7 October 2022
EMA/PDCO/764496/2022
Human Medicines Division

Paediatric Committee (PDCO)

Agenda for the meeting on 11-14 October 2022

Chair: Brian Aylward – Vice-Chair: Sabine Scherer

11 October 2022, 14:00 - 19:30, room 2C / virtual meeting

12 October 2022, 08:30 - 19:30, room 2C / virtual meeting

13 October 2022, 08:30 - 19:30, room 2C / virtual meeting

14 October 2022, 08:30 - 13:00, room 2C / virtual meeting

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 11-14 October 2022. See October 2022 PDCO minutes (to be published post November 2022 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 11-14 October 2022.

1.3. Adoption of the minutes

PDCO minutes for 06-09 September 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. Cedirogant - EMEA-003142-PIP02-21

Treatment of psoriasis

Day 120 opinion

Action: For adoption

Dermatology

2.1.2. Ruxolitinib - EMEA-002618-PIP03-21

Treatment of atopic dermatitis

Day 120 opinion

Action: For adoption

Dermatology

2.1.3. Sirolimus - Orphan - EMEA-003168-PIP01-21

Desitin Arzneimittel GmbH; Treatment of tuberous sclerosis

Day 120 opinion

Action: For adoption

Dermatology

2.1.4. Manganese - EMEA-003035-PIP02-21

Diagnostic evaluation of liver lesions by magnetic resonance imaging (MRI)

Day 120 opinion

Action: For adoption

Diagnostic

2.1.5. Glucagon analogue linked to a human immunoglobulin Fc fragment - Orphan - EMEA-003170-PIP01-21

Hanmi Pharm. Co., Ltd.; Treatment of congenital hyperinsulinism

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.6. Semaglutide - EMEA-001441-PIP07-21

Treatment of obesity

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.7. Batoclimab - EMEA-003162-PIP01-21

Treatment of myasthenia gravis

Day 120 opinion

Action: For adoption

Neurology

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

Invex Therapeutics Ltd; Treatment of idiopathic intracranial hypertension

Day 120 opinion

Action: For adoption

Neurology

2.1.9. Camidanlumab tesirine - EMEA-003160-PIP01-21

Treatment of Hodgkin lymphoma

Day 120 opinion

Action: For adoption

Oncology

2.1.10. Emactuzumab - Orphan - EMEA-003172-PIP01-21

Synox Therapeutics Limited; Treatment of tenosynovial giant cell tumour, local and diffuse type

Day 120 opinion

Action: For adoption

Oncology

2.1.11. Efavaleukin alfa - EMEA-003156-PIP02-22

Treatment of ulcerative colitis

Day 120 opinion

Action: For adoption

Other

2.1.12. EMEA-003165-PIP01-21

Treatment of chronic kidney disease

Day 120 opinion

Action: For adoption

Uro-nephrology

2.1.13. 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 20 – 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

Prevention of disease caused by *Streptococcus pneumoniae*

Day 120 opinion

Action: For adoption

Vaccines

2.1.14. COVID-19 vaccine (recombinant, adjuvanted) - EMEA-003191-PIP01-22

Prevention of coronavirus disease 2019 (COVID-19)

Day 120 opinion

Action: For adoption

Vaccines / Infectious Diseases

2.1.15. Tigulixostat - EMEA-003272-PIP01-22

Treatment of hyperuricemia in primary gout

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.16. 2-[4-Methoxy-3-(2-m-tolyl-ethoxy)-benzoylamino]-indan-2-carboxylic acid - Orphan - EMEA-003282-PIP01-22

Horizon Therapeutics Ireland DAC; Treatment of systemic sclerosis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.17. Namilumab - EMEA-003275-PIP01-22

Treatment of sarcoidosis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.18. Nipocalimab - EMEA-002559-PIP06-22

Treatment of chronic inflammatory demyelinating polyradiculoneuropathy

Day 60 opinion

Action: For adoption

Neurology

2.1.19. EMEA-003278-PIP01-22

Treatment of non-small cell lung cancer (NSCLC) / Treatment of small cell lung cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.20. Cobolimab - EMEA-003273-PIP01-22

Treatment of non-small cell lung cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.21. Lacutamab - Orphan - EMEA-003281-PIP01-22

Innate Pharma SA; Treatment of cutaneous T cell lymphoma

Day 60 opinion

Action: For adoption

Oncology

2.1.22. Pemigatinib - Orphan - EMEA-002370-PIP03-22

Incyte Biosciences Distribution B.V.; Treatment of myeloid / lymphoid neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.1.23. Vusolimogene oderparepvec - EMEA-003265-PIP01-22

Treatment of cutaneous squamous cell carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.24. EMEA-003269-PIP01-22

Treatment of mastocytosis

Day 60 opinion

Action: For adoption

Oncology / Haematology-Hemostaseology

2.2. Opinions on Compliance Check

2.2.1. Dopamine hydrochloride - EMEA-C-001105-PIP01-10-M06

BrePco Biopharma Limited; Treatment of vascular hypotensive disorders

Day 60 opinion

Action: For adoption

Neonatology - Paediatric Intensive Care

2.2.2. Brivaracetam - EMEA-C-000332-PIP01-08-M16

UCB Pharma S.A.; Treatment of epilepsy with partial onset seizures

Day 60 opinion

Action: For adoption

Neurology

2.2.3. Eladocagene exuparvovec - EMEA-C-002435-PIP01-18-M02

PTC Therapeutics International Limited; Treatment of aromatic L-amino acid decarboxylase deficiency

Day 60 opinion

Action: For adoption

Neurology

2.2.4. Vosoritide - EMEA-C4-002033-PIP01-16-M02

BioMarin International Limited; Treatment of achondroplasia

Day 60 letter

Action: For adoption

Other

2.2.5. Agomelatine - EMEA-C-001181-PIP01-11-M06

Les Laboratoires Servier; Treatment of major depressive episodes

Day 60 opinion

Action: For adoption

Psychiatry

2.2.6. Maralixibat chloride - EMEA-C-001475-PIP02-13-M02

Mirum Phamraceuticals; Treatment of Alagille syndrome

Day 30 opinion

Action: For adoption

Gastroenterology-Hepatology

2.2.7. Dabrafenib - EMEA-C-001147-PIP02-20

Novartis Europharm Limited; Treatment of glioma

Day30 opinion

Action: For adoption

Oncology

The PDCO adopted the opinion by written procedure on 27 September 2022

2.2.8. Trametinib - EMEA-C-001177-PIP02-20

Novartis Europharm Limited; Treatment of glioma

Day30 opinion

Action: For adoption

Oncology

The PDCO adopted the opinion by written procedure on 27 September 2022

2.2.9. Eculizumab - EMEA-C-000876-PIP05-15-M05

Alexion Europe SAS; Treatment of myasthenia gravis

Day 30 opinion

Action: For adoption

Neurology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Birch bark extract - EMEA-001299-PIP01-12-M01

Amryt AG; Treatment of skin injuries

Day 60 opinion

Action: For adoption

Dermatology

Note: Withdrawal request received on 29 September 2022

2.3.2. Brodalumab - EMEA-001089-PIP02-13-M03

LEO Pharma A/S; Treatment of psoriasis

Day 60 opinion

Action: For adoption

Dermatology

2.3.3. Glycopyrronium bromide - EMEA-002383-PIP01-18-M02

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

Day 60 opinion

Action: For adoption

Dermatology

2.3.4. Gadoquatrane - EMEA-002778-PIP01-20-M01

Bayer AG; Diagnosis by evaluation of any known or suspected clinical condition with contrast enhanced magnetic resonance imaging

Day 60 opinion

Action: For adoption

Diagnostic

2.3.5. Inclisiran sodium - EMEA-002214-PIP01-17-M01

Novartis Europharm Ltd.; Treatment of elevated cholesterol

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.6. Saxagliptin - EMEA-000200-PIP01-08-M10

AstraZeneca AB; Treatment of type 2 diabetes

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.7. Vedolizumab - EMEA-000645-PIP04-20-M01

Takeda Pharma A/S; Treatment of pouchitis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.8. Recombinant human A disintegrin and metalloprotease with thrombospondin type-1Motifs 13 (rADAMTS13) - Orphan - EMEA-001160-PIP01-11-M03

Baxalta Innovations GmbH; Treatment of thrombotic thrombocytopenic purpura

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.9. Voxelotor - Orphan - EMEA-002356-PIP02-20-M01

Global Blood Therapeutics Netherlands B. V.; Treatment of sickle cell disease

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.10. Risankizumab - EMEA-001776-PIP01-15-M01

AbbVie Ltd; Treatment of psoriasis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Dermatology / Gastroenterology-Hepatology

2.3.11. Bedaquiline (fumarate) - Orphan - EMEA-000912-PIP01-10-M06

Janssen-Cilag International NV; Treatment of multi-drug resistant tuberculosis

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.12. Rilpivirine (RPV) / dolutegravir (DTG) - EMEA-001750-PIP01-15-M06

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.13. Sulbactam / durlobactam - EMEA-002807-PIP01-20-M01

Entasis Therapeutics Inc.; Treatment of infections due to organisms of the *Acinetobacter baumannii-calcoaceticus* complex

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.14. Ataluren - Orphan - EMEA-000115-PIP01-07-M12

PTC Therapeutics International, Limited; Treatment of dystrophinopathy

Day 60 opinion

Action: For adoption

Neurology

2.3.15. Binimetinib - EMEA-001454-PIP03-15-M02

Pierre Fabre Médicament; Treatment of melanoma

Day 60 opinion

Action: For adoption

Oncology

2.3.16. Encorafenib - EMEA-001588-PIP01-13-M02

Pierre Fabre Médicament; Treatment of melanoma

Day 60 opinion

Action: For adoption

Oncology

2.3.17. Isatuximab - EMEA-002205-PIP01-17-M03

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

Day 60 opinion

Action: For adoption

Oncology

2.3.18. Bilastine - EMEA-000347-PIP02-16-M04

Faes Farma S.A.; Treatment of allergic conjuntivitis

Day 60 opinion

Action: For adoption

Ophthalmology

2.3.19. Sodium chloride solution 4.2% (w/v) / idrevloride, 3,5-diamino-6-chloro-N-(N-(4-(4-(2-(hexyl((2S,3R,4R,5R)-2,3,4,5,6-pentahydroxyhexyl)amino)ethoxy)phenyl)butyl)-carbamimidoyl)pyrazine-2-carboxamide - Orphan - EMEA-002935-PIP01-20-M02

Parion Sciences, Inc.; Treatment of primary ciliary dyskinesia (PCD)

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.20. Lanthanum carbonate hydrate - EMEA-000637-PIP02-10-M07

Takeda Pharmaceuticals International AG Ireland Branch; Treatment of hyperphosphataemia

Day 60 opinion

Action: For adoption

Uro-nephrology

2.3.21. Highly purified single-stranded, 5'-capped mRNA encoding full-length SARS-CoV-2 spike protein (BNT162b2) - EMEA-002861-PIP02-20-M05

BioNTech Manufacturing GmbH; Prevention of coronavirus disease 2019 (COVID-19)

Day 8 opinion

Action: For adoption

Infection disease

2.3.22. Vosoritide - EMEA-002033-PIP01-16-M03

BioMarin International Limited; Treatment of achondroplasia

Day 1 opinion

Action: For adoption

Other

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. Baricitinib - EMEA-C3-001220-PIP03-16-M02

Eli Lilly and Company; Treatment of atopic dermatitis

Day 30 letter

Action: For information

Dermatology

2.7.2. Cabozantinib (S)-malate - EMEA-C2-001143-PIP01-11-M03

IPSEN Pharma; Treatment of malignant solid tumours

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. Obefazimod - EMEA-003196-PIP01-22

Treatment of ulcerative colitis / Treatment of Crohn's disease

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.2. Inclacumab - EMEA-003219-PIP01-22

Treatment of sickle cell disease

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.3. HIV-1 maturation inhibitor / dolutegravir - EMEA-003152-PIP01-21

Treatment of human immunodeficiency virus (HIV-1) infection

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.4. HIV-1 maturation inhibitor - EMEA-003153-PIP01-21

Treatment of human immunodeficiency virus (HIV-1) infection

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.5. Posoleucel - Orphan - EMEA-002908-PIP01-20

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

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.6. Humanised monoclonal IgG1-based antibody - EMEA-003100-PIP01-21

Treatment of spinal muscular atrophy

Day 90 discussion

Action: For discussion

Neurology

3.1.7. Pridopidine (hydrochloride) - Orphan - EMEA-003174-PIP01-21

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

Day 90 discussion

Action: For discussion

Neurology

3.1.8. Vodobatinib - EMEA-003014-PIP01-21

Treatment of chronic myeloid leukaemia

Day 90 discussion

Action: For discussion

Oncology

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

Aytu BioPharma Inc.; Treatment of Ehlers-Danlos syndrome

Day 90 discussion

Action: For discussion

Other

3.1.10. Depemokimab - EMEA-003051-PIP04-22

Treatment of eosinophilic granulomatosis with polyangiitis (EGPA)

Day 90 discussion

Action: For discussion

Pneumology - Allergology

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

Biocodex SA; Treatment of primary hyperoxaluria

Day 90 discussion

Action: For discussion

Uro-nephrology

3.1.12. 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 90 discussion

Action: For discussion

Vaccines

3.1.13. Soluble guanylate cyclase (sGC) stimulator - EMEA-003266-PIP01-22

Treatment of pulmonary arterial hypertension

Day 60 discussion

Action: For discussion

Cardiovascular Diseases

3.1.14. EMEA-002612-PIP02-22

Treatment of sickle cell disease

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

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

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

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.16. Albaconazole - EMEA-003279-PIP01-22

Treatment of vulvovaginal candidiasis

Day 60 discussion

Action: For discussion

Infectious Diseases

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

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

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.18. Fosmanogepix - EMEA-003280-PIP01-22

Treatment of invasive fungal infections

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.19. Vilobelimab - EMEA-003080-PIP03-22

Treatment of severe coronavirus disease 2019 (COVID-19)

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.20. Ocrelizumab - EMEA-000310-PIP05-22

Treatment of multiple sclerosis

Day 60 discussion

Action: For discussion

Neurology

3.1.21. EMEA-003271-PIP01-22

Treatment of focal onset seizures

Day 60 discussion

Action: For discussion

Neurology

3.1.22. Adult differentiated autologous T cells from peripheral blood, expanded and transduced with a lentivirus to express a chimeric antigen receptor with anti-CD19 specificity (A3B1) conjugated with the co-stimulatory regions 4-1BB and CD3z - EMEA-003264-PIP01-22

Treatment of acute lymphoblastic leukaemia

Day 60 discussion

Action: For discussion

Oncology

3.1.23. EMEA-003274-PIP01-22

Treatment of melanoma

Day 60 discussion

Action: For discussion

Oncology

3.1.24. Pembrolizumab / favezelimab - EMEA-003104-PIP02-22

Treatment of Hodgkin lymphoma

Day 60 discussion

Action: For discussion

Oncology

3.1.25. Pembrolizumab / vibostolimab - EMEA-003063-PIP02-22

Treatment of Hodgkin lymphoma

Day 60 discussion

Action: For discussion

Oncology

3.1.26. 1-(4-(6-chloropyridazin-3-yl)piperazin-1-yl)-2-(4-cyclopropyl-3-fluorophenyl)ethan-1-one - Orphan - EMEA-003268-PIP01-22

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

Day 60 discussion

Action: For discussion

Other

3.1.27. EMEA-002612-PIP03-22

Prevention of pulmonary dysfunction

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.28. Immunoglobulin G4 [228-proline], anti-(*Betula alleghaniensis* allergen Bet v 1) (human monoclonal γ4-chain), disulphide with human monoclonal κ-chain,dimer / immunoglobulin G4 [227-proline], anti-(*Betula alleghaniensis* allergen Bet v 1) (human monoclonal γ4-chain), disulphide with human monoclonal κ-chain,dimer / immunoglobulin G4 [224-proline], anti-(*Betula alleghaniensis* allergen Bet v 1) (human monoclonal γ4-chain), disulphide with human monoclonal κ-chain,dimer - EMEA-003270-PIP01-22

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

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.29. EMEA-003276-PIP01-22

Treatment of post-traumatic stress disorder

Day 60 discussion

Action: For discussion

Psychiatry

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

Prevention of respiratory syncytial virus (RSV) diseases

Day 60 discussion

Action: For discussion

Vaccines

3.1.31. MVA-BN-RSV - EMEA-003185-PIP01-22

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

Day 60 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.1.32. Dexmedetomidine - EMEA-003283-PIP01-22

Sedation

Day 30 discussion

Action: For discussion

Anaesthesiology

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

Prevention of atherothrombotic events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

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

Treatment of heart failure

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

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

Treatment of hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

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

Treatment of mixed (or combined) dyslipidaemia

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

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

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

Day 30 discussion

Action: For discussion

Cardiovascular Diseases / Neurology

3.1.38. EMEA-003286-PIP01-22

Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.1.39. Isotretinoin - EMEA-003303-PIP01-22

Treatment of congenital ichthyosis

Day 30 discussion

Action: For discussion

Dermatology

3.1.40. EMEA-003301-PIP01-22

Treatment of moderate to severe plaque psoriasis

Day 30 discussion

Action: For discussion

Dermatology

3.1.41. Spesolimab - EMEA-002475-PIP03-22

Treatment of Netherton syndrome

Day 30 discussion

Action: For discussion

Dermatology

3.1.42. EMEA-003299-PIP01-22

Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.43. EMEA-003299-PIP02-22

Treatment of obesity

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.44. Recombinant anti-RANKL fully human monoclonal antibody - EMEA-003293-PIP01-22

Treatment of bone loss associated with sex hormone ablative therapy / Prevention of skeletal related events in patients with bone metastases / Treatment of giant cell tumour of bone / Treatment of osteoporosis

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

Note: Withdrawal request received on 16 September 2022

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

Treatment of type 1 diabetes mellitus (T1DM)

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

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

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

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

Spark Therapeutics Ireland Limited; Treatment of haemophilia A

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

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

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

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.49. Adintrevimab - EMEA-003118-PIP02-22

Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.50. Ensitrelvir - EMEA-003192-PIP01-22

Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.51. Eplontersen - EMEA-003294-PIP01-22

Treatment of transthyretin-mediated amyloidosis

Day 30 discussion

Action: For discussion

Neurology

3.1.52. 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 30 discussion

Action: For discussion

Neurology

3.1.53. EMEA-003288-PIP01-22

Treatment of developmental and epileptic encephalopathies and other seizure syndromes

Day 30 discussion

Action: For discussion

Neurology

3.1.54. Vesleteplirsen - EMEA-003305-PIP01-22

Treatment of Duchenne muscular dystrophy

Day 30 discussion

Action: For discussion

Neurology

3.1.55. Obinutuzumab - Orphan - EMEA-001207-PIP06-22

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

Day 30 discussion

Action: For discussion

Oncology

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

PTC Therapeutics International; Treatment of soft tissue sarcoma

Day 30 discussion

Action: For discussion

Oncology

3.1.57. Cyanocobalamin / pyridoxine / thiamine / diclofenac - EMEA-003292-PIP01-22

Treatment of inflammatory pain / Treatment of inflammatory rheumatic diseases

Day 30 discussion

Action: For discussion

Pain / Immunology-Rheumatology-Transplantation

3.1.58. Humanised IgG4 monoclonal antibody against a proliferation-inducing ligand - Orphan - EMEA-003300-PIP01-22

Chinook Therapeutics, Inc.; Treatment of IgA nephropathy

Day 30 discussion

Action: For discussion

Uro-nephrology

3.1.59. SARS-CoV-2, 19nCoV-CDC-Tan-HB02 strain (inactivated) - EMEA-003203-PIP01-22

Prevention of coronavirus disease 2019 (COVID-19)

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. Omaveloxolone - EMEA-C1-002487-PIP01-18

Reata Ireland Limited; Treatment of Friedreich's ataxia

Day 30 discussion

Action: For discussion

Other

3.2.2. Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA-C2-002330-PIP01-18-M02

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

Day 30 discussion

Action: For discussion

Vaccines

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Baricitinib - EMEA-001220-PIP03-16-M03

Eli Lilly and Company Limited; Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.3.2. Dupilumab - EMEA-001501-PIP04-19-M02

Regeneron Ireland DAC; Treatment of eosinophilic esophagitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.3. Linaclotide - EMEA-000927-PIP01-10-M07

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

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.4. Odevixibat - Orphan - EMEA-002054-PIP03-20-M02

Albireo AB; Treatment of Alagille syndrome

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.5. Upadacitinb - EMEA-001741-PIP02-16-M02

AbbVie Ltd; Treatment of ulcerative colitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.6. (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 30 discussion

Action: For discussion

Infectious Diseases

3.3.7. Doravirine - EMEA-001676-PIP01-14-M05

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

Day 30 discussion

Action: For discussion

Infectious Diseases

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

Nabriva Therapeutics DAC; Treatment of community-acquired pneumonia

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.9. 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 30 discussion

Action: For discussion

Infectious Diseases

3.3.10. 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 30 discussion

Action: For discussion

Infectious Diseases

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

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

Day 30 discussion

Action: For discussion

Neurology

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

Novartis Ireland Limited; Treatment of multiple sclerosis

Day 30 discussion

Action: For discussion

Neurology

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

Novartis Europharm Ltd; Treatment of multiple sclerosis

Day 30 discussion

Action: For discussion

Neurology

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

Kronos Bio Inc.; Treatment of acute myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.3.15. 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 30 discussion

Action: For discussion

Oncology

3.3.16. 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 30 discussion

Action: For discussion

Oncology

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

Cambridge Allergy Ltd; Treatment of peanut allergy

Day 30 discussion

Action: For discussion

Other

3.3.18. Setrusumab - Orphan - EMEA-002169-PIP01-17-M02

Mereo Biopharma 3 Ltd; Treatment of osteogenesis imperfecta

Day 30 discussion

Action: For discussion

Other

3.3.19. 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 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.20. 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 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.21. 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 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.22. 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 30 discussion

Action: For discussion

Pneumology - Allergology

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

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

Day 30 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.3.24. 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 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 October 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. Plasmid expressing variant of human interleukin 10 - EMEA-18-2021

Xalud Therapeutics, Inc; All classes of medicinal products for treatment of primary and secondary osteoarthrosis / Treatment of moderate-to-severe pain and reduced function due to osteoarthritis; and modification of osteoarthritis 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

9.2. 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 ínterim*)

Action: For information

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

Draft Agenda - PCWP-HCPWP joint meeting - 15 November 2022

Meeting summary - PCWP meeting – 22 September 2022

Meeting summary - HCPWP meeting – 22 September 2022

Meeting summary - PCWP-HCPWP joint meeting – 22 September 2022

Action: For information

9.4. Cooperation within the EU regulatory network

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

Report from the annual meeting of Enpr-EMA

PDCO member: Sabine Scherer, Marek Migdal

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

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. Introduction to the DARWIN EU® Coordination Centre

Action: For information

10.3. Online access to procedure data

Action: For information

10.4. Public consultation on Good Practice Guide for the use of the EU metadata catalogue

Action: For information

10.5. Public consultation on Data Quality Framework

Action: For information

11. Breakout sessions

11.1. Vaccines

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

11.2. Paediatric oncology

Action: For discussion on Thursday, 13:00 - 13:30

11.3. Neonatology

Action: For discussion on Thursday, 13:30 - 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/