



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Paediatric Committee (PDCO)

Draft Agenda for the meeting on 08-11 November 2022

Chair: Brian Aylward – Vice-Chair: Sylvie Benchetrit

08 November 2022, 14:00 - 19:00, Virtual meeting

09 November 2022, 08:30 - 19:00, Virtual meeting

10 November 2022, 08:30 - 19:00, Virtual meeting

11 November 2022, 08:30 - 13:00, Virtual meeting

Disclaimers

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

Note on access to documents

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



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1. Introductions

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PDCO plenary session to be held 08-11 November 2022. See November 2022 PDCO minutes (to be published post December 2022 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 08-11 November 2022.

1.3. Adoption of the minutes

PDCO minutes for 11-14 October 2022.

2. Opinions

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

2.1. Opinions on Products

2.1.1. Obefazimod - EMEA-003196-PIP01-22

Treatment of ulcerative colitis / Treatment of Crohn's disease

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.2. Inclacumab - EMEA-003219-PIP01-22

Treatment of sickle cell disease

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

[2.1.3. HIV-1 maturation inhibitor / dolutegravir - EMEA-003152-PIP01-21](#)

Treatment of human immunodeficiency virus (HIV-1) infection

Day 120 opinion

Action: For adoption

Infectious Diseases

[2.1.4. HIV-1 maturation inhibitor - EMEA-003153-PIP01-21](#)

Treatment of human immunodeficiency virus (HIV-1) infection

Day 120 opinion

Action: For adoption

Infectious Diseases

[2.1.5. Posoleucel - Orphan - EMEA-002908-PIP01-20](#)

AlloVir International DAC; Treatment of viral diseases in haematopoietic stem cell transplantation

Day 120 opinion

Action: For adoption. Oral explanation to be held on Wednesday, 9 November 2022 at 14:00

Infectious Diseases

[2.1.6. Humanised monoclonal IgG1-based antibody - EMEA-003100-PIP01-21](#)

Treatment of spinal muscular atrophy

Day 120 opinion

Action: For adoption

Neurology

[2.1.7. Pridopidine \(hydrochloride\) - Orphan - EMEA-003174-PIP01-21](#)

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

Day 120 opinion

Action: For adoption

Neurology

[2.1.8. Vodobatinib - EMEA-003014-PIP01-21](#)

Treatment of chronic myeloid leukaemia

Day 120 opinion

Action: For adoption

Oncology

2.1.9. Enzastaurin hydrochloride - Orphan - EMEA-003096-PIP02-22

Aytu BioPharma Inc.; Treatment of Ehlers-Danlos syndrome

Day 120 opinion

Action: For adoption

Other

2.1.10. Depemokimab - EMEA-003051-PIP04-22

Treatment of eosinophilic granulomatosis with polyangiitis (EGPA)

Day 120 opinion

Action: For adoption

Pneumology - Allergology

2.1.11. Stiripentol - Orphan - EMEA-003200-PIP01-22

Biocodex SA; Treatment of primary hyperoxaluria

Day 120 opinion

Action: For adoption

Uro-nephrology

2.1.12. Live, attenuated, dengue virus, serotype 4 (DENV4) / Live, attenuated, dengue virus, serotype 3 (DENV3) / Live, attenuated, chimeric dengue virus, serotype 2 (DENV2) / Live, attenuated, dengue virus, serotype 1 (DENV1) - EMEA-002999-PIP01-21

Prevention of dengue disease

Day 120 opinion

Action: For adoption

Vaccines

2.1.13. Acetylsalicylic acid / rivaroxaban - EMEA-003291-PIP01-22

Prevention of atherothrombotic events

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.14. Eplerenone / torasemide - EMEA-003289-PIP01-22

Treatment of heart failure

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.15. Indapamide / valsartan - EMEA-003285-PIP01-22

Treatment of hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.16. Rosuvastatin / fenofibrate - EMEA-003295-PIP01-22

Treatment of elevated cholesterol with elevated triglycerides

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.17. Messenger RNA encoding Cas9 and single guide RNA targeting the human TTR gene - Orphan - EMEA-003298-PIP01-22

Intellia Therapeutics, Inc.; Treatment of transthyretin amyloidosis (ATTR)

Day 60 opinion

Action: For adoption

Cardiovascular Diseases / Neurology

2.1.18. Eplontersen - EMEA-003294-PIP01-22

Treatment of transthyretin amyloidosis

Day 60 opinion

Action: For adoption

Neurology

2.1.19. Unesbulin - Orphan - EMEA-003297-PIP01-22

PTC Therapeutics International; Treatment of soft tissue sarcoma

Day 60 opinion

Action: For adoption

Oncology

2.1.20. Treprostinil palmitil - EMEA-003204-PIP01-22

Treatment of pulmonary hypertension due to lung disease and/or hypoxia

Day 60 opinion

Action: For adoption

Pneumology – Allergology

2.1.21. Tozinameran, tozinameran / famtozinameran - EMEA-002861-PIP02-20-M05

Prevention of coronavirus disease 2019 (COVID-19)

Day 30 opinion

Action: For adoption

Infectious Diseases

The PDCO adopted the opinion by written procedure on 4 November 2022

2.1.22. Ezeprogind - Orphan - EMEA-003320-PIP01-22

Alzprotect S.A.S., France; Treatment of progressive supranuclear palsy

Day 30 opinion

Action: For adoption

Neurology

2.2. Opinions on Compliance Check

2.2.1. Naloxegol (as naloxegol oxalate) - EMEA-C-001146-PIP01-11-M07

Kyowa Kirin Pharmaceutical Development Limited; Treatment of opioid-induced constipation

Day 30 opinion

Action: For adoption

Gastroenterology-Hepatology

2.2.2. Edoxaban tosilate - EMEA-C-000788-PIP02-11-M11

Daiichi Sankyo Europe GmbH; Treatment of venous thromboembolism

Day 30 opinion

Action: For adoption

2.2.3. [Trametinib - EMEA-C-001177-PIP01-11-M06](#)

Novartis Europharm Limited; Treatment of melanoma

Day 30 opinion

Action: For adoption

Oncology

2.2.4. [Recombinant 10 kDa culture filtrate protein of *Mycobacterium tuberculosis* \(rCFP-10\) / recombinant dimer of *Mycobacterium tuberculosis* 6 kDa early secretory antigenic target \(rdESAT-6\) - EMEA-C-001156-PIP01-11-M07](#)

Vakzine Projekt Management GmbH; Diagnosis of tuberculosis

Day 30 opinion

Action: For adoption

Diagnostic

2.2.5. [Dabrafenib - EMEA-C-001147-PIP01-11-M07](#)

Novartis Europharm Limited; Treatment of melanoma

Day 30 opinion

Action: For adoption

Oncology

2.3. **Opinions on Modification of an Agreed Paediatric Investigation Plan**

2.3.1. [Baricitinib - EMEA-001220-PIP03-16-M03](#)

Eli Lilly and Company Limited; Treatment of atopic dermatitis

Day 60 opinion

Action: For adoption

Dermatology

Note: Withdrawal request received on 24 October 2022

2.3.2. [Dupilumab - EMEA-001501-PIP04-19-M02](#)

Regeneron Ireland DAC; Treatment of eosinophilic esophagitis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.3. [Linaclotide - EMEA-000927-PIP01-10-M07](#)

AbbVie Deutschland GmbH & Co. KG; Treatment of functional constipation

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.4. [Odevixibat - Orphan - EMEA-002054-PIP03-20-M02](#)

Albireo AB; Treatment of Alagille syndrome

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.5. [Upadacitinb - EMEA-001741-PIP02-16-M02](#)

AbbVie Ltd; Treatment of ulcerative colitis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.6. [\(1R,2S,5S\)-N-\(\(1S\)-1-cyano-2-\(\(3S\)-2-oxopyrrolidin-3-yl\)ethyl\)-6,6-dimethyl-3-\[3-methyl-N-\(trifluoroacetyl\)-L-valyl\]-3-azabicyclo\[3.1.0\]hexane-2-carboxamide - EMEA-003081-PIP01-21-M02](#)

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.7. [Doravirine - EMEA-001676-PIP01-14-M05](#)

Merck Sharp & Dohme (Europe), Inc.; Treatment of human immunodeficiency virus-1 (HIV-1) infection

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.8. Lefamulin - EMEA-002075-PIP01-16-M03

Nabriva Therapeutics DAC; Treatment of community-acquired pneumonia

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.9. Tecovirimat monohydrate - Orphan - EMEA-001205-PIP02-19-M02

SIGA Technologies, Inc.; Treatment of the following viral infections in adults and children with body weight at least 13 kg: smallpox, monkeypox, cowpox. Also indicated to treat complications due to replication of vaccinia virus following vaccination against smallpox in adults and children with body weight at least 13 kg

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.10. Tenofovir disoproxil fumarate / lamivudine / doravirine - EMEA-001695-PIP01-14-M05

Merck Sharp & Dohme (Europe), Inc.; Treatment of human immunodeficiency virus-1 (HIV-1) infection

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.11. Givinostat - Orphan - EMEA-000551-PIP04-21-M01

Italfarmaco S.p.A.; Treatment of Duchenne muscular dystrophy

Day 60 opinion

Action: For adoption

Neurology

2.3.12. Ofatumumab - EMEA-002397-PIP01-18-M03

Novartis Ireland Limited; Treatment of multiple sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.3.13. Siponimod (hemifumarate) - EMEA-000716-PIP01-09-M05

Novartis Europharm Ltd; Treatment of multiple sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.3.14. Entospletinib - Orphan - EMEA-002058-PIP01-16-M01

Kronos Bio Inc.; Treatment of acute myeloid leukaemia

Day 60 opinion

Action: For adoption

Oncology

2.3.15. Imetelstat - Orphan - EMEA-001910-PIP03-20-M01

Geron Corporation; Treatment of acute myeloid leukaemia (AML) / Treatment of myelodysplastic syndromes (MDS), including juvenile myelomonocytic leukaemia (JMML)

Day 60 opinion

Action: For adoption

Oncology

2.3.16. Lenvatinib - EMEA-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

2.3.17. Characterised peanut powder - EMEA-001753-PIP02-15-M01

Cambridge Allergy Ltd; Treatment of peanut allergy

Day 60 opinion

Action: For adoption

Other

2.3.18. [Setrusumab - Orphan - EMEA-002169-PIP01-17-M02](#)

Mereo Biopharma 3 Ltd; Treatment of osteogenesis imperfecta

Day 60 opinion

Action: For adoption

Other

2.3.19. [Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of *Betula alba* pollen \(birch pollen\) - EMEA-000630-PIP02-09-M05](#)

LETI Pharma GmbH; Treatment of allergic rhinitis / rhino-conjunctivitis

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.20. [Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of birch pollen - EMEA-000837-PIP01-10-M02](#)

LETI Pharma GmbH; Treatment of allergic rhinitis / rhino-conjunctivitis

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.21. [Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extracts of birch, alder and hazel pollen - EMEA-000662-PIP02-09-M05](#)

LETI Pharma GmbH; Treatment of allergic rhinitis / rhino-conjunctivitis

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.22. [Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extracts of birch, alder and hazel pollen - EMEA-000838-PIP01-10-M02](#)

LETI Pharma GmbH; Treatment of allergic rhinitis / rhino-conjunctivitis

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.23. Modified vaccinia Ankara - Bavarian Nordic virus (smallpox) - EMEA-001161-PIP02-11-M02

Bavarian Nordic A/S; Prevention of smallpox, monkeypox and disease caused by vaccinia virus

Day 60 opinion

Action: For adoption

Vaccines

2.3.24. Ad26.COV2.S - EMEA-002880-PIP01-20-M01

Janssen-Cilag International N.V.; Prevention of coronavirus disease 2019 (COVID-19)

Day 60 opinion

Action: For adoption

Vaccines / Infectious Diseases

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. *N. meningitidis* serogroup A polysaccharide conjugated to tetanus toxoid / *N. meningitidis* serogroup C polysaccharide conjugated to tetanus toxoid / *N. meningitidis* serogroup W polysaccharide conjugated to tetanus toxoid / *N. meningitidis* serogroup Y polysaccharide conjugated to tetanus toxoid - EMEA-C3-001930-PIP01-16-M04

Sanofi Pasteur; Prevention of invasive meningococcal disease

Day 30 letter

Action: For information

Vaccines

2.7.2. [Live, attenuated dengue virus, serotype 2 / Live, attenuated, chimeric dengue virus, serotype 4 / Live, attenuated, chimeric dengue virus, serotype 3 / Live, attenuated, chimeric dengue virus, serotype 1 - EMEA-C2-001888-PIP01-15-M01](#)

Takeda Vaccines, Inc.; Prevention of dengue fever

Day 30 letter

Action: For information

Vaccines

2.7.3. [Nivolumab - EMEA-C4-001407-PIP02-15-M05](#)

Bristol-Myers Squibb Pharma EEIG; Treatment of malignant neoplasms of lymphoid tissue

Day 30 letter

Action: For information

Oncology

2.7.4. [Nirsevimab - EMEA-C3-001784-PIP01-15-M04](#)

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

Day 30 letter

Action: For information

Infectious Diseases

2.7.5. [Migalastat hydrochloride - EMEA-C2-001194-PIP01-11-M05](#)

Amicus Therapeutics Europe Limited; Treatment of Fabry disease

Day 30 letter

Action: For information

Endocrinology-Gynaecology-Fertility-Metabolism

2.7.6. [Enmetazobactam / cefepime - EMEA-C1-002240-PIP02-17-M01](#)

Allegra Therapeutics GmbH; Treatment of urinary tract infections

Day 30 letter

Action: For information

Infectious Diseases

2.7.7. [Tezacaftor / ivacaftor / elexacaftor - EMEA-C4-002324-PIP01-17-M03](#)

Vertex Pharmaceuticals (Ireland) Limited; Treatment of cystic fibrosis

Day 30 letter

Action: For information

Other

2.7.8. [Fidanacogene elaparvovec - EMEA-C1-002362-PIP02-19-M02](#)

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

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. [Asundexian - EMEA-003144-PIP01-21](#)

Prevention of arterial thromboembolism

Day 90 discussion

Action: For discussion

Cardiovascular Diseases

3.1.2. [A 2'-MOE antisense oligonucleotide targeting apoC-III - EMEA-003177-PIP01-21](#)

Treatment of familial chylomicronaemia syndrome / Treatment of severe and extreme hypertriglyceridaemia

Day 90 discussion

Action: For discussion

Cardiovascular Diseases

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

Diagnostic evaluation of focal hepatic lesions

Day 90 discussion

Action: For discussion

Diagnostic / Oncology

3.1.4. Avexitide acetate - Orphan - EMEA-003125-PIP02-21

EigerBio Europe Limited; Treatment of congenital hyperinsulinism

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.5. Triheptanoin - Orphan - EMEA-001920-PIP04-19

Ultragenyx Germany GmbH; Treatment of long-chain fatty acid oxidation disorders (LC-FAOD)

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.6. Depemokimab - EMEA-003051-PIP05-22

Treatment of hypereosinophilic syndrome (HES)

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

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

Roche Registration GmbH; Treatment of autoimmune encephalitis

Day 90 discussion

Action: For discussion

Neurology

3.1.8. Troriluzole (hydrochloride) - Orphan - EMEA-003084-PIP03-22

Biohaven Pharmaceutical Ireland DAC; Treatment of hereditary spinocerebellar ataxia / Treatment of spinocerebellar ataxia

Day 90 discussion

Action: For discussion

Neurology

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

Treatment of mature B cell neoplasms

Day 90 discussion

Action: For discussion

Oncology

3.1.10. Fianlimab - EMEA-003207-PIP01-22

Treatment of melanoma

Day 90 discussion

Action: For discussion

Oncology

3.1.11. Naxitamab - Orphan - EMEA-002346-PIP01-18

Y-mAbs Therapeutics A/S; Short-term symptomatic treatment of pain / Treatment of neuroblastoma

Day 90 discussion

Action: For discussion

Oncology

3.1.12. Tirzepatide - EMEA-002360-PIP02-22

Treatment of obesity

Day 90 discussion

Action: For discussion

Other

3.1.13. Dexmedetomidine - EMEA-003283-PIP01-22

Sedation

Day 60 discussion

Action: For discussion

Anaesthesiology

3.1.14. EMEA-003286-PIP01-22

Treatment of atopic dermatitis

Day 60 discussion

Action: For discussion

Dermatology

3.1.15. [Isotretinoin - EMEA-003303-PIP01-22](#)

Treatment of congenital ichthyosis

Day 60 discussion

Action: For discussion

Dermatology

3.1.16. [EMEA-003301-PIP01-22](#)

Treatment of moderate to severe plaque psoriasis

Day 60 discussion

Action: For discussion

Dermatology

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

Treatment of Netherton syndrome

Day 60 discussion

Action: For discussion

Dermatology

3.1.18. [EMEA-003299-PIP01-22](#)

Treatment of type 2 diabetes mellitus

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.19. [EMEA-003299-PIP02-22](#)

Treatment of obesity

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.20. Wharton's jelly derived mesenchymal stromal cells - EMEA-003287-PIP01-22

Treatment of type 1 diabetes mellitus (T1DM)

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

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

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.22. Dirloctocogene samoparvovec - Orphan - EMEA-003290-PIP01-22

Spark Therapeutics Ireland Limited; Treatment of haemophilia A

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.23. Mocravimod - Orphan - EMEA-003304-PIP01-22

Priothera SAS; Treatment in haematopoietic stem cell transplantation (HSCT)

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.24. Adintrevimab - EMEA-003118-PIP02-22

Treatment of coronavirus disease 2019 (COVID-19)

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.25. Ensitrelvir - EMEA-003192-PIP01-22

Treatment of coronavirus disease 2019 (COVID-19)

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.26. [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 60 discussion

Action: For discussion

Neurology

3.1.27. [EMEA-003288-PIP01-22](#)

Treatment of developmental and epileptic encephalopathies and other seizure syndromes

Day 60 discussion

Action: For discussion

Neurology

3.1.28. [Vesleteplirsen - EMEA-003305-PIP01-22](#)

Treatment of Duchenne muscular dystrophy

Day 60 discussion

Action: For discussion

Neurology

3.1.29. [Obinutuzumab - Orphan - EMEA-001207-PIP06-22](#)

Roche Registration GmbH; Prevention of cytokine release syndrome induced by anti CD20/CD3 antibodies

Day 60 discussion

Action: For discussion

Oncology

3.1.30. [Humanised IgG4 monoclonal antibody against A proliferation-inducing ligand - Orphan - EMEA-003300-PIP01-22](#)

Chinook Therapeutics, Inc.; Treatment of IgA nephropathy

Day 60 discussion

Action: For discussion

Uro-nephrology

3.1.31. Furosemide - EMEA-003316-PIP01-22

Treatment of fluid retention

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.32. Landiolol - EMEA-001150-PIP03-22

Treatment of ventricular arrhythmias

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.33. Ziltivekimab - EMEA-002840-PIP02-22

Treatment of heart failure

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.34. Barzolvolimab - EMEA-003327-PIP01-22

Treatment of chronic spontaneous urticaria

Day 30 discussion

Action: For discussion

Dermatology

3.1.35. Efgartigimod alfa - EMEA-002597-PIP09-22

Treatment of bullous pemphigoid

Day 30 discussion

Action: For discussion

Dermatology

3.1.36. Povorcitinib - EMEA-003313-PIP01-22

Treatment of hidradenitis suppurativa

Day 30 discussion

Action: For discussion

Dermatology

3.1.37. Rilzabrutinib - EMEA-002438-PIP03-22

Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.1.38. Ritlecitinib - EMEA-002451-PIP03-22

Treatment of vitiligo

Day 30 discussion

Action: For discussion

Dermatology

3.1.39. Upadacitinib - EMEA-001741-PIP07-22

Treatment of vitiligo

Day 30 discussion

Action: For discussion

Dermatology

3.1.40. Recombinant human glutamic acid dextranase (rhGAD65) - EMEA-000609-PIP02-22

Prevention or delay of clinical type 1 diabetes mellitus / Prevention of type 1 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.41. Setanaxib - Orphan - EMEA-003310-PIP01-22

Calliditas Therapeutics France SAS; Treatment of primary biliary cholangitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.42. Acetylsalicylic acid / rivaroxaban - EMEA-003308-PIP01-22

Prevention of atherothrombotic events

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.43. Ciraparantag - EMEA-003321-PIP01-22

Treatment of FXa inhibitor-associated haemorrhage / Prevention of FXa inhibitor-associated haemorrhage

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.44. Izokibep - EMEA-003325-PIP01-22

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

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.45. EMEA-003326-PIP01-22

Treatment of infections caused by gram-negative organisms / Complicated urinary tract infections (cUTI) / Hospital associated pneumonia or ventilator associated pneumonia

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.46. Lenacapavir / bictegravir - EMEA-003324-PIP01-22

Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.47. Luminol - EMEA-003322-PIP01-22

Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.48. Posoleucel - Orphan - EMEA-002908-PIP02-22

Allovir International DAC; Prevention of viral disease in haematopoietic stem cell transplantation

Day 30 discussion

Action: For discussion

Infectious Diseases

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

Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.50. Icerguastat - Orphan - EMEA-003312-PIP01-22

InFlectis BioScience S.A.S; Treatment of amyotrophic lateral sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.1.51. Retifanlimab - Orphan - EMEA-002798-PIP03-22

Incyte Biosciences Distribution B.V.; Treatment of Merkel cell carcinoma

Day 30 discussion

Action: For discussion

Oncology

3.1.52. Uproleselan - Orphan - EMEA-003307-PIP01-22

GlycoMimetics, Inc.; Treatment of acute myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.1.53. [Vutrisiran - Orphan - EMEA-002425-PIP02-22](#)

Alnylam Netherlands B.V.; Treatment of Stargardt disease

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.54. [Dersimelagon - EMEA-002850-PIP03-22](#)

Treatment of systemic sclerosis

Day 30 discussion

Action: For discussion

Other

3.1.55. [MRNA encoding modified human ornithine transcarbamylase - Orphan - EMEA-003315-PIP01-22](#)

Arcturus Therapeutics Europe B.V.; Treatment of ornithine transcarbamylase deficiency / Treatment of ornithine transcarbamylase deficiency, which is characterised by episodes of hyperammonemia and consequent sequelae

Day 30 discussion

Action: For discussion

Other

3.1.56. [Dexpramipexole - EMEA-003328-PIP01-22](#)

Treatment of asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.57. [Pamrevlumab - EMEA-002979-PIP04-22](#)

Treatment of interstitial lung diseases with fibrosis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.58. EMEA-003319-PIP01-22

Treatment of borderline personality disorder (BPD)

Day 30 discussion

Action: For discussion

Psychiatry

3.1.59. EMEA-003319-PIP02-22

Treatment of major depressive disorder (MDD)

Day 30 discussion

Action: For discussion

Psychiatry

3.1.60. EMEA-003319-PIP03-22

Treatment of post-traumatic stress disorder (PTSD)

Day 30 discussion

Action: For discussion

Psychiatry

3.1.61. Influenza recombinant H7 haemagglutinin - EMEA-003314-PIP01-22

Prevention of influenza infection

Day 30 discussion

Action: For discussion

Vaccines

3.1.62. Phuket modRNA / Darwin modRNA / Austria modRNA / Wisconsin modRNA - EMEA-003318-PIP01-22

Prevention of influenza disease

Day 30 discussion

Action: For discussion

Vaccines

3.1.63. Single-stranded 5' capped mRNA encoding the respiratory syncytial virus glycoprotein F stabilised in the prefusion conformation - EMEA-003309-PIP01-22

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

Day 30 discussion

Action: For discussion

Vaccines

3.1.64. Tetanus toxoid - EMEA-003311-PIP01-22

Prevention of infectious disease caused by *Clostridium tetani*

Day 30 discussion

Action: For discussion

Vaccines

3.1.65. Live attenuated varicella virus - EMEA-003317-PIP01-22

Prevention of varicella

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. Alogliptin - EMEA-C-000496-PIP01-08-M08

Takeda Development Centre Europe Ltd; Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.2. Denosumab - EMEA-C1-000145-PIP02-12-M04

Amgen Europe B.V.; Treatment of osteoporosis

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.3. Lisocabtagene maraleucel - EMEA-C3-001995-PIP01-16-M03

Bristol-Myers Squibb Pharma EEIG; Treatment of mature B cell neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.2.4. [Ivacaftor \[N-\(2,4-Di-tert-butyl-5-hydroxyphenyl\)-1,4-dihydro-4-oxoquinoline-3-carboxamide\] - EMEA-C-000335-PIP01-08-M14](#)

Vertex Pharmaceuticals (Ireland) Limited; Treatment of cystic fibrosis

Day 30 discussion

Action: For discussion

Other

3.2.5. [Baricitinib - EMEA-C-001220-PIP03-16-M02](#)

Eli Lilly and Company; Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.3. **Discussions on Modification of an Agreed Paediatric Investigation Plan**

3.3.1. [Macitentan - Orphan - EMEA-001032-PIP01-10-M05](#)

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

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. [Human, recombinant, non-fucosylated IgG1k monoclonal antibody targeting OX-40 receptor on activated T cells - EMEA-002886-PIP01-20-M02](#)

Amgen Europe B.V.; Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.3.3. [Avatrombopag maleate - EMEA-001136-PIP01-11-M02](#)

Swedish Orphan Biovitrum AB; Treatment of chronic immune thrombocytopenia

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.4. Crovalimab - EMEA-002709-PIP01-19-M01

Roche Registration GmbH; Treatment of paroxysmal nocturnal haemoglobinuria

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.5. Garadacimab - Orphan - EMEA-002726-PIP01-19-M03

CSL Behring GmbH; Prevention of hereditary angioedema attacks

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.6. Allogeneic bone marrow derived mesenchymal stromal cells, ex-vivo expanded - Orphan - EMEA-002706-PIP01-19-M02

medac Gesellschaft für klinische Spezialpräparate mbH; Treatment of acute graft-versus-host-disease

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.7. Avibactam / ceftazidime - EMEA-001313-PIP01-12-M13

Pfizer Europe MA EEIG; Treatment of bacterial infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.8. Aztreonam / avibactam - EMEA-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

3.3.9. [Cobicistat / atazanavir sulphate - EMEA-001465-PIP01-13-M05](#)

Bristol-Myers Squibb Pharma EEIG; Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.10. [Cobicistat / darunavir - EMEA-001280-PIP01-12-M05](#)

Janssen-Cilag International NV; Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.11. [Lamivudine / abacavir / dolutegravir - EMEA-001219-PIP01-11-M06](#)

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.12. [Tazobactam / ceftolozane - EMEA-001142-PIP02-16-M01](#)

Merck Sharp & Dohme (Europe), Inc.; Treatment of pneumonia

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.13. [Tenofovir alafenamide / emtricitabine / cobicistat / darunavir - EMEA-001825-PIP01-15-M04](#)

Janssen-Cilag International NV; Treatment of human immunodeficiency virus type-1 (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.14. Isoflurane - EMEA-002320-PIP01-17-M03

Sedana Medical AB; Sedation of mechanically ventilated patients

Day 30 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.3.15. Fordadistrogene movaparvovec - Orphan - EMEA-002741-PIP01-20-M01

Pfizer Europe MA EEIG; Treatment of Duchenne muscular dystrophy

Day 30 discussion

Action: For discussion

Neurology

3.3.16. Galcanezumab - EMEA-001860-PIP03-16-M08

Eli Lilly and Company Limited; Prevention of migraine headache

Day 30 discussion

Action: For discussion

Neurology

3.3.17. Evoncabtagene pazurgedleucel - EMEA-002881-PIP01-20-M01

CRISPR Therapeutics AG; Treatment of B-lymphoblastic leukaemia/lymphoma / Treatment of mature B cell neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.3.18. Calcium chloride / aprotinin / thrombin / fibrinogen - EMEA-001079-PIP01-10-M06

Kedrion S.p.A.; Treatment of haemorrhage resulting from a surgical procedure; Prevention of haemorrhage resulting from a surgical procedure

Day 30 discussion

Action: For discussion

Other

3.3.19. Lanadelumab - Orphan - EMEA-001864-PIP03-19-M01

Takeda Pharmaceuticals International AG Ireland Branch; Prevention of attacks of idiopathic non-histaminergic angioedema (INHA)

Day 30 discussion

Action: For discussion

Other

3.3.20. [Azelastine hydrochloride / mometasone furoate - EMEA-003122-PIP01-21-M01](#)

Lek Pharmaceuticals d.d.; Treatment of seasonal allergic rhinitis

Day 30 discussion

Action: For discussion

Oto-rhino-laryngology

3.3.21. [Zuranolone - EMEA-003119-PIP01-21-M01](#)

Biogen Netherlands B.V.; Treatment of postpartum depression

Day 30 discussion

Action: For discussion

Psychiatry

3.3.22. [Mirabegron - EMEA-000597-PIP02-10-M09](#)

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

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3.23. [Synthetic double-stranded siRNA oligonucleotide directed against lactate dehydrogenase A mRNA and containing four modified nucleosides which form a ligand cluster of four N-acetylgalactosamine residues \(DCR-PHXC, nedosiran\) - Orphan - EMEA-002493-PIP01-18-M05](#)

Dicerna Ireland Limited; Treatment of primary hyperoxaluria

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3.24. [Neisseria meningitidis serogroup B fHbp subfamily B / Neisseria meningitidis serogroup B fHbp subfamily A / Neisseria meningitidis group Y polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis group W-135 polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis group C polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria](#)

Pfizer Europe MA EEIG; Invasive disease caused by *Neisseria meningitidis* group A, B, C, W and Y from 12 months of age to less than 18 years of age

Day 30 discussion

Action: For discussion

Vaccines

3.3.25. SARS-CoV-2 virus, beta-propiolactone inactivated adjuvanted with CpG 1018 (VLA2001) - EMEA-003077-PIP01-21-M01

Valneva Austria 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 17 November 2022 for Nomination of Rapporteur and Peer reviewer

Action: For adoption

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

Action: For adoption

4.3. Nominations for other activities

Action: For adoption

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

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

6. Discussion on the applicability of class waivers

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

6.1. Discussions on the applicability of class waiver for products

6.1.1. Humanised recombinant IgG1 monoclonal antibody (ABBV-916) – EMEA-05-2022

AbbVie Ltd.; All classes of medicinal products for treatment of Alzheimer's disease;
Treatment of early Alzheimer's disease

Action: For adoption

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

No item

9.1.3. Evolutionary PIP

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

9.2.2. Conditions for orphan designation in inherited retinal diseases

Action: For information

9.2.3. Revision of Paediatric Addendum to the guidelines on clinical investigation of medicinal products for treatment and prevention of venous thromboembolic (VTE)

Action: For adoption

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. EMA Emergency task force (ETF) – Endorsement PDCO nomination

PDCO member: Brian Aylward

Action: For information

9.3.4. Upcoming Innovation Task Force (ITF) meetings

Action: For information

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

9.7.1. Draft Workplan for 2023

PDCO Chair: Brian Aylward

Action: For discussion

9.8. Planning and reporting

No item

10. Any other business

10.1. COVID-19 update

Action: For information

10.2. Reflection paper on Digital Support to Risk Minimisation

Action: For information

11. Breakout sessions

11.1. Internal operations

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

11.2. Paediatric oncology

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

11.3. 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/