15 March 2024
EMA/PDCO/87226/2024
Human Medicines Division

Paediatric Committee (PDCO)

Draft Agenda for the meeting on 19-22 March 2024

Chair: Brian Aylward – Vice-Chair: Sylvie Benchetrit

19 March 2024, 14:00 - 19:45, room 2C

20 March 2024, 08:30 - 19:45, room 2C

21 March 2024, 08:30 - 19:45, room 2C

22 March 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 19-22 March 2024. See March 2024 PDCO minutes (to be published post April 2024 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 19-22 March 2024.

1.3. Adoption of the minutes

PDCO minutes for 20-23 February 2024.

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. Oral inhibitor of PCSK9 - EMEA-003453-PIP01-23

Treatment of hypercholesterolaemia

Day 120 opinion

Action: For adoption

Cardiovascular Diseases

2.1.2. Lutikizumab - EMEA-003481-PIP01-23

Treatment of hidradenitis suppurativa

Day 120 opinion

Action: For adoption

Dermatology

2.1.3. Spesolimab - EMEA-002475-PIP04-23

Treatment of hidradenitis suppurativa

Day 120 opinion

Action: For adoption

Dermatology

2.1.4. GIPR antagonist/GLP-1R agonist - EMEA-003439-PIP02-23

Treatment of obesity

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.5. Plecanatide - EMEA-003441-PIP01-23

Treatment of irritable bowel syndrome with constipation / Treatment of chronic idiopathic constipation

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

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

Novo Nordisk A/S; Treatment of sickle cell disease

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.7. Tozorakimab - EMEA-003360-PIP01-22

Treatment of acute respiratory failure

Day 120 opinion

Action: For adoption

Infectious Diseases / Pneumology - Allergology

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

Treatment of melanoma

Day 120 opinion

Action: For adoption

Oncology

2.1.9. Laruparetigene zovaparvovec - Orphan - EMEA-003457-PIP01-23

FGK Representative Service GMBH; Treatment of X-linked retinitis pigmentosa

Day 120 opinion

Action: For adoption

Ophthalmology

2.1.10. Hemopexin, human - Orphan - EMEA-003333-PIP01-22

CSL Behring GmbH; Treatment of sickle cell disease

Day 120 opinion

Action: For adoption

Other

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

Intellia Therapeutics, Inc.; Treatment of hereditary angioedema (HAE)

Day 120 opinion

Action: For adoption

Other

2.1.12. Mometasone - EMEA-003454-PIP01-23

Treatment of chronic rhinosinusitis (CRS)

Day 120 opinion

Action: For adoption

Oto-rhino-laryngology

2.1.13. Tanimilast - EMEA-003393-PIP01-23

Treatment of asthma

Day 120 opinion

Action: For adoption

Pneumology - Allergology

2.1.14. Live attenuated respiratory syncytial virus (RSV) - EMEA-003277-PIP02-23

Prevention of respiratory syncytial virus (RSV) disease

Day 120 opinion

Action: For adoption

Vaccines

2.1.15. Atorvastatin / fenofibrate - EMEA-003563-PIP01-23

Treatment of mixed hyperlipidaemia

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.16. Fenofibrate / ezetimibe / rosuvastatin - EMEA-003562-PIP01-23

Treatment of mixed hyperlipidaemia

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.17. Volixibat - EMEA-003567-PIP01-23

Treatment of primary biliary cholangitis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.18. Acetylcysteine - EMEA-003554-PIP01-23

Treatment of hereditary cystatin C amyloid angiopathy

Day 60 opinion

Action: For adoption

Neurology

2.1.19. *Clostridium botulinum* neurotoxin type A (150 kD), free from complexing proteins - EMEA-001039-PIP04-23

Treatment of essential tremor

Day 60 opinion

Action: For adoption

Neurology

2.1.20. Amivantamab - EMEA-002573-PIP02-23

Treatment of colorectal carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.21. Camreluzimab - EMEA-003566-PIP01-23

Treatment of hepatocellular carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.22. Erdafitinib - EMEA-002042-PIP03-23

Treatment of urothelial carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.23. Modified messenger ribonucleic acid encoding individual patient-specific tumour neoantigens - EMEA-003434-PIP02-23

Treatment of renal neoplasms / Treatment of urothelial carcinomas / Treatment of cutaneous squamous cell carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.24. EMEA-003485-PIP01-23

Treatment of non-small cell lung cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.25. Petosemtamab - EMEA-003557-PIP01-23

Treatment of head and neck epithelial neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.1.26. Raludotatug deruxtecan - EMEA-003569-PIP01-23

Treatment of ovarian cancer / Treatment of primary peritoneal cancer / Treatment of fallopian tube cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.27. Riletamotide / tapderimotide / alrefimotide - EMEA-003555-PIP01-23

Treatment of malignant mesothelioma

Day 60 opinion

Action: For adoption

Oncology

2.1.28. Carbachol / brimonidine - EMEA-003561-PIP01-23

Treatment of presbyopia

Day 60 opinion

Action: For adoption

Ophthalmology

2.1.29. Human alpha-1-proteinase inhibitor immunoglobulin G fusion protein, recombinant - EMEA-003570-PIP01-23

Treatment of emphysema secondary to congenital deficiency of alpha-1 antitrypsin

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.1.30. Dapagliflozin propanediol / baxdrostat - EMEA-003559-PIP01-23

Treatment of chronic kidney disease

Day 60 opinion

Action: For adoption

Uro-nephrology

2.1.31. Sargramostim - EMEA-003568-PIP01-23

Treatment for patients acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome [H-ARS])

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.32. Ezetimibe / pitavastatin - EMEA-003573-PIP01-23

Treatment of dyslipidaemia

Day 30 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.33. Mirikizumab - EMEA-002208-PIP02-24

Treatment of ulcerative colitis

Day 30 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.34. Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain / Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain / Split influenza virus, inactivated containing antigens equivalent to B-like strain - EMEA-003603-PIP01-24

Prevention of influenza disease

Day 7 opinion

Action: For information

Vaccines

The PDCO adopted the opinion by written procedure on 14 March 2024

2.2. Opinions on Compliance Check

2.2.1. Tasimelteon - EMEA-C1-001531-PIP01-13-M04

Vanda Pharmaceuticals Netherlands B.V.; Treatment of non-24-hour sleep-wake disorder in

the totally blind

Day 60 letter

Action: For adoption

Neurology

2.2.2. Bilastine - EMEA-C-000347-PIP02-16-M05

Faes Farma, S.A.; Treatment of allergic conjunctivitis

Day 60 opinion

Action: For adoption

Ophthalmology / Pneumology - Allergology

2.2.3. Influenza virus type B, Victoria lineage / influenza virus type A, H3N2 / influenza virus type A, H1N1 - EMEA-C-003589-PIP01-24

AstraZeneca AB; Prevention of influenza infection

Day 30 opinion

Action: For adoption

Vaccines

2.2.4. Atropine sulfate - EMEA-C-002744-PIP01-19-M01

Nevakar Inc.; Treatment of myopia

Day 30 opinion

Action: For adoption

Ophthalmology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Apixaban - EMEA-000183-PIP02-12-M05

Bristol-Myers Squibb / Pfizer EEIG; Treatment of venous thromboembolism

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. Levonorgestrel - EMEA-002474-PIP02-18-M02

Chemo Research, S.L.; Contraception

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.3. Venglustat - Orphan - EMEA-001716-PIP07-22-M01

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

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.4. Avatrombopag maleate - EMEA-001136-PIP01-11-M03

Swedish Orphan Biovitrum AB; Treatment of idiopathic thrombocytopenic purpura / Treatment of thrombocytopenic purpura secondary to liver disease

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.5. Giroctocogene fitelparvovec - Orphan - EMEA-002724-PIP01-19-M03

Pfizer Europe MA EEIG; Treatment of haemophilia A

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.6. Pegcetacoplan - Orphan - EMEA-002600-PIP01-19-M02

Swedish Orphan Biovitrum AB (publ); Treatment of paroxysmal nocturnal haemoglobinuria

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.7. Onasemnogene abeparvovec - Orphan - EMEA-002168-PIP01-17-M06

Novartis Europharm Limited; Treatment of spinal muscular atrophy

Day 60 opinion

Action: For adoption

Neurology

2.3.8. Brexucabtagene autoleucel - Orphan - EMEA-001862-PIP03-20-M02

Kite Pharma EU B.V.; Treatment of mature B-cell neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.3.9. Loncastuximab tesirine - EMEA-002665-PIP02-20-M01

Swedish Orphan Biovitrum AB (publ); Treatment of mature B-cell neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.3.10. Nivolumab - EMEA-001407-PIP02-15-M07

Bristol-Myers Squibb Pharma EEIG; Treatment of malignant neoplasms of lymphoid tissue / Treatment of malignant neoplasms of the central nervous system

Day 60 opinion

Action: For adoption

Oncology

2.3.11. Olaparib - EMEA-002269-PIP01-17-M03

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

Day 60 opinion

Action: For adoption

Oncology

2.3.12. Selumetinib - Orphan - EMEA-001585-PIP01-13-M06

AstraZeneca AB; Treatment of melanoma / Treatment of neurofibromatosis type 1 / Treatment of thyroid cancer

Day 60 opinion

Action: For adoption

Oncology

2.3.13. Berotralstat - EMEA-002449-PIP02-18-M02

BioCryst Ireland Limited; Treatment of hereditary angioedema

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.14. Glycopyrronium bromide / formoterol fumarate dihydrate / beclometasone dipropionate - EMEA-001875-PIP02-18-M04

Chiesi Farmaceutici S.p.A.; Treatment of asthma

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.15. Mometasone (furoate) / glycopyrronium bromide / indacaterol - EMEA-001812-PIP01-15-M03

Novartis Europharm Limited; Treatment of asthma

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.16. Atrasentan - Orphan - EMEA-001666-PIP02-21-M01

Chinook Therapeutics, Inc.; Treatment of IgA nephropathy

Day 60 opinion

Action: For adoption

Uro-nephrology

2.3.17. Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) - EMEA-002068-PIP01-16-M05

Seqirus Netherlands; Prevention of influenza

Day 60 opinion

Action: For adoption

Vaccines

2.3.18. 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-M01

MSD Europe Belgium SRL; Prevention of dengue disease

Day 60 opinion

Action: For adoption

Vaccines

2.3.19. Multivalent pneumococcal polysaccharide conjugate to carrier protein - EMEA-002780-PIP02-20-M01

Sanofi Pasteur; Prevention of disease caused by *Streptococcus pneumoniae*

Day 60 opinion

Action: For adoption

Vaccines

2.3.20. Recombinant influenza hemagglutinin-strain B (Yamagata lineage) / recombinant influenza hemagglutinin-strain B (Victoria lineage) / recombinant influenza hemagglutinin-strain A (H3N2 subtype) / recombinant influenza hemagglutinin-strain A (H1N1 subtype) - EMEA-002418-PIP01-18-M03

Sanofi Pasteur; Prevention of influenza infection

Day 60 opinion

Action: For adoption

Vaccines

2.3.21. Mirikizumab - EMEA-002208-PIP01-17-M04

Eli Lilly and Company; Treatment of Crohn's disease

Day 30 opinion

Action: For adoption

Gastroenterology-Hepatology

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. Dupilumab - EMEA-C3-001501-PIP02-13-M08

Sanofi Winthrop Industrie; Treatment of asthma

Day 30 letter

Action: For information

Pneumology – Allergology

2.7.2. Delandistrogene moxeparvovec - EMEA-C1-002677-PIP01-19-M03

Roche Registration GmbH; Treatment of Duchenne muscular dystrophy

Day 30 letter

Action: For information

Neurology

2.7.3. Pneumococcal polysaccharide serotype 3 – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 8 – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 15C – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 6A – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 15A – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 16F – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 19A – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 23A – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 24F – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 17F – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 33F – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 10A – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 12F – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 20A – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 31 – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 35B – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 7F – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 22F – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 9N – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 11A – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 23B – diphtheria CRM197 conjugate (V116) - EMEA-C1-003155-PIP01-21-M01

MSD Europe Belgium S.R.L.; Prevention of disease caused by *Streptococcus pneumoniae*

Day 30 letter

Action: For information

Vaccines

3. Discussion of applications

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

3.1. Discussions on Products D90-D60-D30

3.1.1. EMEA-003480-PIP01-23

Treatment of psoriasis

Day 90 discussion

Action: For discussion

Dermatology

3.1.2. EMEA-003478-PIP01-23

Treatment of psoriasis

Day 90 discussion

Action: For discussion

Dermatology

3.1.3. Human alpha-1 proteinase inhibitor, modified - EMEA-003463-PIP01-23

Treatment of haemophilia B

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.4. Ianalumab - EMEA-002338-PIP05-23

Treatment of immune thrombocytopenia (ITP)

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.5. Mavorixafor - Orphan - EMEA-002490-PIP01-18

X4 Pharmaceuticals (Austria) GmbH; Treatment of warts, hypogammaglobulinemia, infections and myelokathexis (WHIM) syndrome

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.6. Ganaxolone - Orphan - EMEA-002341-PIP02-23

Marinus Pharmaceuticals, Inc.; Treatment of tuberous sclerosis complex

Day 90 discussion

Action: For discussion

Neurology

3.1.7. Radiprodil - EMEA-003462-PIP01-23

Treatment of GRIN-related disorders

Day 90 discussion

Action: For discussion

Neurology

3.1.8. Recombinant adeno-associated virus Olig001 containing human aspartoacylase cDNA - Orphan - EMEA-003459-PIP01-23

Myrtelle,Inc.; Treatment of Canavan disease

Day 90 discussion

Action: For discussion

Neurology

3.1.9. Brigimadlin - Orphan - EMEA-003260-PIP03-23

Boehringer Ingelheim International GmbH; Treatment of soft tissue sarcoma / Treatment of soft tissue sarcoma excluding liposarcoma

Day 90 discussion

Action: For discussion

Oncology

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

Prevention of migraine

Day 90 discussion

Action: For discussion

Pain / Neurology

3.1.11. Povorcitinib - EMEA-003313-PIP02-23

Treatment of vitiligo

Day 60 discussion

Action: For discussion

Dermatology

3.1.12. Sonelokimab - EMEA-002568-PIP02-23

Treatment of hidradenitis suppurativa

Day 60 discussion

Action: For discussion

Dermatology

3.1.13. Linaprazan - EMEA-003558-PIP01-23

Treatment of gastro-oesophageal reflux disease

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.14. Humanised IgG4 monoclonal antibody against FIXa and FX - EMEA-003550-PIP01-23

Treatment of coagulation factor deficiencies

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.15. Tulisokibart - EMEA-003556-PIP01-23

Treatment of ulcerative colitis

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.16. Human rabies immune globulin - EMEA-003552-PIP01-23

Prevention of rabies infection

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.17. Olorofim - Orphan - EMEA-003564-PIP01-23

Shionogi BV; Treatment of fungal infectious disorders

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.18. N-{(2S,3R)-4,4-difluoro-1-(2-hydroxy-2-methylpropanoyl)-2-[(2,3',5'-trifluoro[1,1'-biphenyl]-3-yl)methyl]pyrrolidin-3-yl}ethanesulfonamide - Orphan - EMEA-003553-PIP01-23

Takeda Pharma A/S; Treatment of idiopathic hypersomnia / Treatment of narcolepsy

Day 60 discussion

Action: For discussion

Neurology

3.1.19. Idroxioleic acid, sodium - Orphan - EMEA-003565-PIP01-23

Laminar Pharmaceuticals SA; Treatment of malignant glioma in children, including paediatric-type diffuse high-grade glioma

Day 60 discussion

Action: For discussion

Oncology

3.1.20. Rilonacept - Orphan - EMEA-003571-PIP01-23

Kiniksa Pharmaceuticals (UK), Ltd.; Treatment of idiopathic pericarditis

Day 60 discussion

Action: For discussion

Other / Cardiovascular Diseases

3.1.21. Atogepant - EMEA-002530-PIP02-23

Treatment of migraine headaches

Day 60 discussion

Action: For discussion

Pain

3.1.22. EMEA-003560-PIP01-23

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

Day 60 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.1.23. EMEA-003580-PIP01-24

Treatment of elevated cholesterol / Treatment of mixed dyslipidaemia

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.24. Ezetimibe / rosuvastatin - EMEA-003582-PIP01-24

Treatment of hypercholesterolaemia / Prevention of cardiovascular events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.25. Gallium (68Ga) boclatixafortide - EMEA-003408-PIP02-24

Diagnosis of primary aldosteronism

Day 30 discussion

Action: For discussion

Diagnostic

3.1.26. Ersodetug - Orphan - EMEA-002813-PIP02-24

Rezolute (Bio) Ireland Limited; Treatment of congenital hyperinsulinism

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.27. Sitagliptin / dapagliflozin - EMEA-003572-PIP01-23

Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.28. Crofelemer - Orphan - EMEA-003296-PIP02-24

Napo Therapeutics S.p.A.; Treatment of microvillus inclusion disease

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.29. 6-(4-((1s,3s)-1-amino-3-hydroxycyclobutyl)phenyl)-1-ethyl-7-phenyl-1H-pyrido [2,3-b][1,4]oxazin-2(3H)-one, L-tartrate salt - Orphan - EMEA-003585-PIP01-24

Vaderis Therapeutics AG; Treatment of hereditary haemorrhagic telangiectasia

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.30. Mezagitamab - EMEA-003502-PIP02-24

Treatment of primary immunoglobulin A nephropathy

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.31. Tildrakizumab - EMEA-001451-PIP02-24

Treatment of chronic idiopathic arthritis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.32. Tulisokibart - EMEA-003556-PIP02-24

Treatment of Crohn's disease

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.33. Trofinetide - Orphan - EMEA-003587-PIP01-24

Acadia Pharmaceuticals Inc.; Treatment of Rett syndrome

Day 30 discussion

Action: For discussion

Neurology

3.1.34. EMEA-003586-PIP01-24

Treatment of all solid and haematological malignancies

Day 30 discussion

Action: For discussion

Oncology

3.1.35. 3,3-Dimethyl-N-(6-methyl-5-{[2-(1-methyl-1H-pyrazol-4-yl)pyridine-4-yl]oxy}pyridine-2-yl)-2-oxopyrrolidine-1-carboxamide hydrochloride hydrate - Orphan - EMEA-003495-PIP02-24

Abbisko Therapeutics., Co., Ltd.; Treatment of tenosynovial giant cell tumours

Day 30 discussion

Action: For discussion

Oncology

3.1.36. 7-ethyl-10-hydroxy-camptothecin - Orphan - EMEA-003588-PIP01-24

CEBIOTEX S.L. Biomedical Nanofibers; Treatment of soft tissue neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.1.37. EMEA-003576-PIP01-24

Treatment of prostate cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.38. Autologous T-cells from a melanoma metastasis - EMEA-003535-PIP02-24

Treatment of melanoma

Day 30 discussion

Action: For discussion

Oncology

3.1.39. Certepetide - Orphan - EMEA-003577-PIP01-24

Lisata Therapeutics Ireland Limited; Treatment of pancreatic cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.40. EMEA-003581-PIP01-24

Treatment of lung cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.41. Evencaleucel - Orphan - EMEA-003579-PIP01-24

XNK Therapeutics AB; Treatment of multiple myeloma

Day 30 discussion

Action: For discussion

Oncology

3.1.42. Rivoceranib - EMEA-002489-PIP02-24

Treatment of hepatocellular carcinoma

Day 30 discussion

Action: For discussion

Oncology

3.1.43. EMEA-003574-PIP01-24

Treatment of colorectal cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.44. Lebrikizumab - EMEA-002536-PIP02-24

Treatment of chronic rhinosinusitis with nasal polyps

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.45. Ravulizumab - EMEA-001943-PIP07-24

Treatment of primary IgA nephropathy

Day 30 discussion

Action: For discussion

Uro-nephrology

3.1.46. MRNA encoding the influenza virus B/Victoria strain neuraminidase / mRNA encoding the influenza virus B/Victoria strain hemagglutinin / mRNA encoding the influenza virus H3N2 strain neuraminidase / mRNA encoding the influenza virus H3N2 strain hemagglutinin / mRNA encoding the influenza virus H1N1 strain neuraminidase / mRNA encoding the influenza virus H1N1 strain hemagglutinin - EMEA-003578-PIP01-24

Influenza immunisation

Day 30 discussion

Action: For discussion

Vaccines

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. Maralixibat chloride - EMEA-C-001475-PIP03-17-M04

Mirum Pharmaceuticals; Treatment of progressive familial intrahepatic cholestasis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.2.2. Itolizumab - EMEA-C1-003208-PIP02-22

Biocon Pharma Malta I Limited; Treatment of acute graft versus host disease

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.3. Cobicistat / darunavir - EMEA-C4-001280-PIP01-12-M06

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.4. Binimetinib - EMEA-C-001454-PIP03-15-M03

Pierre Fabre Médicament; Treatment of melanoma

Day 30 discussion

Action: For discussion

Oncology

3.2.5. Encorafenib - EMEA-C-001588-PIP01-13-M03

Pierre Fabre Médicament; Treatment of melanoma

Day 30 discussion

Action: For discussion

Oncology

3.2.6. Birch pollen extract (*Betula verrucosa*) - EMEA-C-001879-PIP01-15-M03

ALK-Abelló A/S; Treatment of allergic rhinitis / rhino-conjunctivitis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.2.7. Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) - EMEA-C-002330-PIP01-18-M03

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. Ertugliflozin - EMEA-001533-PIP01-13-M03

MSD Europe Belgium SRL; Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.2. Linaclotide - EMEA-000927-PIP01-10-M08

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

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.3. Inebilizumab - EMEA-001911-PIP03-23-M01

Horizon Therapeutics Ireland Designated Activity Company (DAC); Treatment of immunoglobulin G4-related disease (IgG4-RD)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.4. Olokizumab - EMEA-001222-PIP01-11-M01

Accelsiors GmbH; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis,

ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.5. Relebactam monohydrate / cilastatin sodium / imipenem monohydrate - EMEA-001809-PIP01-15-M05

MSD Europe Belgium SRL; Treatment of gram-negative bacterial infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.6. Mecasermin rinfabate - Orphan - EMEA-000534-PIP03-17-M01

OHB Neonatology Ltd; Prevention of chronic lung disease of prematurity

Day 30 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.3.7. Inebilizumab - EMEA-001911-PIP02-22-M01

Horizon Therapeutics Ireland Designated Activity Company (DAC); Treatment of myasthenia gravis

Day 30 discussion

Action: For discussion

Neurology

3.3.8. Soticlestat - Orphan - EMEA-002572-PIP02-19-M05

Takeda Pharma A/S; Treatment of Dravet syndrome / Treatment of Lennox-Gastaut syndrome

Day 30 discussion

Action: For discussion

Neurology

3.3.9. Tasimelteon - Orphan - EMEA-001531-PIP01-13-M05

Vanda Pharmaceuticals Netherlands B.V.; Treatment of non-24-hour sleep-wake disorder in the totally blind

Day 30 discussion

Action: For discussion

Neurology

3.3.10. Quizartinib - EMEA-001821-PIP01-15-M08

Daiichi Sankyo Europe GmbH; Treatment of acute myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.3.11. Calcifediol - EMEA-002093-PIP02-17-M02

Vifor Fresenius Medical Care Renal Pharma France; Treatment of secondary hyperparathyroidism (SHPT)

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3.12. Pegcetacoplan - Orphan - EMEA-002600-PIP03-21-M02

Apellis Ireland Limited; Treatment of glomerulonephritis and nephrotic syndrome

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3.13. *Neisseria meningitidis* serogroup W polysaccharide conjugated to *tetanus* toxoid / *Neisseria meningitidis* serogroup Y polysaccharide conjugated to *tetanus* toxoid / *Neisseria meningitidis* serogroup C polysaccharide conjugated to *tetanus* toxoid / *Neisseria meningitidis* serogroup A polysaccharide conjugated to *tetanus* toxoid - EMEA-001930-PIP01-16-M05

Sanofi Pasteur; Prevention of invasive meningococcal disease

Day 30 discussion

Action: For discussion

Vaccines

3.3.14. mRNA encoding for the linked NTD and RBD domains of the spike glycoprotein of SARS-CoV-2 (mRNA-1283) - EMEA-003426-PIP01-23-M01

MODERNA BIOTECH SPAIN, S.L.; Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Vaccines / Infectious Diseases

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 02 April 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

6.1.1. Zanidatamab – EMEA-17-2023

Jazz Pharmaceuticals Ireland Limited; The class of Her- / Epidermal growth factor-receptor antibody medicinal products for treatment of intestinal malignant neoplasms.

Zanidatamab in combination with capecitabine plus oxaliplatin (CAPOX) or 5-fluorouracil (5-FU) plus cisplatin (FP), with or without tislelizumab as first line (1L) treatment in patients with Human epidermal growth factor receptor 2 (HER2)-positive, unresectable locally advanced or metastatic gastroesophageal adenocarcinoma (GEA).

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

Action: For information

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

Action: For information

9.2. Coordination with EMA Scientific Committees or CMDh-v

9.2.1. Committee for Medicinal Products for Human Use (CHMP)

Action: For information

9.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

9.3.1. Non-clinical Working Party: D30 Products identified

PDCO member: Karen van Malderen

Action: For information

9.3.2. Paediatric Formulation Operational Expert Group (PFOEG)

PDCO member: Brian Aylward (*ad interim*)

Action: For information

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

No item

9.3.4. Overview of Innovation Task Force (ITF) activities for the year 2023

Action: For information

9.3.5. 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)

Action: For information

9.4.2. EU Network Training Centre (NTC): training webinar on the regulatory / Health Technology Assessment (HTA) interface under the HTA Regulation

Action: For information

9.5. Cooperation with International Regulators

9.5.1. Paediatric Cluster Teleconference

Action: For information

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

No item

9.7. PDCO work plan

No Item

9.8. Planning and reporting

9.8.1. EMA Business Pipeline activity and Horizon scanning

Q1/2024 Update of the Business Pipeline report for the human scientific committees

Action: For information

10. Any other business

10.1. Real World Evidence, including DARWIN EU®

Action: For information

10.2. PDCO and Clinical Trials Coordination Group (CTCG) interaction

Action: For information

11. Breakout sessions

11.1. Paediatric oncology

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

11.2. Neonatology

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

11.3. HIV

Action: For discussion on 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.

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/