



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Paediatric Committee (PDCO)

Agenda for the meeting on 28-30 April 2020

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

28 April 2020, 08:30- 19:00, Virtual meeting

29 April 2020, 08:30- 19:00, Virtual meeting

30 April 2020, 08:30- 19:00, Virtual meeting

Disclaimers

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

Note on access to documents

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



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1. Introductions

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PDCO plenary session to be held 28-30 April 2020. See 28-30 April 2020 PDCO minutes (to be published post 26-29 May 2020 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 28-30 April 2020.

1.3. Adoption of the minutes

PDCO minutes for 24-27 March 2020.

2. Opinions

Disclosure of some information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

2.1. Opinions on Products

2.1.1. Bis-choline tetrathiomolybdate - Orphan - EMEA-002232-PIP02-19

Alexion Europe S.A.S.; Wilson disease

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.2. Fidanacogene elaparovvec - Orphan - EMEA-002362-PIP02-19

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

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.3. [Gepotidacin - EMEA-002443-PIP01-18](#)

Treatment of uncomplicated urinary tract infection (uUTI) / Treatment of uncomplicated urinary tract infection (acute cystitis) in children aged >2 years to <18 years

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.4. [Gepotidacin - EMEA-002443-PIP02-18](#)

Treatment of uncomplicated urogenital gonorrhoea (GC) / Treatment of uncomplicated urogenital gonorrhoea in children ≥ 12 to <18 years

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.5. [Dexamethasone \(sodium phosphate\) encapsulated in human autologous erythrocytes - Orphan - EMEA-001957-PIP02-19](#)

EryDel S.p.A; Treatment of ataxia telangiectasia (AT) / Treatment of neurological symptoms in patients with AT

Day 120 opinion

Action: For adoption

Neurology

2.1.6. [Autologous inactivated glioma cells - Orphan - EMEA-002663-PIP01-19](#)

ERC Belgium; Recurrent high grade glioma / Treatment of recurrent high grade glioma

Day 120 opinion

Action: For adoption

Oncology

2.1.7. [Autologous inactivated glioma cells - Orphan - EMEA-002662-PIP01-19](#)

ERC Belgium; Recurrent high grade glioma / Treatment of recurrent high grade glioma

Day 120 opinion

Action: For adoption

Oncology

2.1.8. Autologous inactivated glioma cells - Orphan - EMEA-002664-PIP01-19

ERC Belgium; Recurrent high grade glioma / Treatment of recurrent high grade glioma

Day 120 opinion

Action: For adoption

Oncology

2.1.9. Autologous inactivated glioma cells - Orphan - EMEA-002661-PIP01-19

ERC Belgium; Recurrent high grade glioma / Treatment of recurrent high grade glioma

Day 120 opinion

Action: For adoption

Oncology

2.1.10. Lenvatinib - EMEA-001119-PIP03-19

Treatment of all conditions included in the category of malignant neoplasms except haematopoietic and lymphoid tissue

Day 120 opinion

Action: For adoption

Oncology

2.1.11. Adeno-associated viral vector serotype 8 containing the human RPGR gene - Orphan - EMEA-002601-PIP01-19

Nightstar Europa Limited; Treatment of X-linked retinitis pigmentosa

Day 120 opinion

Action: For adoption

Ophthalmology

2.1.12. Atropine - EMEA-002545-PIP01-19

Myopia

Day 120 opinion

Action: For adoption

Ophthalmology

2.1.13. Sodium alginate oligosaccharide - Orphan - EMEA-002321-PIP01-17

AlgiPharma AS; Symptomatic treatment of cystic fibrosis

Day 120 opinion

Action: For adoption

Pneumology - Allergology

2.1.14. Chloroprocaine - EMEA-000639-PIP06-20

Ocular surface anaesthesia

Day 60 opinion

Action: For adoption

Anaesthesiology

2.1.15. Ezetimibe / atorvastatin - EMEA-002649-PIP02-20

Prevention of cardiovascular events / Atorvastatin/ezetimibe is indicated as substitution therapy to reduce the risk of cardiovascular events in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS), for adults receiving atorvastatin and ezetimibe concurrently at the same dose level

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.16. Bilastine - EMEA-000347-PIP05-20

Acute urticaria / Short-term treatment as single therapy or in severe cases as additional therapy option of histamine-mediated type I hypersensitivity reactions, such as acute urticaria, when immediate action is required or parenteral formulation is preferred

Day 60 opinion

Action: For adoption

Dermatology / Pneumology - Allergology / Oto-rhino-laryngology

2.1.17. N-[(2S)-5-{[(1R, 2S)-2-(4-fluorophenyl)cyclopropyl] amino}-1-(4-methylpiperazin-1-yl)-1-oxopentan-2-yl]-4-(1H-1,2,3-triazol-1-yl)benzamide, bis-tosylate salt - Orphan - EMEA-002752-PIP01-19

Imago Biosciences BV; Treatment of myeloproliferative neoplasms

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.18. Adeno-associated virus serotype 2 (AAV2) encoding human aromatic L-amino acid decarboxylase (hAADC) - EMEA-002753-PIP01-19

Parkinson's disease

Day 60 opinion

Action: For adoption

Neurology

2.1.19. Monalizumab - EMEA-002751-PIP01-19

Head and neck epithelial malignant neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.1.20. Ribociclib - EMEA-002765-PIP01-19

Treatment of breast cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.21. EMEA-002748-PIP01-20

Secondary lymphedema associated with the treatment of breast cancer

Day 60 opinion

Action: For adoption

Other

2.1.22. Betahistine - EMEA-002652-PIP01-19

Acute peripheral vertigo

Day 60 opinion

Action: For adoption

Oto-rhino-laryngology / Neurology

2.2. Opinions on Compliance Check

The following compliance checks have been put up for discussion and the members of the PDCO have been invited to comment on issues of possible non-compliance

2.2.1. Adalimumab - EMEA-C-000366-PIP02-09-M06

AbbVie Limited; Treatment of ulcerative colitis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.2.2. (3R,4R)-4-methyl-3-(methyl-7H-pyrrolo[2,3-d]pyrimidin-4-ylamino)- β -oxo-1-piperidinepropanenitrile, 2-hydroxy-1,2,3-propanetricarboxylate (1:1)- EMEA-C4-000576-PIP01-09-M10

Pfizer Europe MA EEIG; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis)

Day 60 letter

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Apixaban - EMEA-000183-PIP01-08-M08

Bristol-Myers Squibb / Pfizer EEIG; Prevention of arterial thromboembolism / Prevention of venous thromboembolism / Prevention of TE in paediatric patients with cardiac disease / Prevention of venous thromboembolism VTE) in paediatric subjects with a newly diagnosed acute lymphoblastic leukemia (ALL) or lymphoma (T or B cell), a functioning central venous access device (CVAD) and receiving asparaginase during chemotherapy induction

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. Apixaban - EMEA-000183-PIP02-12-M03

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

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.3. Ticagrelor - EMEA-000480-PIP01-08-M13

AstraZeneca AB; Thromboembolic events (children) / Acute coronary syndrome, history of myocardial infarction / Reduction in occurrence of vaso-occlusive crises in paediatric patients with sickle cell disease

Day 60 opinion

Action: For adoption

Cardiovascular Diseases / Haematology-Hemostaseology

2.3.4. [Ligelizumab - EMEA-001811-PIP02-15-M03](#)

Novartis Europharm Limited; Treatment of chronic spontaneous urticaria

Day 60 opinion

Action: For adoption

Dermatology

2.3.5. [Lucerastat - Orphan - EMEA-002095-PIP01-16-M01](#)

Idorsia Pharmaceuticals Deutschland GmbH; Treatment of Fabry disease

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.6. [Darvadstrocel - Orphan - EMEA-001561-PIP01-13-M01](#)

Takeda Pharma A/S; Anal fistula

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.7. [Autologous CD34+ cells transduced with lentiviral vector encoding the human beta-globin gene - Orphan - EMEA-001933-PIP01-16-M01](#)

Orchard Therapeutics (Europe) Ltd; Beta-thalassemia major and intermedia / Treatment of beta-thalassemia major and intermedia

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.8. Human fibrinogen concentrate - EMEA-001931-PIP01-16-M02

Biotech AG; Treatment of congenital fibrinogen deficiency

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.9. Tofacitinib citrate - EMEA-000576-PIP01-09-M12

Pfizer Europe MA EEIG; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis) / Juvenile idiopathic arthritis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.10. Upadacitinib - EMEA-001741-PIP04-17-M01

AbbVie Ltd; Treatment of atopic dermatitis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Dermatology

2.3.11. Tenofovir alafenamide / emtricitabine / cobicistat / elvitegravir - EMEA-001460-PIP01-13-M04

Gilead Sciences International Ltd.; Treatment of human immunodeficiency virus (HIV-1) infection / Genvoya is indicated for the treatment of HIV-1 infection in paediatric patients from 6 years to less than 18 years

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.12. Eptinezumab - EMEA-002243-PIP01-17-M01

H. Lundbeck A/S; Prevention of migraine headaches / Prophylaxis of migraine

Day 60 opinion

Action: For adoption

Neurology

2.3.13. Erenumab - EMEA-001664-PIP02-15-M04

Novartis Europharm Limited; Prevention of migraine headaches / Prophylaxis of migraine

Day 60 opinion

Action: For adoption

Neurology

2.3.14. Humanised anti-IL-6 receptor (IL-6R) monoclonal antibody (INN: satralizumab) - Orphan - EMEA-001625-PIP01-14-M05

Roche Registration GmbH; Treatment of neuromyelitis optica

Day 60 opinion

Action: For adoption

Neurology

2.3.15. Meningococcal group Y oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein (MenABCWY) / recombinant *Neisseria meningitidis* group B Protein 961c / recombinant *Neisseria meningitidis* 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 / Outer Membrane Vesicles (OMV) from *Neisseria meningitidis* Strain NZ 98/254 / meningococcal group W-135 oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / recombinant *Neisseria meningitidis* group B Protein 936-741 - EMEA-001260-PIP01-11-M01

GSK Vaccines s.r.l.; A39.9 Meningococcal infection in adults and paediatrics patients

Day 60 opinion

Action: For adoption

Vaccines

2.3.16. *Neisseria meningitidis* serogroup B recombinant lipoprotein (rLP2086; subfamily B; *Escherichia coli*) / *Neisseria meningitidis* serogroup B recombinant lipoprotein (rLP2086; subfamily A; *Escherichia coli*) - EMEA-001037-PIP02-11-M07

Pfizer Europe MA EEIG; Invasive meningococcal disease caused by *Neisseria meningitidis* serogroup B

Day 60 opinion

Action: For adoption

Vaccines

2.3.17. Ad26.RSV.preF - Monovalent, recombinant, replication-incompetent human adenovirus serotype 26-vectored vaccine encoding the pre-fusion conformation-stabilised F protein derived from the RSV A2 strain - EMEA-002172-PIP02-17-M01

Janssen-Cilag International NV; Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)

Day 60 opinion

Action: For adoption

Vaccines / Infectious Diseases

2.4. Opinions on Re-examinations

No items

2.5. Opinions on Review of Granted Waivers

No items

2.6. Finalisation and adoption of opinions

2.6.1. Cilastatin sodium / relebactam / imipenem monohydrate - EMEA-C2-001809-PIP01-15-M01

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

Day 60 letter

Action: Adopted via written procedure

Infectious Diseases

2.7. Partial Compliance Checks completed by EMA

For the following partial compliance checks, no need to refer them to PDCO Committee for discussion, were identified by the PME coordinator and PDCO Rapporteur. The PDCO has been informed in writing.

2.7.1. Vosoritide - EMEA-C3-002033-PIP01-16-M01

BioMarin International Limited; Treatment of achondroplasia

Day 30 letter

Action: For information

Other

2.7.2. Autologous CD4+ and CD8+ cells expressing a CD19-specific chimeric antigen receptor (JCAR017) - EMEA-C2-001995-PIP01-16-M02

Celgene Europe B.V.; Treatment of mature B-cell neoplasms

Day 30 letter

Action: For information

Oncology

2.7.3. Cannabidiol - EMEA-C2-001964-PIP01-16-M01

GW Pharma (International) B.V.; Dravet syndrome / Lennox-Gastaut syndrome / Tuberous sclerosis complex / Infantile spasms

Day 30 letter

Action: For information

Neurology

3. Discussion of applications

Disclosure of some information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

3.1. Discussions on Products D90-D60-D30

3.1.1. Pegzilarginase - Orphan - EMEA-001925-PIP02-19

Aeglea BioTherapeutics, Inc.; Arginase 1 deficiency

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.2. Ravagalimab - EMEA-002617-PIP01-19

Ulcerative colitis

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.3. Tecovirimat monohydrate - Orphan - EMEA-001205-PIP02-19

SIGA Technologies, Inc.; Orthopoxvirus disease (smallpox, monkeypox, cowpox, and vaccinia complications)

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.4. Chimeric 2'-O-(2-methoxyethyl) modified antisense oligonucleotide - Orphan - EMEA-002546-PIP01-19

Roche Registration GmbH; Huntington's disease

Day 90 discussion

Action: For discussion

Neurology

3.1.5. Rozanolixizumab - Orphan - EMEA-002681-PIP01-19

UCB Pharma S.A.; Treatment of myasthenia gravis

Day 90 discussion

Action: For discussion

Neurology

3.1.6. Ondansetron - EMEA-002623-PIP01-19

Treatment of alcohol use disorder (AUD)

Day 90 discussion

Action: For discussion

Other / Neurology

3.1.7. Autologous CD34+ hematopoietic stem cells with a CRISPR-edited erythroid enhancer region of the BCL11A gene - Orphan - EMEA-002730-PIP02-19

Vertex Pharmaceuticals (Ireland) Limited; Treatment of sickle cell disease

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.8. Bimekizumab - EMEA-002189-PIP03-19

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondyloarthritis,

psoriatic arthritis and juvenile idiopathic arthritis(JIA)) / Treatment of JIA (enthesitis-related arthritis (ERA)and juvenile psoriatic arthritis (JPsA)) in patients from ≥ 2 years to <18 years of age

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.9. EMEA-002742-PIP01-19

Treatment of parainfluenza infection

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.10. 1-[(4-[(4-fluoro-2-methyl-1H-indol-5-yl)oxy]-6-methoxyquinolin-7-yl)oxy)methyl]cyclopropan-1-amine - Orphan - EMEA-002486-PIP03-20

Advenchen Laboratories, LLC.; Treatment of soft tissue sarcomas / Treatment of alveolar soft part sarcoma / Treatment of synovial sarcoma

Day 60 discussion

Action: For discussion

Oncology

3.1.11. Atropine - EMEA-002744-PIP01-19

Myopia / Treatment to slow myopia progression

Day 60 discussion

Action: For discussion

Ophthalmology

3.1.12. Rituximab / CD3⁺CD4⁺CD25⁺CD127-FoxP3⁺ regulatory T cells - EMEA-002737-PIP01-19

Treatment of type 1 diabetes mellitus (T1DM)

Day 60 discussion

Action: For discussion

Other / Endocrinology-Gynaecology-Fertility-Metabolism

3.1.13. Dexmedetomidine - EMEA-002758-PIP01-19

Treatment of acute agitation in bipolar disorder / Treatment of acute agitation in schizophrenia

Day 60 discussion

Action: For discussion

Psychiatry

3.1.14. Allopurinol / verinurad - EMEA-002754-PIP01-19

Chronic kidney Disease / Treatment of chronic kidney disease in children and adolescents (6 to <18 years old) with hyperuricaemia and albuminuria

Day 60 discussion

Action: For discussion

Uro-nephrology

3.1.15. EMEA-002630-PIP01-19

Chikungunya virus infection

Day 60 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.1.16. EMEA-002735-PIP01-19

Cardioplegia / For induction of cardioplegia in paediatric patients of all ages undergoing cardiac surgery to correct congenital heart malformation in operations requiring CPB support

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.17. Ezetimibe / rosuvastatin - EMEA-002202-PIP02-20

I51.6 Prevention of cardiovascular events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.18. EMEA-002786-PIP01-20

Prevention of cardiovascular events due to atherosclerotic cardiovascular disease in patients with elevated lipoprotein a (Lp(a))

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.19. Recombinant human IgG1 λ monoclonal Fab antibody - EMEA-002766-PIP01-20

Reversal of antiplatelet effects of ticagrelor in patients with uncontrolled major or life-threatening bleeding or requiring urgent surgery or invasive procedure

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.20. Trimetazidine / bisoprolol - EMEA-002768-PIP01-20

Treatment of ischaemic coronary artery disorders

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.21. Insulin- EMEA-002761-PIP01-20

Type 2 diabetes mellitus / Type 1 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.22. Metformin / Sitagliptin - EMEA-002732-PIP02-20

Improvement of glycaemic control in patients with type 2 diabetes

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.23. Venglustat - Orphan - EMEA-001716-PIP05-20

Genzyme Europe B.V.; ICD 10: Q61.2 Polycystic kidney, autosomal dominant / Long term

treatment to slow the progression of cysts development in paediatric patients from 12 years to <18 years old with autosomal dominant polycystic kidney disease.

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology

3.1.24. Bispecific antibody binding to clotting factor IX and X - EMEA-002762-PIP02-20

Treatment of haemophilia A / Routine prophylaxis to prevent or reduce frequency of bleeding episodes in patients with haemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors / For use in all age groups

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.25. Human fibrinogen - EMEA-002769-PIP01-20

Treatment of congenital fibrinogen deficiency

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.26. Ravagalimab - EMEA-002617-PIP02-19

Sjogrens syndrome

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.27. Secukinumab - EMEA-000380-PIP06-19

Lupus nephritis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.28. Sutimlimab - EMEA-002542-PIP02-19

Immune thrombocytopenia purpura (ICD 9-CM code: 287.31 and ICD 10 code: D69.3)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology

3.1.29. Fully human IgG1 RB-1 YTE anti-RSV F monoclonal antibody (mAb) - EMEA-002755-PIP01-19

Prevention of lower respiratory tract infection caused by respiratory syncytial virus

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.30. Itraconazole - Orphan - EMEA-002787-PIP01-20

Laboratoires SMB S.A.; Prevention of invasive mould disease / Prevention of invasive mould disease in adolescents with acute leukaemia and neutropaenia

Day 30 discussion

Action: For discussion

Infectious Diseases / Oncology

3.1.31. Retinol (Vitamin A) - Orphan - EMEA-002790-PIP01-20

Orphanix GmbH; Prevention of bronchopulmonary dysplasia (BPD)

Day 30 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.1.32. Acetyl-L-leucine - Orphan - EMEA-002796-PIP01-20

IntraBio Ltd.; Niemann-Pick disease type C

Day 30 discussion

Action: For discussion

Neurology

3.1.33. Adeno-associated viral vector serotype 9 containing the human mini-dystrophin gene - Orphan - EMEA-002741-PIP01-20

Pfizer Europe MA EEIG; Treatment of Duchenne muscular dystrophy

Day 30 discussion

Action: For discussion

Neurology

3.1.34. Edaravone - Orphan - EMEA-002785-PIP01-20

Treeway B.V.; Amyotrophic lateral sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.1.35. EMEA-002763-PIP01-20

Paediatric low grade glioma / Relapsed or refractory paediatric low grade glioma in adolescents and children 1 year of age and older

Day 30 discussion

Action: For discussion

Oncology

3.1.36. Abiraterone / niraparib - EMEA-002789-PIP01-20

Treatment of prostate malignant neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.1.37. Autologous tumor-infiltrating lymphocytes: lifileucel - EMEA-002776-PIP01-20

Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic neoplasms)

Day 30 discussion

Action: For discussion

Oncology

3.1.38. Humanised antibody targeting the inducible T cell co-stimulatory receptor - EMEA-002781-PIP01-20

Head and neck squamous cell carcinoma / Treatment of head and neck squamous cell carcinoma

Day 30 discussion

Action: For discussion

Oncology

3.1.39. Neratinib - EMEA-002783-PIP01-20

C50 - Malignant neoplasm of breast

Day 30 discussion

Action: For discussion

Oncology

3.1.40. Rucaparib - EMEA-002760-PIP01-19

Treatment of fallopian tube cancer / Treatment of ovarian cancer / Treatment of prostate malignant neoplasms / Treatment of primary peritoneal cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.41. Tabelecleucel - Orphan - EMEA-002025-PIP04-19

Atara Biotherapeutics, Inc.; Treatment of Epstein-Barr virus associated post-transplant lymphoproliferative disorder / Treatment of allogeneic haematopoietic cell transplant patients with Epstein-Barr virus associated post-transplant lymphoproliferative disease who have received one prior therapy / Treatment of solid organ transplant patients with Epstein-Barr virus associated post-transplant lymphoproliferative disease who have received one prior therapy

Day 30 discussion

Action: For discussion

Oncology

3.1.42. Adrenaline (epinephrine) - EMEA-002749-PIP01-19

Treatment of allergic reactions / The emergency treatment of allergic reactions including anaphylaxis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.43. Codon-optimised human cystic fibrosis transmembrane conductance regulator messenger ribonucleic acid complexed with lipid-based nanoparticles - Orphan - EMEA-002733-PIP01-19

Real Regulatory Limited; Cystic fibrosis / Treatment of cystic fibrosis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.44. Timapiprant - EMEA-002788-PIP01-20

Treatment of asthma / Add-on maintenance treatment for severe eosinophilic asthmatic patients, aged 6-17 years, inadequately controlled on ICS plus other controller medication

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.45. Esketamine - EMEA-002772-PIP01-20

Bipolar depression /Major depressive disorder / Treatment-resistant bipolar depression / Treatment-resistant depression in the course of major depressive disorder

Day 30 discussion

Action: For discussion

Psychiatry

3.1.46. EMEA-002329-PIP02-20

Treatment of dermatitis and eczema / Treatment of chronic hand eczema, Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.1.47. Remdesivir - EMEA-002826-PIP01-20

Coronavirus disease 2019 (COVID-19) / Treatment of paediatric patients aged from birth to < 18 years (weighing < 40kg) with coronavirus disease 2019 (COVID-19) / Indicated for the treatment of adults and adolescents 12 years or older $\geq$ 40kg with coronavirus disease 2019 (COVID-19)

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2. Discussions on Compliance Check

The following compliance checks have been put up for discussion and the members of the PDCO have been invited to comment on issues of possible non-compliance.

3.2.1. Autologous CD4+ and CD8+ cells expressing a CD19-specific chimeric antigen receptor (JCAR017) - EMEA-C2-001995-PIP01-16-M02

Celgene Europe B.V.; Treatment of B-lymphoblastic leukemia/lymphoma

Day 30 discussion

Action: For discussion

Oncology

3.2.2. Lipegfilgrastim - EMEA-C-001019-PIP01-10-M05

UAB "Sicor Biotech"; Treatment of chemotherapy-induced neutropenia

Day 30 discussion

Action: For discussion

Oncology

3.2.3. Live, attenuated, chimeric dengue virus, serotype 3 / Live, attenuated, chimeric dengue virus, serotype 4 / Live, attenuated, chimeric dengue virus, serotype 1 / Live, attenuated, chimeric dengue virus, serotype 2 - EMEA-C-001545-PIP01-13-M02

Sanofi Pasteur; Prevention of dengue disease

Day 30 discussion

Action: For discussion

Vaccines

3.2.4. Cannabidiol - EMEA - C2-001964-PIP01-16-M01

GW Pharma (International) B.V.; Dravet syndrome / Lennox-Gastaut syndrome / Tuberous sclerosis complex / Infantile spasms

Day 30 discussion

Action: For discussion

Neurology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Ambrisentan - Orphan - EMEA-000434-PIP01-08-M07

Glaxo Group Limited; Pulmonary arterial hypertension / Treatment of pulmonary arterial hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. Alogliptin benzoate (as alogliptin) - EMEA-000496-PIP01-08-M08

Takeda Development Centre Europe Ltd; Type 2 diabetes melitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.3. Drospirenone / estetrol monohydrate - EMEA-001332-PIP01-12-M03

Estetra SPRL; Prevention of pregnancy

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. Maralixibat chloride - Orphan - EMEA-001475-PIP03-17-M02

Mirum Pharmaceuticals; Treatment of progressive familial intrahepatic cholestasis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.5. Mepolizumab - Orphan - EMEA-000069-PIP01-07-M06

GSK Trading Services Limited; Treatment of hypereosinophilic syndrome (HES)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.6. RFVIIIIFc-VWF-XTEN - Orphan - EMEA-002501-PIP01-18-M01

Bioverativ Therapeutics, Inc., a Sanofi Company; Treatment of haemophilia A / Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital FVIII deficiency)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.7. Otilimab - EMEA-001882-PIP02-16-M02

GlaxoSmithKline Trading Services Limited; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis) / Treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 1 year of age and older / Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.8. Doravirine - EMEA-001676-PIP01-14-M03

Merck Sharp & Dohme (Europe), Inc.; Treatment of human immunodeficiency virus-1 (HIV-1) infection / Antiretroviral therapy, in combination with other antiretroviral agents, for the treatment of HIV-1 infection in children aged from birth to 18 years

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.9. Eravacycline - EMEA-001555-PIP01-13-M04

Tetraphase Pharmaceuticals, Inc.; Complicated intra-abdominal infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.10. Fostemsavir (tromethamine) - EMEA-001687-PIP01-14-M04

ViiV Healthcare UK Ltd; Treatment of human immunodeficiency virus (HIV-1) infection / Treatment of HIV-1 infection as part of a combination therapy in paediatric patients who have no more than 2 remaining available fully active antiretroviral therapies

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.11. Tenofovir disoproxil fumarate / lamivudine / doravirine - EMEA-001695-PIP01-14-M03

Merck Sharp & Dohme (Europe), Inc.; Treatment of human immunodeficiency virus-1 (HIV-1) infection / Antiretroviral combination therapy, for the treatment of HIV-1 infection in adults and children aged 12 to 18 years

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.12. Vaborbactam / meropenem - EMEA-001731-PIP01-14-M02

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.13. Alemtuzumab - EMEA-001072-PIP01-10-M04

Genzyme Europe B.V.; Multiple sclerosis / For paediatric patients with relapsing remitting multiple sclerosis (RRMS) with active disease on prior disease modifying treatment (DMT) defined by clinical or imaging features

Day 30 discussion

Action: For discussion

Neurology

3.3.14. Brivaracetam - Orphan - EMEA-000332-PIP02-17-M01

UCB Pharma S.A.; Treatment of paediatric epilepsy syndromes / Monotherapy in patients 4 to 25 years of age with childhood absence epilepsy (CAE) and juvenile absence epilepsy (JAE)

Day 30 discussion

Action: For discussion

Neurology

3.3.15. Bempegaldesleukin - EMEA-002492-PIP01-18-M01

Nektar Therapeutics; Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoietic, and lymphoid tissue neoplasms) / Bempegaldesleukin in combination with nivolumab for treatment of patients with unresectable or metastatic melanoma in the age group from 12 years to less than 18 years of age / Bempegaldesleukin in combination with nivolumab for treatment of a relapsed or refractory paediatric malignant solid tumour in paediatric patients less than 18 years of age

Day 30 discussion

Action: For discussion

Oncology

3.3.16. Bosutinib - EMEA-000727-PIP01-09-M04

Pfizer Europe MA EEIG; Treatment of chronic myeloid leukaemia (CML) / Treatment of chronic, accelerated or blast phase CML with resistance or intolerance to prior tyrosine kinase inhibitor (TKI therapy) / Treatment of newly-diagnosed chronic phase of Philadelphia chromosome positive chronic myeloid leukaemia (Ph+ CML)

Day 30 discussion

Action: For discussion

Oncology

3.3.17. Brentuximab vedotin - Orphan - EMEA-000980-PIP01-10-M06

Takeda Pharma A/S; Treatment of Hodgkin lymphoma / Treatment of paediatric patients with newly diagnosed relapse or refractory Hodgkin lymphoma (from 5 years of age)

Day 30 discussion

Action: For discussion

Oncology

3.3.18. Olaparib - EMEA-002269-PIP01-17-M01

AstraZeneca AB; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic, and lymphoid tissue) / Treatment of paediatric patients from 6 months to ≤ 18 years old with homologous recombination repair (HRR) mutated solid tumours

Day 30 discussion

Action: For discussion

Oncology

3.3.19. Tapentadol - EMEA-000325-PIP01-08-M10

Grünenthal GmbH; Chronic pain / Treatment of chronic pain

Day 30 discussion

Action: For discussion

Pain

3.3.20. Vortioxetine - EMEA-000455-PIP02-10-M06

H. Lundbeck A/S; Major depressive disorder

Day 30 discussion

Action: For discussion

Psychiatry

4. Nominations

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

4.1. List of letters of intent received for submission of applications with start of procedure 30 April 2020 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

No items

4.3. Nominations for other activities

Action: For adoption

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

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

5.1. New Scientific Advice

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

5.2. Ongoing Scientific Advice

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

5.3. Final Scientific Advice (Reports and Scientific Advice letters)

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

6. Discussion on the applicability of class waivers

Disclosure of some information related to this section cannot be released 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 items

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 items

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. Updated meeting dates of PDCO plenaries for 2020-2021

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 Group: D30 Products identified

PDCO member: Karen van Malderen

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.4. Cooperation within the EU regulatory network

No items

9.5. Cooperation with International Regulators

No items

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

No items

9.7. PDCO work plan

No items

9.8. Planning and reporting

No items

10. Any other business

10.1.1. Annex to reflection paper on wording of the indication

PDCO Member: Siri Wang, Agnes Gyurasics

Action: For information

11. Breakout sessions

11.1.1. Neonatology

Action: For discussion on Tuesday, 19:00 - 20:00, virtual meeting

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/