-21-M01

Apellis Ireland Limited; Treatment of glomerulonephritis and nephrotic syndrome

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3.18. Dengue tetravalent vaccine (live, attenuated) - EMEA-001888-PIP01-15-M02

Takeda Vaccines, Inc.; Prevention of dengue fever

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 20 November 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

6.1.1. Palazestrant- EMEA-11-2023

Olema Pharmaceuticals Inc.; The classes of androgen receptor modulator, of oestrogen receptor modulator, of growth and sex hormone as well as their releasing or inhibiting factors, and of sex hormone-metabolism modulator medicinal products for treatment of breast malignant neoplasms, prostate malignant neoplasms and neuroendocrine malignant neoplasms / Treatment of advanced and/or metastatic hormone receptor (HR)-positive (HR+), human epidermal growth factor 2-neu (HER2)-negative (HER2-) breast cancer following CDK4/6 inhibitor therapy

Action: For adoption

7. Discussion on the inclusion of 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 \(SRLM\) - Madrid, Spain 17-18 October 2023](#)

Update on the SRLM meeting held in Madrid during the Spanish Presidency

PDCO members: Maria Jesús Fernández Cortizo, Fernando de Andrés Trelles

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 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 \(HCPWP\)](#)

Draft Agenda – PCWP/HCPWP and all eligible meeting on 14 and 15 November 2023

Action: For information

9.3.4. [Upcoming Innovation Task Force \(ITF\) meetings](#)

Action: For information

9.4. **Cooperation within the EU regulatory network**

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

9.7.1. Draft PDCO Work Plan for 2024

PDCO Chair: Brian Aylward

Action: For discussion

9.8. Planning and reporting

9.8.1. EMA Business Pipeline activity and Horizon scanning

No item

10. Any other business

10.1. Quick tour of the clinical trial approval process under Clinical Trial Regulation (CTR)

PDCO member: Anette Solli Karlsen

Action: For information

10.2. Feedback from 12th Paediatric Oncology Strategy Forum

PDCO member: Sylvie Benchetrit

Action: For information

11. Breakout sessions

11.1. Paediatric oncology

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

11.2. Neonatology

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

11.3. HIV

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/