



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 January 2024
EMA/PDCO/550/2024

Paediatric Committee (PDCO)

Draft Agenda for the meeting on 16-19 January 2024

Chair: Brian Aylward – Vice-Chair: Sylvie Benchetrit

16 January 2024, 14:00 - 19:45, room 2C

17 January 2024, 08:30 - 19:45, room 2C

18 January 2024, 08:30 - 19:45, room 2C

19 January 2024, 08:30 - 13:00, room 2C

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

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

Note on access to documents

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



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1. Introductions

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PDCO plenary session to be held 16-19 January 2024. See December 2023 PDCO minutes (to be published post January 2024 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 16-19 January 2024.

1.3. Adoption of the minutes

PDCO minutes for 12-15 December 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. Upadacitinib - EMEA-001741-PIP10-23

Treatment of alopecia areata

Day 120 opinion

Action: For adoption

Dermatology

2.1.2. Orforglipron - EMEA-003299-PIP02-22

Treatment of obesity

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.3. [Sepsipaterin - Orphan - EMEA-003027-PIP02-23](#)

PTC Therapeutics International; Treatment of hyperphenylalaninaemia

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.4. [Synthetic double-stranded siRNA oligonucleotide directed against apolipoprotein C-III mRNA and covalently linked to a ligand containing three N-acetylgalactosamine residues - Orphan - EMEA-003420-PIP01-23](#)

Arrowhead Pharmaceuticals, Inc.; Treatment of familial chylomicronemia syndrome (FCS)

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.5. [Dupilumab - EMEA-001501-PIP12-23](#)

Treatment of eosinophilic gastritis / gastroenteritis

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.6. [Ianalumab - EMEA-002338-PIP04-23](#)

Treatment of autoimmune haemolytic anaemia

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.7. [Belumosudil - Orphan - EMEA-003425-PIP01-23](#)

Sanofi Winthrop Industrie; Treatment of graft versus host disease (GVHD)

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.8. [Blinatumomab - Orphan - EMEA-000574-PIP03-23](#)

Amgen Europe B.V.; Treatment of B-lymphoblastic leukaemia/lymphoma

Day 120 opinion

Action: For adoption

Oncology

2.1.9. Clobetasol - EMEA-003458-PIP01-23

Treatment of ocular infections, inflammations and associated manifestations

Day 120 opinion

Action: For adoption

Ophthalmology

2.1.10. Tinalarebant - Orphan - EMEA-003225-PIP01-22

Belite Bio, Inc; Treatment of Stargardt disease

Day 120 opinion

Action: For adoption

Ophthalmology

2.1.11. EMEA-003515-PIP01-23

Treatment of Parkinson's disease

Day 60 opinion

Action: For adoption

Neurology

2.1.12. IgG-like T cell engager binding to DLL3 and CD3 - EMEA-003516-PIP01-23

Treatment of neuroendocrine carcinoma (excluding glioblastoma) / Treatment of small cell lung carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.13. Interferon gamma / Tumour necrosis factor-alpha / Granulocyte colony-stimulating factor / Interleukin-1 beta, human / Interleukin-2 - EMEA-003523-PIP01-23

Treatment of squamous cell carcinoma of the head and neck (SCCHN)

Day 60 opinion

Action: For adoption

Oncology

2.1.14. Isatuximab - EMEA-002205-PIP02-23

Treatment of malignant neoplasms of the haematopoietic and lymphoid tissue

Day 60 opinion

Action: For adoption

Oncology

2.1.15. Volrustomig - EMEA-003423-PIP02-23

Treatment of head and neck epithelial malignant neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.1.16. Zanzalintinib - EMEA-003522-PIP01-23

Treatment of colorectal cancer / Treatment of renal cell carcinoma / Treatment of head and neck squamous cell carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.17. Zenocutuzumab - EMEA-003519-PIP01-23

Treatment of pancreatic cancer / Treatment of lung cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.18. EMEA-003520-PIP01-23

Treatment of dry eye disease

Day 60 opinion

Action: For adoption

Ophthalmology

2.1.19. *Borrelia* outer surface protein A (OspA) serotypes (ST1-6) lipidated, fusion protein vaccine - EMEA-003130-PIP02-23

Prevention of Lyme disease

Day 90 opinion

Action: For adoption

Vaccines

2.2. Opinions on Compliance Check

2.2.1. Pegfilgrastim - EMEA-C-002671-PIP02-20

Accord Healthcare S.L.U.; Prevention of chemotherapy-induced febrile neutropenia

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.2.2. Casirivimab - EMEA-C-002964-PIP01-21-M02

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.2.3. Imdevimab - EMEA-C-002965-PIP01-21-M02

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.2.4. Talimogene laherparepvec - EMEA-C-001251-PIP01-11-M06

Amgen Europe B.V.; Treatment of melanoma

Day 60 opinion

Action: For adoption

Oncology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Azilsartan medoxomil - EMEA-000237-PIP01-08-M12

Takeda Development Centre Europe Ltd; Treatment of hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. Difelikefalin - EMEA-002565-PIP02-19-M01

Vifor Fresenius Medical Care Renal Pharma France; Treatment of chronic kidney disease associated pruritus

Day 60 opinion

Action: For adoption

Dermatology

2.3.3. Sodium zirconium cyclosilicate - EMEA-001539-PIP01-13-M06

AstraZeneca AB; Treatment of hyperkalaemia

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.4. Eluxadoline - EMEA-001579-PIP01-13-M06

AbbVie Limited; Treatment of diarrhoea-predominant irritable bowel syndrome

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.5. Mepolizumab - EMEA-000069-PIP01-07-M08

GSK Trading Services Limited; Treatment of hypereosinophilic syndrome

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.6. Recombinant human A disintegrin and metalloprotease with thrombospondin type-1 motifs 13 (rADAMTS13) - Orphan - EMEA-001160-PIP01-11-M04

Takeda Pharmaceuticals International AG; Treatment of thrombotic thrombocytopenic purpura

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.7. Upadacitinib - EMEA-001741-PIP04-17-M05

AbbVie Ltd; Treatment of atopic dermatitis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Dermatology

2.3.8. Oritavancin (diphosphate) - EMEA-001270-PIP01-12-M07

Menarini International Operations Luxembourg S.A; Treatment of acute bacterial skin and skin structure infections

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.9. Acetyl-L-leucine ((s)-(acetylamino)-4-methylpentanoic acid) - Orphan - EMEA-002796-PIP01-20-M02

IntraBio Ltd.; Treatment of Niemann-Pick disease type C

Day 60 opinion

Action: For adoption

Neurology

2.3.10. Fordadistrogene movaparvovec - Orphan - EMEA-002741-PIP01-20-M02

Pfizer Europe MA EEIG; Treatment of Duchenne muscular dystrophy

Day 60 opinion

Action: For adoption

Neurology

2.3.11. Givinostat - Orphan - EMEA-000551-PIP04-21-M03

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

Day 60 opinion

Action: For adoption

Neurology

2.3.12. Abemaciclib - EMEA-002342-PIP01-18-M04

Eli Lilly and Company Limited; Treatment of Ewing's sarcoma

Day 60 opinion

Action: For adoption

Oncology

2.3.13. Abemaciclib - EMEA-002342-PIP02-18-M03

Eli Lilly and Company Limited; Treatment of glioma

Day 60 opinion

Action: For adoption

Oncology

2.3.14. Dinutuximab beta - Orphan - EMEA-001314-PIP01-12-M02

Recordati Netherlands B.V.; Treatment of neuroblastoma

Day 60 opinion

Action: For adoption

Oncology

2.3.15. Midostaurin - Orphan - EMEA-000780-PIP01-09-M07

Novartis Europharm Limited; Treatment of acute myeloid leukaemia / Treatment of mast cell leukaemia / Treatment of malignant mastocytosis

Day 60 opinion

Action: For adoption

Oncology

2.3.16. Atropine sulfate - EMEA-002744-PIP01-19-M01

Nevakar Inc.; Treatment of myopia

Day 60 opinion

Action: For adoption

Ophthalmology

2.3.17. Molgramostim - Orphan - EMEA-002282-PIP01-17-M02

Savara Aps; Treatment of pulmonary alveolar proteinosis

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.18. Nedosiran - Orphan - EMEA-002493-PIP01-18-M06

Novo Nordisk A/S; Treatment of primary hyperoxaluria

Day 60 opinion

Action: For adoption

Uro-nephrology

2.3.19. Purified rabies virus, WISTAR PM/WI 38-1503-3M strain (inactivated) - EMEA-002234-PIP01-17-M02

Sanofi Pasteur; Prevention of rabies viral infection

Day 60 opinion

Action: For adoption

Vaccines

2.3.20. Recombinant SARS-CoV-2 spike protein - EMEA-002915-PIP01-20-M03

Sanofi Pasteur; Prevention of coronavirus disease 2019 (COVID-19)

Day 60 opinion

Action: For adoption

Vaccines

2.3.21. Chikungunya virus virus-like particle vaccine / aluminum hydroxide - EMEA-002656-PIP01-19-M01

Bavarian Nordic A/S; Prevention of chikungunya disease

Day 60 opinion

Action: For adoption

2.3.22. Daridorexant - EMEA-002121-PIP03-19-M02

Idorsia Pharmaceuticals Deutschland GmbH; Treatment of insomnia

Day 30 opinion

Action: For adoption

Psychiatry

2.4. Opinions on Re-examinations

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

Pfizer Europe MA EEIG; Treatment of alopecia areata

Day 30 opinion

Action: For adoption. Oral explanation to be held on Wednesday 17 January 2024 at 14:00

Dermatology

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. Obecabtagene autoleucel - EMEA-C1-003171-PIP01-21

Autolus GmbH; Treatment of acute lymphoblastic leukaemia

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. Navepegritide - Orphan - EMEA-002689-PIP02-23

Ascendis Pharma Growth Disorders A/S; Treatment of achondroplasia

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.2. Iodine (¹³¹I) apamistamab - Orphan - EMEA-003395-PIP02-23

Immedica Pharma AB; Treatment in allogenic stem cell transplantation

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Oncology

3.1.3. Trimodulin (human IgM, IgA, IgG solution) - EMEA-002883-PIP03-23

Treatment of lower respiratory tract and lung infections

Day 90 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care / Infectious Diseases / Pneumology - Allergology

3.1.4. EMEA-003477-PIP01-23

Treatment of appetite and general nutrition disorders

Day 90 discussion

Action: For discussion

Nutrition

3.1.5. Disitamab vedotin - EMEA-003443-PIP02-23

Treatment of HER2 expressing tumours / Treatment of solid tumours

Day 90 discussion

Action: For discussion

Oncology

3.1.6. Alpelisib - Orphan - EMEA-002016-PIP05-23

Novartis Europharm Limited; Treatment of lymphatic malformations associated with a PIK3CA mutation

Day 90 discussion

Action: For discussion

Other

3.1.7. Garetosmab - Orphan - EMEA-002736-PIP02-23

Regeneron Ireland DAC; Treatment of fibrodysplasia ossificans progressiva

Day 90 discussion

Action: For discussion

Other

3.1.8. Losmapimod - Orphan - EMEA-003448-PIP01-23

Fulcrum Therapeutics, Inc.; Treatment of facioscapulohumeral muscular dystrophy

Day 90 discussion

Action: For discussion

Other

3.1.9. Cannabidiol - Orphan - EMEA-003176-PIP02-22

Zynerba Pharmaceuticals Inc; Treatment of fragile X syndrome (FXS)

Day 90 discussion

Action: For discussion

Psychiatry

3.1.10. mRNA encoding CMV gB / mRNA encoding the gH protein in the CMV glycoprotein complex pentamer / mRNA encoding the UL131A protein in the CMV glycoprotein complex pentamer / mRNA encoding the UL130 protein in the CMV glycoprotein complex pentamer / mRNA encoding the gL protein in the CMV glycoprotein complex pentamer / mRNA encoding the UL128 protein in the CMV glycoprotein complex pentamer - EMEA-003405-PIP01-23

Prevention of cytomegalovirus infection

Day 90 discussion

Action: For discussion

Vaccines

3.1.11. Orforglipron - EMEA-003299-PIP01-22

Treatment of type 2 diabetes mellitus

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.12. Belimumab - EMEA-000520-PIP03-23

Treatment of systemic sclerosis

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.13. EMEA-003394-PIP01-23

Treatment of Duchenne/Becker muscular dystrophy

Day 90 discussion

Action: For discussion

Other / Neurology

3.1.14. Pegtibatase - Orphan - EMEA-003518-PIP01-23

Traverse Therapeutics Ireland Limited; Treatment of classical homocystinuria

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.15. Nomacopan - Orphan - EMEA-003517-PIP01-23

Akari Malta Ltd; Treatment in haematopoietic stem cell transplantation

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.16. Ensitrelvir - EMEA-003192-PIP02-23

Treatment of coronavirus disease 2019 (COVID-19)

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.17. Lenacapavir - EMEA-002740-PIP02-23

Prevention of human immunodeficiency virus (HIV-1) infection

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.18. Iptacopan - EMEA-002705-PIP06-23

Treatment of generalised myasthenia gravis (gMG)

Day 60 discussion

Action: For discussion

Neurology

3.1.19. Adeno-associated viral vector serotype 8 containing the 3' human otoferlin coding sequence / adeno-associated viral vector serotype 8 containing the 5' human otoferlin coding sequence - Orphan - EMEA-003524-PIP01-23

Sensorion SA; Treatment of otoferlin gene-mediated hearing loss

Day 60 discussion

Action: For discussion

Other

3.1.20. Mirdametinib - Orphan - EMEA-003525-PIP01-23

Springworks Therapeutics Ireland Limited; Treatment of neurofibromatosis type 1 - plexiform neurofibroma

Day 60 discussion

Action: For discussion

Other

3.1.21. Vosoritide - EMEA-002033-PIP02-23

Treatment of hypochondroplasia

Day 60 discussion

Action: For discussion

Other

3.1.22. Recombinant varicella zoster virus glycoprotein E adjuvanted - EMEA-003526-PIP01-23

Prevention of herpes zoster

Day 60 discussion

Action: For discussion

Vaccines

3.1.23. Single-stranded 5' capped mRNA encoding the HAs of the influenza virus and the N-terminal domain (NTD) and receptor binding domain (RBD) of the SARS-CoV-2 spike glycoprotein - EMEA-003521-PIP01-23

Prevention of influenza and coronavirus disease 2019 (COVID-19)

Day 60 discussion

Action: For discussion

Vaccines

3.1.24. Ramipril / nebivolol - EMEA-003530-PIP01-23

Treatment of hypertension / Treatment of heart failure / Treatment of coronary artery disease / Treatment of hypertension with coexisting heart failure / Treatment of hypertension with coexisting coronary artery disease

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.25. Human IgG1 monoclonal antibody targeting amyloid transthyretin - EMEA-003548-PIP01-23

Treatment of transthyretin-mediated amyloidosis

Day 30 discussion

Action: For discussion

Cardiovascular Diseases / Neurology

3.1.26. Urea / propylene glycol - EMEA-003542-PIP01-23

Treatment of dry skin

Day 30 discussion

Action: For discussion

Dermatology

3.1.27. EMEA-003531-PIP01-23

Treatment of hyperphenylalaninemia

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.28. Dapagliflozin / sitagliptin - EMEA-003534-PIP01-23

Treatment of type II diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.29. Human HSD17B1 enzyme inhibitor - EMEA-003537-PIP01-23

Treatment of endometriosis

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.30. Efinopegdutide - EMEA-003549-PIP01-23

Treatment of non-alcoholic steatohepatitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.31. 2-[4-Methoxy-3-(2-m-tolyl-ethoxy)-benzoylamino]-indan-2-carboxylic acid (fipaxalparant) - Orphan - EMEA-003539-PIP01-23

Horizon Therapeutics Ireland DAC; Treatment of progressive fibrosing interstitial lung disease

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.32. [Anti-alpha-synuclein recombinant humanised monoclonal antibody - EMEA-003541-PIP01-23](#)

Treatment of Parkinson's disease

Day 30 discussion

Action: For discussion

Neurology

3.1.33. [Empasiprubart - EMEA-003528-PIP01-23](#)

Treatment of multifocal motor neuropathy

Day 30 discussion

Action: For discussion

Neurology

3.1.34. [Glenzocimab - EMEA-003536-PIP01-23](#)

Treatment of acute ischemic stroke

Day 30 discussion

Action: For discussion

Neurology

3.1.35. [Suvecaltamide - EMEA-003248-PIP02-23](#)

Treatment of moderate to severe tremor in patients with Parkinson's disease

Day 30 discussion

Action: For discussion

Neurology

3.1.36. [Unasnemab - EMEA-003529-PIP01-23](#)

Treatment of spinal cord injury

Day 30 discussion

Action: For discussion

Neurology

3.1.37. Ursodoxicoltaurine / sodium phenylbutyrate - Orphan - EMEA-002876-PIP02-23

Amylyx Pharmaceuticals EMEA B.V.; Treatment of progressive supranuclear palsy

Day 30 discussion

Action: For discussion

Neurology

3.1.38. Autologous T-cells expressing a chimeric antigenic receptor against G protein coupled receptor family C group 5 member D (GPRC5D) - EMEA-003543-PIP01-23

Treatment of multiple myeloma

Day 30 discussion

Action: For discussion

Oncology

3.1.39. Budigalimab - EMEA-003532-PIP01-23

Treatment of solid tumours

Day 30 discussion

Action: For discussion

Oncology

3.1.40. Livmoniplimab - EMEA-003533-PIP01-23

Treatment of solid tumours

Day 30 discussion

Action: For discussion

Oncology

3.1.41. Zongertinib - EMEA-003546-PIP01-23

Treatment of non-small cell lung cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.42. Fragment antibody targeting human TfR1 conjugated to phosphorodiamidate morpholino oligomer - EMEA-003538-PIP01-23

Treatment of Duchenne muscular dystrophy

Day 30 discussion

Action: For discussion

Other

3.1.43. [Gastric inhibitory peptide \(GIP\), glucagon like peptide \(GLP\) and Gcg tri-agonist - EMEA-003258-PIP02-23](#)

Treatment of obesity

Day 30 discussion

Action: For discussion

Other

3.1.44. [Vixarelimab - EMEA-003540-PIP01-23](#)

Treatment of idiopathic pulmonary fibrosis

Day 30 discussion

Action: For discussion

Pneumology – Allergology

3.1.45. [Efgartigimod alfa - EMEA-002597-PIP10-23](#)

Treatment of thyroid eye disease

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.46. [Ensitrelvir - EMEA-003192-PIP03-23](#)

Post exposure prophylaxis of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.47. [Palonosetron / netupitant - EMEA-001198-PIP04-23](#)

Prevention of chemotherapy-induced nausea and vomiting

Day 30 discussion

Action: For discussion

Other

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. Avacopan - EMEA-C5-002023-PIP01-16-M07

Amgen Europe B.V.; Treatment of antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.2. Letemovir - EMEA-C-001631-PIP01-14-M05

Merck Sharp & Dohme B.V.; Prevention of cytomegalovirus infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.3. Tedizolid phosphate - EMEA-C2-001379-PIP01-12-M08

Merck Sharp & Dohme (Europe) Inc; Treatment of acute bacterial skin and skin structure infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.4. Anti-neonatal Fc receptor human monoclonal antibody - EMEA-C1-002559-PIP02-19

Janssen-Cilag International NV; Treatment of myasthenia gravis

Day 30 discussion

Action: For discussion

Neurology

3.2.5. Blinatumomab - EMEA-C-000574-PIP02-12-M04

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

Day 30 discussion

Action: For discussion

Oncology

3.2.6. Selexipag - EMEA-C-000997-PIP01-10-M07

Janssen-Cilag International NV; Treatment of pulmonary arterial hypertension

Day 30 discussion

Action: For discussion

Other

3.2.7. Hydrocortisone - EMEA-C-002305-PIP01-17-M01

Laboratoire AGUETTANT; Prevention of bronchopulmonary dysplasia

Day 30 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Chloroprocaine (hydrochloride) - EMEA-000639-PIP03-16-M03

Sintetica GmbH; Peripheral nerve block (local anaesthesia by perineural injection)

Day 30 discussion

Action: For discussion

3.3.2. Aficamten - EMEA-002958-PIP01-21-M01

Cytokinetics, Inc.; Treatment of hypertrophic cardiomyopathy

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.3. Milvexian - EMEA-003220-PIP01-22-M01

Janssen-Cilag International N.V.; Prevention of thromboembolism in patients with cardiovascular diseases

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.4. Ruxolitinib phosphate - EMEA-002618-PIP02-20-M01

Incyte Biosciences Distribution B.V.; Treatment of vitiligo

Day 30 discussion

Action: For discussion

Dermatology

3.3.5. Glucagon analogue linked to a human immunoglobulin Fc fragment - Orphan - EMEA-003170-PIP01-21-M02

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

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. Fidanacogene elaparovvec - Orphan - EMEA-002362-PIP02-19-M03

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

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.7. Filgotinib - EMEA-001619-PIP04-17-M03

Galapagos NV; 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

3.3.8. BNT162b2 / tozinameran / famtozinameran / riltozinameran / raxtozinameran- EMEA-002861-PIP02-20-M07

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.9. Satralizumab - Orphan - EMEA-001625-PIP02-21-M03

Roche Registration GmbH; Treatment of generalised myasthenia gravis

Day 30 discussion

Action: For discussion

Neurology

3.3.10. [Cedazuridine / decitabine - EMEA-003071-PIP01-21-M01](#)

Otsuka Pharmaceutical Netherlands B.V.; Treatment of acute myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.3.11. [Vamikibart - EMEA-003215-PIP01-22-M01](#)

Roche Registration GmbH; Treatment of macular oedema

Day 30 discussion

Action: For discussion

Ophthalmology

3.3.12. [Afamelanotide - Orphan - EMEA-000737-PIP02-11-M03](#)

Clinuvel Europe Limited; Treatment of erythropoietic protoporphyria

Day 30 discussion

Action: For discussion

Other

3.3.13. [In vitro expanded autologous human articular chondrocytes - EMEA-001823-PIP01-15-M03](#)

TETEC Tissue Engineering Technologies AG; Treatment of cartilage disorders

Day 30 discussion

Action: For discussion

Other

3.3.14. [Seltorexant - EMEA-002746-PIP01-20-M03](#)

Janssen-Cilag International NV; Treatment of major depressive disorder

Day 30 discussion

Action: For discussion

Psychiatry

3.3.15. L-Carnitine / glucose / calcium chloride dihydrate / magnesium chloride hexahydrate / sodium lactate / sodium chloride - EMEA-003049-PIP01-21-M01

Iperboreal Pharma Srl; Treatment of patients in need of peritoneal dialysis

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3.16. Mirabegron - EMEA-000597-PIP03-15-M06

Astellas Pharma Europe B.V.; Treatment of neurogenic detrusor overactivity

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3.17. Meningococcal group Y oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / recombinant *Neisseria meningitis* group B protein 961c / recombinant *Neisseria meningitis* group B protein 287- 953 / meningococcal group C oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / meningococcal group A oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / meningococcal group W-135 oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / recombinant *Neisseria meningitis* group B protein 936-741 / outer membrane vesicles (OMV) from *N. meningitidis* strain NZ 98/254 - EMEA-001260-PIP01-11-M03

GlaxoSmithKline Biologicals SA; Prevention of meningococcal meningitis

Day 30 discussion

Action: For discussion

Vaccines

3.3.18. 1-[[[4-(4-fluoro-2-methyl-1H-indol-5-yloxy)-6-methoxyquinolin-7-yl]oxy]methyl]cyclopropanamine-dihydrochloride - Orphan - EMEA-002486-PIP04-21-M01

Advenchen Laboratories, LLC; Treatment of Ewing sarcomas / Treatment of soft tissue sarcomas

Day 30 discussion

Action: For discussion

Oncology

3.3.19. 12 Grass pollen extract and cultivated rye pollen extract - EMEA-000813-PIP01-09-M01

Allergy Therapeutics (UK) Ltd.; Treatment of allergic rhinitis/rhino-conjunctivitis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

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 22 January 2024 for Nomination of Rapporteur and Peer reviewer

Action: For adoption

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

Action: For adoption

4.3. Nominations for other activities

Action: For adoption

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

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

6. Discussion on the applicability of class waivers

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

6.1. Discussions on the applicability of class waiver for products

No item

7. Discussion on the inclusion of an indication within a condition in an agreed PIP/waiver

7.1. Discussion on the possibility to include an indication within a condition in an agreed PIP/waiver

No item

8. Annual reports on deferrals

Note: The annual reports on deferrals to be noted by the members of the PDCO are flagged in the Annex B.

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. PDCO membership

Action: For information

9.1.2. Vote by Proxy

Action: For information

9.1.3. Strategic Review and Learning Meeting (SRLM) - Leuven, Belgium 16-17 May 2024

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. Paediatric Formulation Operational Expert Group (PFOEG, former Formulation Working Group)

PDCO-PFOEG joint session

PDCO Chair: Brian Aylward; PDCO members: Dina Apele-Freimane, Siri Wang, Louisa Braun Exner and Jana Lass

Action: For discussion

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. PDCO - Modelling and Simulation Operational Expert Group (MSOEG)

Draft summary slide for PDCO-MSOEG BINGO

PDCO members: Sara Vennberg and David Khan; Expert: Kristin Karlsson

Action: For discussion

9.4. Cooperation within the EU regulatory network

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

No item

9.5. Cooperation with International Regulators

9.5.1. Paediatric Cluster Teleconference

Action: For information

9.6. Contacts of the PDCO with external parties and interaction with the Interested Parties to the Committee

No item

9.7. PDCO work plan

No item

9.8. Planning and reporting

9.8.1. EMA Business Pipeline activity and Horizon scanning

No item

10. Any other business

10.1. Feedback from oncology break out session – framework discussions supporting regulatory decision-making

Action: For information

10.2. Onboarding of Paediatrics processes on IRIS

Action: For information

10.3. Training on Proxy votes

Action: For information

10.4. Report from paediatric clinical trial breakout session, ACT EU-methodology workshop

PDCO members: Dina Apele-Freimane and Anette Solli Karlsen

Action: For information

10.5. EU Network Training Centre (EU NTC): Paediatric curriculum follow-up

PDCO members: Sylvie Benchetrit, Sara Vennberg and Francesca Rocchi

Action: For information

11. Breakout sessions

11.1. Neonatology

Action: For discussion on Wednesday, 13:00 - 14:00, room 2C

11.2. Vaccines

Action: For discussion on Thursday, 13:00 – 14:00, room 2C

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.

For a list of acronyms and abbreviations, see:

[Abbreviations used in EMA scientific committees & CMD documents and in relation to EMA's regulatory activities](#)

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/