



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

06 October 2023
EMA/PDCO/413254/2023
Human Medicines Division

Paediatric Committee (PDCO)

Draft Agenda for the meeting on 10-13 October 2023

Chair: Brian Aylward – Vice-Chair: Sylvie Benchetrit

10 October 2023, 14:00 - 19:00, Virtual meeting

11 October 2023, 08:30 - 19:00, Virtual meeting

12 October 2023, 08:30 - 19:00, Virtual meeting

13 October 2023, 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 ongoing 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 10-13 October 2023. See October 2023 PDCO minutes (to be published post November 2023 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 10-13 October 2023.

1.3. Adoption of the minutes

PDCO minutes for 05-08 September 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. Amlitelimab - EMEA-003233-PIP01-22

Treatment of atopic dermatitis

Day 120 opinion

Action: For adoption

Dermatology

2.1.2. Upadacitinib - EMEA-001741-PIP08-22

Treatment of hidradenitis suppurativa

Day 120 opinion

Action: For adoption

Dermatology

2.1.3. Upadacitinib - EMEA-001741-PIP09-23

Treatment of systemic lupus erythematosus

Day 120 opinion

Action: For adoption

Dermatology

2.1.4. *Escherichia coli*, expressing high affinity phenylalanine transporter, modified phenylalanine ammonia lyase and L-amino acid deaminase - EMEA-003381-PIP01-22

Treatment of hyperphenylalaninemia

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.5. Recombinant human monoclonal antibody to insulin receptor - Orphan - EMEA-002813-PIP01-23

Rezolute (Bio) Ireland Limited; Treatment of congenital hyperinsulinism

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.6. Venglustat - Orphan - EMEA-001716-PIP07-22

Sanofi B.V.; Treatment of Gaucher disease type 3 / Treatment of Gaucher disease

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.7. Cemdisiran - Orphan - EMEA-003237-PIP02-22

Regeneron Ireland DAC; Treatment of paroxysmal nocturnal haemoglobinuria

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.8. [Pozelimab - EMEA-003238-PIP02-22](#)

Treatment of paroxysmal nocturnal haemoglobinuria

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.9. [Tetrahydrouridine / decitabine - Orphan - EMEA-003404-PIP01-23](#)

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

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.10. [Bidridistrogene xeboparvovec - Orphan - EMEA-003400-PIP01-23](#)

Sarepta Therapeutics Ireland; Treatment of limb-girdle muscular dystrophy

Day 120 opinion

Action: For adoption

Neurology

2.1.11. [Inebilizumab - EMEA-001911-PIP02-22](#)

Treatment of generalised myasthenia gravis

Day 120 opinion

Action: For adoption

Neurology

2.1.12. [Cobolimab - EMEA-003273-PIP02-22](#)

Treatment of all conditions included in the category of malignant neoplasms including lymphoma (except lung cancers and hematopoietic malignancies)

Day 120 opinion

Action: For adoption

Oncology

2.1.13. [Iptacopan - EMEA-002705-PIP05-23](#)

Treatment of immune-complex mediated membranoproliferative glomerulonephritis

Day 120 opinion

Action: For adoption

Other

2.1.14. Candesartan / atorvastatin / amlodipine - EMEA-003466-PIP01-23

Prevention of cardiovascular events

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.15. Ezetimibe / rosuvastatin - EMEA-003472-PIP01-23

Treatment of hypercholesterolaemia / Prevention of cardiovascular events

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.16. Fusion protein consisting of relaxin and Fc domain of IgG1 - EMEA-003476-PIP01-23

Treatment of pulmonary hypertension due to left heart disease

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.17. Glyceryl - EMEA-003479-PIP01-23

Treatment of ischaemic coronary artery disorders / Treatment of heart failure signs and symptoms / Prevention of cardiac and vascular procedural complications

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.18. EMEA-003470-PIP01-23

Treatment of breast malignant neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.1.19. [Gotistobart - EMEA-003467-PIP01-23](#)

Treatment of non-small cell lung cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.20. [Humanised IgG1 monoclonal antibody against integrin beta-6 conjugated to monomethyl auristatin E via a valine-citrulline linker - EMEA-003471-PIP01-23](#)

Treatment of solid tumours

Day 60 opinion

Action: For adoption

Oncology

2.1.21. [Ilginatnib - EMEA-003468-PIP01-23](#)

Treatment of myelofibrosis

Day 60 opinion

Action: For adoption

Oncology

2.1.22. [Relatlimab / nivolumab - EMEA-002727-PIP02-23](#)

Treatment of all conditions included in the category of malignant neoplasms (except nervous system neoplasms, haematopoietic and lymphoid tissue neoplasms and melanoma)

Day 60 opinion

Action: For adoption

Oncology

2.1.23. [EMEA-003469-PIP01-23](#)

Treatment of non-small cell lung cancer

Day 60 opinion

Action: For adoption

Other

2.1.24. Naproxen / paracetamol - EMEA-003475-PIP01-23

Treatment of rheumatoid arthritis / Treatment of febrile disorders / Treatment of acute pain

Day 60 opinion

Action: For adoption

Pain

2.1.25. Povidone, iodinated - EMEA-003484-PIP01-23

Preoperative preparation for ophthalmic surgeries

Day 30 opinion

Action: For adoption

Ophthalmology

2.1.26. Indapamide / ramipril - EMEA-003498-PIP01-23

Treatment of hypertension

Day 30 opinion

Action: For adoption

Cardiovascular Diseases

2.2. Opinions on Compliance Check

2.2.1. Macitentan - EMEA-C3-001032-PIP01-10-M05

Janssen-Cilag International NV; Treatment of pulmonary arterial hypertension

Day 60 letter

Action: For adoption

Cardiovascular Diseases

2.2.2. Nirsevimab - EMEA-C-001784-PIP01-15-M04

AstraZeneca AB; Prevention of lower respiratory tract infection caused by respiratory syncytial virus

Day 60 opinion

Action: For adoption

Infectious Diseases

2.2.3. Ataluren - EMEA-C-000115-PIP01-07-M13

PTC Therapeutics International, Limited; Treatment of dystrophinopathy

Day 60 opinion

Action: For adoption

Neurology

2.2.4. Lenvatinib - EMEA-C-001119-PIP03-19-M03

Eisai GmbH; Treatment of all conditions included in the category of malignant neoplasms except haematopoietic and lymphoid tissue neoplasms, papillary thyroid cancer, follicular thyroid cancer and osteosarcoma

Day 60 opinion

Action: For adoption

Oncology

2.2.5. Durvalumab - EMEA-C-002028-PIP01-16-M04

AstraZeneca AB; Treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lymphoid tissue)

Day 30 opinion

Action: For adoption

Oncology

2.2.6. Tremelimumab - EMEA-C-002029-PIP01-16-M04

AstraZeneca AB; Treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lymphoid tissue)

Day 30 opinion

Action: For adoption

Oncology

2.2.7. Ruxolitinib (phosphate) - EMEA-C-000901-PIP03-16-M02

Novartis Europharm Limited; Treatment of acute graft versus host disease (aGvHD)

Day 30 opinion

Action: For adoption

Oncology

2.2.8. Ruxolitinib (phosphate) - EMEA-C-000901-PIP04-17-M02

Novartis Europharm Limited; Treatment of chronic graft versus host disease

Day 30 opinion

Action: For adoption

Oncology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Macitentan - Orphan - EMEA-001032-PIP01-10-M07

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

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. Treprostinil sodium - EMEA-003182-PIP01-22-M01

AOP Orphan Pharmaceuticals GmbH; Treatment of pulmonary arterial hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.3. Abrocitinib - EMEA-002312-PIP01-17-M02

Pfizer Europe MA EEIG; Treatment of moderate to severe atopic dermatitis

Day 60 opinion

Action: For adoption

Dermatology

2.3.4. Remibrutinib - EMEA-002582-PIP01-19-M03

Novartis Europharm Limited; Treatment of chronic spontaneous urticaria

Day 60 opinion

Action: For adoption

Dermatology

2.3.5. [Liraglutide - EMEA-000128-PIP02-09-M05](#)

Novo Nordisk A/S; Treatment of obesity

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.6. [Pegzilarginase - Orphan - EMEA-001925-PIP02-19-M01](#)

Immedica Pharma AB; Treatment of hyperargininaemia

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.7. [Maralixibat chloride - Orphan - EMEA-001475-PIP03-17-M04](#)

Mirum Pharmaceuticals; Treatment of progressive familial intrahepatic cholestasis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.8. [Denecimig - EMEA-002762-PIP02-20-M02](#)

Novo Nordisk A/S; Treatment of haemophilia A

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.9. [Human fibrinogen concentrate - EMEA-001931-PIP01-16-M03](#)

Biotest AG; Treatment of congenital fibrinogen deficiency

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.10. [Sebetralstat - Orphan - EMEA-002723-PIP01-19-M02](#)

KalVista Pharmaceuticals Ltd; Treatment of hereditary angioedema

Day 60 opinion

Action: For adoption
Haematology-Hemostaseology

2.3.11. Risankizumab - EMEA-001776-PIP02-17-M02

AbbVie Ltd; Treatment of chronic idiopathic arthritis
Day 60 opinion
Action: For adoption
Immunology-Rheumatology-Transplantation

2.3.12. Upadacitinib - EMEA-001741-PIP03-16-M04

AbbVie Ltd; Treatment of Crohn's disease
Day 60 opinion
Action: For adoption
Immunology-Rheumatology-Transplantation / Gastroenterology-Hepatology

2.3.13. Bemnifosbuvir - EMEA-002963-PIP01-21-M01

Atea Pharmaceuticals, Inc; Treatment of coronavirus disease 2019 (COVID-19)
Day 60 opinion
Action: For adoption
Infectious Diseases

2.3.14. Cilgavimab (AZD1061) - EMEA-002925-PIP01-20-M02

AstraZeneca AB; Prevention and treatment of coronavirus disease 2019 (COVID-19)
Day 60 opinion
Action: For adoption
Infectious Diseases

2.3.15. Dalbavancin hydrochloride - EMEA-000016-PIP01-07-M09

AbbVie Ltd; Treatment of acute bacterial skin and skin structure infections (ABSSSI)
Day 60 opinion
Action: For adoption
Infectious Diseases

2.3.16. [Letemovir - Orphan - EMEA-001631-PIP01-14-M05](#)

Merck Sharp & Dohme (Europe), Inc.; Prevention of cytomegalovirus infection

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.17. [Relebactam monohydrate / cilastatin sodium / imipenem monohydrate - EMEA-001809-PIP01-15-M04](#)

Merck Sharp & Dohme (Europe), Inc.; Treatment of gram-negative bacterial infections

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.18. [Ritonavir / nirmatrelvir - EMEA-003081-PIP01-21-M03](#)

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.19. [Tixagevimab \(AZD8895\) - EMEA-002900-PIP01-20-M02](#)

AstraZeneca AB; Prevention and treatment of coronavirus disease 2019 (COVID-19)

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.20. [Zanamivir - EMEA-001318-PIP01-12-M05](#)

GlaxoSmithKline Trading Services Limited; Treatment of influenza / Prevention of influenza

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.21. [Alprazolam - EMEA-003043-PIP01-21-M01](#)

UCB Pharma SA.; Treatment of epileptic seizures

Day 60 opinion

Action: For adoption

Neurology

2.3.22. Ravulizumab - EMEA-001943-PIP04-20-M01

Alexion Europe SAS; Treatment of neuromyelitis optica spectrum disorders

Day 60 opinion

Action: For adoption

Neurology

2.3.23. Satralizumab - Orphan - EMEA-001625-PIP02-21-M02

Roche Registration GmbH; Treatment of generalised myasthenia gravis

Day 60 opinion

Action: For adoption

Neurology

2.3.24. Blinatumomab - Orphan - EMEA-000574-PIP02-12-M04

Amgen Europe B.V.; Treatment of acute lymphoblastic leukaemia

Day 60 opinion

Action: For adoption

Oncology

2.3.25. Lisocabtagene maraleucel - EMEA-001995-PIP01-16-M04

Bristol-Myers Squibb Pharma EEIG; Treatment of B-lymphoblastic leukaemia/lymphoma /
Treatment of mature B-cell neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.3.26. Lutetium (¹⁷⁷Lu) oxodotreotide - Orphan - EMEA-002950-PIP01-20-M01

Advanced Accelerator Applications; Treatment of gastroenteropancreatic neuroendocrine
tumours

Day 60 opinion

Action: For adoption

Oncology

2.3.27. Tirzepatide - EMEA-002360-PIP02-22-M02

Eli Lilly and Company; Treatment of obesity

Day 60 opinion

Action: For adoption

Other

2.3.28. Tapentadol (hydrochloride) - EMEA-000325-PIP01-08-M11

Grünenthal GmbH; Treatment of chronic pain

Day 60 opinion

Action: For adoption

Pain

2.3.29. Mometasone (furoate) / glycopyrronium bromide / indacaterol - EMEA-001812-PIP01-15-M02

Novartis Europharm Limited; Treatment of asthma

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.30. Seltorexant - EMEA-002746-PIP01-20-M02

Janssen-Cilag International NV; Treatment of major depressive disorder

Day 60 opinion

Action: For adoption

Psychiatry

2.3.31. Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live) - EMEA-001786-PIP01-15-M03

Merck Sharp & Dohme (Europe), Inc.; Prevention of Ebola disease

Day 30 opinion

Action: For adoption

Vaccines

2.3.32. Lacosamide - EMEA-000402-PIP03-17-M08

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

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. Bilayer, engineered, collagen hydrogel-based skin graft composed of autologous keratinocytes and fibroblasts - EMEA-C1-002699-PIP01-19-M01

YES Pharmaceutical Development Services GmbH; Treatment of burns

Day 30 letter

Action: For information

Dermatology

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. EMEA-002674-PIP01-19

Treatment of acne vulgaris

Day 90 discussion

Action: For discussion

Dermatology

3.1.2. [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 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.3. [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 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

Prevention of coronavirus disease 2019 (COVID-19)

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

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

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

Treatment of human immunodeficiency virus (HIV-1) infection

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.7. Vemircopan - Orphan - EMEA-002863-PIP02-23

Alexion Europe SAS; Treatment of generalised myasthenia gravis

Day 90 discussion

Action: For discussion

Neurology

3.1.8. Olutasidenib - Orphan - EMEA-003421-PIP01-23

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

Day 90 discussion

Action: For discussion

Oncology

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

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

Day 90 discussion

Action: For discussion

Oncology

3.1.10. Cedazuridine / decitabine - Orphan - EMEA-003071-PIP02-23

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

Day 90 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

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

Biohaven Bioscience Ireland Limited; Treatment of spinal muscular atrophy

Day 90 discussion

Action: For discussion

Other

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

Treatment of immunoglobulin A nephropathy (IgAN)

Day 90 discussion

Action: For discussion

Uro-nephrology

3.1.13. EMEA-003480-PIP01-23

Treatment of psoriasis

Day 60 discussion

Action: For discussion

Dermatology

3.1.14. Lutikizumab - EMEA-003481-PIP01-23

Treatment of hidradenitis suppurativa

Day 60 discussion

Action: For discussion

Dermatology

3.1.15. EMEA-003478-PIP01-23

Treatment of psoriasis

Day 60 discussion

Action: For discussion

Dermatology

3.1.16. Bitopertin - Orphan - EMEA-000439-PIP03-23

Disc Medicine B.V.; Treatment of erythropoietic protoporphyria / Treatment of X-linked protoporphyria

Day 60 discussion

Action: For discussion

Dermatology / Haematology-Hemostaseology

3.1.17. Etavopivat - Orphan - EMEA-002924-PIP02-23

Novo Nordisk A/S; Treatment of sickle cell disease

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.18. [Human alpha-1 proteinase inhibitor, modified - EMEA-003463-PIP01-23](#)

Treatment of haemophilia B

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.19. [Ianalumab - EMEA-002338-PIP05-23](#)

Treatment of immune thrombocytopenia (ITP)

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.20. [EMEA-003002-PIP04-23](#)

Treatment of systemic sclerosis (SSc)

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.21. [Iodine \(¹³¹I\) apamistamab - Orphan - EMEA-003395-PIP02-23](#)

Immedica Pharma AB; Treatment in allogenic stem cell transplantation

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Oncology

3.1.22. [Radiprodil - EMEA-003462-PIP01-23](#)

Treatment of GRIN-related disorders

Day 60 discussion

Action: For discussion

Neurology

3.1.23. EMEA-003477-PIP01-23

Treatment of appetite and general nutrition disorders

Day 60 discussion

Action: For discussion

Nutrition

3.1.24. (3S,3'S,3a'S,10a'S)-6-chloro-3'-(3-chloro-2-fluorophenyl)-1' (cyclopropylmethyl)-6'-methyl-2-oxo-1,2,3',3a',10',10a'-hexahydro-1'H-spiro[indole-3,2'-pyrrolo[2',3':4,5]pyrrolo[1,2-b]indazole]-7'-carboxylic acid - Orphan - EMEA-003260-PIP03-23

Boehringer Ingelheim International GmbH; Treatment of soft tissue sarcoma

Day 60 discussion

Action: For discussion

Oncology

3.1.25. Relatlimab / nivolumab - EMEA-002727-PIP03-23

Treatment of melanoma

Day 60 discussion

Action: For discussion

Oncology

3.1.26. Messenger RNA encoding Cas9, single guide RNA targeting the human KLKB1 gene - EMEA-003465-PIP01-23

Treatment of hereditary angioedema (HAE)

Day 60 discussion

Action: For discussion

Other

3.1.27. Imlifidase - Orphan - EMEA-002183-PIP03-23

Hansa Biopharma AB; Treatment of anti-glomerular basement membrane (anti-GBM) disease

Day 60 discussion

Action: For discussion

Other / Uro-nephrology

3.1.28. Humanised IgG1 monoclonal antibody against pituitary adenylate cyclase-activating polypeptide - EMEA-003483-PIP01-23

Prevention of migraine

Day 60 discussion

Action: For discussion

Pain / Neurology

3.1.29. Atacicept - EMEA-002004-PIP04-23

Treatment of immunoglobulin A nephropathy

Day 60 discussion

Action: For discussion

Uro-nephrology

3.1.30. EMEA-003487-PIP01-23

Prevention of cardiovascular events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.31. Seralutinib - Orphan - EMEA-002972-PIP02-23

Gossamer Bio 002 Limited; Treatment of pulmonary arterial hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.32. Elinzanetant - EMEA-003500-PIP01-23

Treatment of vasomotor symptoms caused by endocrine therapy in women with, or at high risk for developing hormone-receptor positive breast cancer

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.33. [Humanised IgG1 kappa monoclonal antibody directed against IGF-1R - EMEA-003499-PIP01-23](#)

Treatment of thyroid eye disease

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.34. [Sitagliptin / dapagliflozin - EMEA-003486-PIP01-23](#)

Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

Applied Therapeutics, Inc; Treatment of galactosemia

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Neurology

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

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

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

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

Enzyvant Therapeutics Ireland Limited; Treatment of congenital athymia

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

Sanofi Winthrop Industrie; Treatment of chronic lung allograft dysfunction

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.39. *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 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.40. *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 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.41. *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 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.42. Proline derivative - EMEA-003440-PIP01-23

Treatment of type 1 interferonopathies

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.43. [Diflunisal - Orphan - EMEA-003490-PIP01-23](#)

AO Pharma AB; Treatment of transthyretin amyloid amyloidosis

Day 30 discussion

Action: For discussion

Neurology

3.1.44. [EMEA-003495-PIP01-23](#)

Treatment of tenosynovial giant cell tumours

Day 30 discussion

Action: For discussion

Oncology

3.1.45. [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 30 discussion

Action: For discussion

Oncology

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

Treatment of ovarian cancer

Day 30 discussion

Action: For discussion

Oncology

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

Treatment of biliary tract cancer / Treatment of lung cancer

Day 30 discussion

Action: For discussion

Oncology

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

Treatment of *Demodex* blepharitis

Day 30 discussion

Action: For discussion

Ophthalmology / Infectious Diseases

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

Prevention of respiratory syncytial virus (RSV) disease

Day 30 discussion

Action: For discussion

Vaccines

[3.1.50. 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 low-grade squamous intraepithelial lesions (LSIL) of the anus caused by HPV types 16 and 18 / Treatment of high-grade squamous intraepithelial lesions (HSIL) of the anus caused by HPV types 16 and 18

Day 30 discussion

Action: For discussion

Vaccines / Infectious Diseases

[3.1.51. 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 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. Dupilumab - EMEA-C1-001501-PIP07-20-M01](#)

Sanofi Winthrop Industrie; Treatment of chronic spontaneous urticaria

Day 30 discussion

Action: For discussion

Dermatology

3.2.2. Ixekizumab - EMEA-C-001050-PIP01-10-M05

Eli Lilly and Company; Treatment of psoriasis

Day 30 discussion

Action: For discussion

Dermatology

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

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

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

Pfizer Europe MA EEIG; Treatment of intra-abdominal infections

Day 30 discussion

Action: For discussion

Infectious Diseases

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

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

Day 30 discussion

Action: For discussion

Other

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

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

Amryt Pharmaceuticals DAC; Treatment of skin injuries

Day 30 discussion

Action: For discussion

Dermatology

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

LEO Pharma A/S; Treatment of chronic hand eczema

Day 30 discussion

Action: For discussion

Dermatology

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

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

Day 30 discussion

Action: For discussion

Dermatology

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

Janssen-Cilag International NV; Treatment of psoriasis

Day 30 discussion

Action: For discussion

Dermatology

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

Pfizer Europe MA EEIG; Treatment of alopecia areata

Day 30 discussion

Action: For discussion

Dermatology

3.3.6. 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 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

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

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

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

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

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.9. 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 30 discussion

Action: For discussion

Gastroenterology-Hepatology

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

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

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

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

Norgine BV; Treatment of iron deficiency

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.12. 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 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

Bristol-Myers Squibb Pharma EEIG; Treatment of eosinophilic esophagitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

Sanofi B.V.; Treatment of immune thrombocytopenia

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.15. 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 30 discussion

Action: For discussion

Infectious Diseases

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

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

Day 30 discussion

Action: For discussion

Infectious Diseases

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

Horizon Therapeutics Ireland DAC; Treatment of neuromyelitis optica spectrum disorders (NMOSD)

Day 30 discussion

Action: For discussion

Neurology

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

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

Day 30 discussion

Action: For discussion

Neurology

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

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

Day 30 discussion

Action: For discussion

Other

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

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

Day 30 discussion

Action: For discussion

Pain

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

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

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3.22. 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 30 discussion

Action: For discussion

Vaccines

3.3.23. 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 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 16 October 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. Lasofoxifene- EMEA-08-2023

Sermonix 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 adults with oestrogen receptor positive, human epidermal receptor negative advanced or metastatic breast cancer with an ESR1 mutation

Action: For adoption

6.1.2. Anti-microtubule binding region tau antibody - EMEA-09-2023

Eisai Limited; All classes of medicinal products for treatment of Alzheimer's disease / Treatment of Alzheimer's disease (AD) / Treatment of dominantly inherited Alzheimer's disease (DIAD)

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 to be held in Madrid during the Spanish Presidency

PDCO member: 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)

No item

9.3.4. Upcoming Innovation Task Force (ITF) meetings

Action: For information

9.3.5. EMA's Working Parties in the New Model – Formulations Working Group integration

PDCO member: Brian Aylward

Action: For information

9.4. Cooperation within the EU regulatory network

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

Update from annual Enpr-EMA meeting

Action: For information

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. 14 years of standard allergen PIP

Update on the 16th International Paul-Ehrlich-Seminar held on 07 September 2023

Experts: Susanne Kaul, Birgit Ahrens

Action: For information

10.2. ACT EU priority action (PA) 8 on methodology

Expert: Ditte Zerlang Andersen

Action: For information

10.3. Patient Experience Data (PED) project

Action: For information

10.4. Request for feedback on recommendation for inclusion of adolescents in adult trials from the Clinical Trials Coordination Group (CTCG)

PDCO member: Anette Solli Karlsen

Action: For adoption

10.5. Internal review of the ICH M15 MIDD Guideline

The objective of this guideline is to outline general model-informed drug development (MIDD) principles and describe recommended practices with respect to planning, conduct, reporting, interpretation, and alignment on the impact on regulatory decision-making.

Action: For information

11. Breakout sessions

11.1. Neonatology

Action: For discussion on Tuesday, 12:00 - 13:00

11.2. Paediatric oncology

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

11.3. HIV

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/