



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 May 2020
EMA/PDCO/247681/2020
Human Medicines Division

Paediatric Committee (PDCO)

Agenda for the meeting on 26-29 May 2020

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

26 May 2020, 14:00- 19:00, Virtual meeting

27 May 2020, 08:30- 19:00, Virtual meeting

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

29 May 2020, 08:30- 13:00, Virtual meeting

Health and safety information

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

Disclaimers

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

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to 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 26-29 May 2020. See May 2020 PDCO minutes (to be published post June 2020 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 26-29 May 2020

1.3. Adoption of the minutes

PDCO minutes from the meeting held on 28-30 April 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. Pegzilarginase - Orphan - EMEA-001925-PIP02-19

Aeglea BioTherapeutics, Inc.; Arginase 1 deficiency

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.2. Ravagalimab - EMEA-002617-PIP01-19

Ulcerative colitis

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.3. [Tecovirimat monohydrate - Orphan - EMEA-001205-PIP02-19](#)

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

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.4. [Chimeric 2'-O-\(2-methoxyethyl\) modified antisense oligonucleotide - Orphan - EMEA-002546-PIP01-19](#)

Roche Registration GmbH; Huntington's disease

Day 120 opinion

Action: For adoption

Neurology

2.1.5. [Rozanolixizumab - Orphan - EMEA-002681-PIP01-19](#)

UCB Pharma S.A.; Treatment of myasthenia gravis

Day 120 opinion

Action: For adoption

Neurology

2.1.6. [Ondansetron - EMEA-002623-PIP01-19](#)

Treatment of alcohol use disorder (AUD)

Day 120 opinion

Action: For adoption

Other / Neurology

2.1.7. [Ezetimibe / rosuvastatin - EMEA-002202-PIP02-20](#)

I51.6 Prevention of cardiovascular events

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.8. [EMEA-002786-PIP01-20](#)

Prevention of cardiovascular events due to atherosclerotic cardiovascular disease in patients

with elevated lipoprotein a (Lp(a))

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.9. 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 60 opinion

Action: For adoption

Cardiovascular Diseases

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

Treatment of ischaemic coronary artery disorders

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.11. Metformin / sitagliptin - EMEA-002732-PIP02-20

Improvement of glycaemic control in patients with type 2 diabetes

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.12. Ravagalimab - EMEA-002617-PIP02-19

Sjogren's syndrome

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.13. Sutimlimab - EMEA-002542-PIP02-19

Treatment of immune thrombocytopenia purpura

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology

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

Treatment of prostate malignant neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.1.15. 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 60 opinion

Action: For adoption

Oncology

2.1.16. Neratinib - EMEA-002783-PIP01-20

Malignant neoplasm of breast

Day 60 opinion

Action: For adoption

Oncology

2.1.17. 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 60 opinion

Action: For adoption

Oncology

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. [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 60 opinion

Action: For adoption

Vaccines

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

2.3.1. [Ambrisentan - Orphan - EMEA-000434-PIP01-08-M07](#)

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

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. [Alogliptin benzoate \(as alogliptin\) - EMEA-000496-PIP01-08-M08](#)

Takeda Development Centre Europe Ltd; Type 2 diabetes mellitus

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.3. [Drospirenone / estetrol monohydrate - EMEA-001332-PIP01-12-M03](#)

Estetra SPRL; Prevention of pregnancy

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.4. RFVIIIFc-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 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.5. 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 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.6. 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 60 opinion

Action: For adoption

Infectious Diseases

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

Tetraphase Pharmaceuticals, Inc.; Treatment of complicated intra-abdominal infection

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.8. 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 60 opinion

Action: For adoption

Infectious Diseases

2.3.9. 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 60 opinion

Action: For adoption

Infectious Diseases

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

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.11. 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 60 opinion

Action: For adoption

Neurology

2.3.12. 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 60 opinion

Action: For adoption

Neurology

2.3.13. 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 60 opinion

Action: For adoption

Oncology

2.3.14. 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 Philadelphia chromosome positive chronic myeloid leukaemia (Ph+ CML)

Day 60 opinion

Action: For adoption

Oncology

2.3.15. 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 60 opinion

Action: For adoption

Oncology

2.3.16. 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 60 opinion

Action: For adoption

Oncology

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

Grünenthal GmbH; Chronic pain / Treatment of chronic pain

Day 60 opinion

Action: For adoption

Pain

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

H. Lundbeck A/S; Major depressive disorder

Day 60 opinion

Action: For adoption

Psychiatry

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

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. [N-(2,4-Di-tert-butyl-5-hydroxyphenyl)-1,4-dihydro-4-oxoquinoline-3-carboxamide] - EMEA-C10-000335-PIP01-08-M14

Vertex Pharmaceuticals (Ireland) Limited; Treatment of cystic fibrosis

Letter adopted

Action: For information

Other

2.7.2. Nirsevimab (anti-respiratory syncytial virus human IgG1k monoclonal antibody) - EMEA-C1-001784-PIP01-15-M02

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

Letter adopted

Action: For information

Infectious diseases

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. Lonapegsomatropin - EMEA-002692-PIP01-19

Growth hormone deficiency

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.2. Cilofexor - Orphan - EMEA-002554-PIP02-19

Gilead Sciences International Ltd.; Treatment of primary sclerosing cholangitis (PCS) (DB96.2)

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.3. Guselkumab - EMEA-001523-PIP05-19

Crohn's disease / Treatment of Crohn's disease

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.4. Marstacimab - Orphan - EMEA-002285-PIP02-19

Pfizer Europe MA EEIG; Treatment of congenital haemophilia B / Treatment of congenital haemophilia A / Prophylaxis of bleeding in haemophilia B / Prophylaxis of bleeding in haemophilia A

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.5. Rilzabrutinib - Orphan - EMEA-002438-PIP02-19

Principia Biopharma, Inc.; Immune thrombocytopenia / Treatment of immune thrombocytopenia

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.6. Ritonavir / darunavir - EMEA-002537-PIP02-19

Treatment of human immunodeficiency virus (HIV-1) infection

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.7. EMEA-002566-PIP01-19

Treatment of multiple sclerosis / Treatment of secondary progressive multiple sclerosis / Treatment of primary progressive multiple sclerosis / Treatment of relapsing remitting multiple sclerosis

Day 90 discussion

Action: For discussion

Neurology

3.1.8. Soticlestat - EMEA-002572-PIP02-19

Dravet syndrome, Lennox-Gastaut syndrome / Treatment of seizures associated with Dravet syndrome / Treatment of seizures associated with Lennox-Gastaut syndrome

Day 90 discussion

Action: For discussion

Neurology

3.1.9. Orphan - EMEA-002571-PIP01-19

Audentes Therapeutics, Inc.; X-linked myotubular myopathy (XLMTM)

Day 90 discussion

Action: For discussion

Other

3.1.10. Fasinumab - EMEA-002059-PIP02-19

Chronic pain / Chronic musculoskeletal pain / Chronic non-musculoskeletal pain / Treatment of chronic cancer pain in a palliative care setting / Treatment of moderate to severe chronic pain associated with osteoarthritis (OA) of the knee or hip in patients who achieve an inadequate response to or are intolerant to currently available analgesics (adults only)

Day 90 discussion

Action: For discussion

Pain

3.1.11. 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 cardiopulmonary bypass (CPB) support

Day 60 discussion

Action: For discussion

Cardiovascular Diseases

3.1.12. EMEA-002329-PIP02-20

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

Day 60 discussion

Action: For discussion

Dermatology

3.1.13. Insulin - EMEA-002761-PIP01-20

Type 2 diabetes mellitus / Type 1 diabetes mellitus

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

Genzyme Europe B.V.; 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 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology

3.1.15. 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 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.16. Human Fibrinogen - EMEA-002769-PIP01-20

Treatment of congenital fibrinogen deficiency

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.17. Secukinumab - EMEA-000380-PIP06-19

Lupus nephritis

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.18. 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 60 discussion

Action: For discussion

Infectious Diseases

3.1.19. 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 60 discussion

Action: For discussion

Infectious Diseases / Oncology

3.1.20. Retinol (vitamin A) - Orphan - EMEA-002790-PIP01-20

Orphanix GmbH; Prevention of bronchopulmonary dysplasia (BPD)

Day 60 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

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

IntraBio Ltd.; Niemann-Pick disease type C

Day 60 discussion

Action: For discussion

Neurology

3.1.22. 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 60 discussion

Action: For discussion

Neurology

3.1.23. [Edaravone - Orphan - EMEA-002785-PIP01-20](#)

Treeway B.V.; Treatment of amyotrophic lateral sclerosis

Day 60 discussion

Action: For discussion

Neurology

3.1.24. [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 60 discussion

Action: For discussion

Oncology

3.1.25. [Autologous tumour-infiltrating lymphocytes: lifileucel - EMEA-002776-PIP01-20](#)

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

Day 60 discussion

Action: For discussion

Oncology

3.1.26. [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 60 discussion

Action: For discussion

Oncology

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

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

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.28. 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 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.29. 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 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.30. 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 60 discussion

Action: For discussion

Psychiatry

3.1.31. Ezetimibe / pravastatin - EMEA-002805-PIP01-20

Hypercholesterolaemia / Cardiovascular events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.32. Sacubitril / valsartan - EMEA-000316-PIP03-20

Prevention of heart failure

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.33. Benralizumab - EMEA-001214-PIP06-20

Bullous pemphigoid

Day 30 discussion

Action: For discussion

Dermatology

3.1.34. Dupilumab - EMEA-001501-PIP05-20

Treatment of bullous pemphigoid

Day 30 discussion

Action: For discussion

Dermatology

3.1.35. Cotadutide - EMEA-002712-PIP02-20

Treatment of chronic kidney disease (CKD) in patients with type 2 diabetes mellitus (T2DM)

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.36. Levonorgestrel - EMEA-002767-PIP01-20

Prevention of pregnancy

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

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

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.38. EMEA-002757-PIP01-19

Treatment of ulcerative colitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.39. Elafibranor - Orphan - EMEA-001857-PIP02-20

Genfit SA; Treatment of primary biliary cholangitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.40. EMEA-002773-PIP01-20

Treatment of non-alcoholic steatohepatitis (NASH)

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.41. Crovalimab - EMEA-002709-PIP01-19

Treatment of paroxysmal nocturnal hemoglobinuria (PNH)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.42. Olinciguat - EMEA-002759-PIP01-19

Treatment of sickle cell disease (SCD)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.43. [Voxelotor - Orphan - EMEA-002356-PIP02-20](#)

Synteract GmbH; Sickle cell disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.44. [Tacrolimus - EMEA-001642-PIP02-20](#)

Solid organ transplant rejection / Prophylaxis of transplant rejection in liver, kidney or heart allograft recipients (children aged from birth to less than 18 years) / Treatment of allograft rejection resistant to treatment with other immunosuppressive medical products in children aged from birth to less than 18 years

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.45. [Human anti-interleukin-15 \(IL-15\) monoclonal antibody - EMEA-002775-PIP01-20](#)

Non-responsive coeliac disease (NRCD) with symptoms despite 12 months of following a gluten-free diet (GFD)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Gastroenterology-Hepatology

3.1.46. [EMEA-002740-PIP01-19](#)

Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.47. [Sulbactam / durlobactam - EMEA-002807-PIP01-20](#)

Treatment of bacterial infections / Treatment of infections caused by acinetobacter baumannii-calcoaceticus complex

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.48. [Rimegepant - EMEA-002812-PIP01-20](#)

Prevention of migraine

Day 30 discussion

Action: For discussion

Neurology

3.1.49. [EMEA-002779-PIP01-20](#)

Treatment of Canavan disease / Treatment of Canavan disease in patients from birth to less than 18 years of age

Day 30 discussion

Action: For discussion

Neurology

3.1.50. [2-\(Isopropylamino\)-3-methyl-5-\(6-methyl-5-\(\(2-\(1-methyl-1H-pyrazol-4-yl\)pyridin-4-yl\)oxy\)pyridin-2-yl\)pyrimidin-4\(3H\)-one - Orphan - EMEA-002802-PIP01-20](#)

Deciphera Pharmaceuticals; Benign soft tissue neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.1.51. [Balixafortide - EMEA-002718-PIP02-20](#)

Treatment of breast cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.52. EMEA-002655-PIP02-20

Treatment of prostate cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.53. Nivolumab - EMEA-001407-PIP03-20

Treatment of all conditions in the category of malignant neoplasms (except haematopoietic and lymphoid tissue other than Hodgkin lymphoma)

Day 30 discussion

Action: For discussion

Oncology

3.1.54. Oportuzumab monatox - EMEA-002797-PIP01-20

Treatment, including prevention of recurrence, of urothelial carcinoma

Day 30 discussion

Action: For discussion

Oncology

3.1.55. Sasanlimab - EMEA-002777-PIP01-20

Non-muscle invasive bladder cancer (NMIBC)

Day 30 discussion

Action: For discussion

Oncology

3.1.56. 2-(hydroxymethyl)-2-(methoxymethyl)-1-azabicyclo[2,2,2]octan-3-one - Orphan - EMEA-002621-PIP01-19

Aprea Therapeutics Inc; Treatment of malignant neoplasms of the haematopoietic and lymphoid tissue / Treatment of solid malignant tumours

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.1.57. Benzimidazole - EMEA-002394-PIP02-20

Treatment of cystic fibrosis / To improve lung function and reduce pulmonary exacerbations for patients with cystic fibrosis (CF) in conjunction with standard therapies

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.58. Seltorexant - EMEA-002746-PIP01-20

Major depressive disorder (MDD)

Day 30 discussion

Action: For discussion

Psychiatry

3.1.59. Sparsentan - Orphan - EMEA-001984-PIP02-20

Retrophin Europe Ltd.; Treatment of focal segmental glomerular sclerosis (FSGS)

Day 30 discussion

Action: For discussion

Uro-nephrology

3.1.60. EMEA-002814-PIP01-20

Invasive disease caused by Neisseria meningitidis group A, B, C, W and Y from 2 months of age

Day 30 discussion

Action: For discussion

Vaccines

3.1.61. EMEA-002795-PIP01-20

Prevention of respiratory syncytial virus (RSV)-associated medically attended lower respiratory tract illness (MA-LRTI) and/or RSV-associated severe MA LRTI in neonates and infants by maternal immunisation / Prevention of RSV-associated medically attended lower respiratory tract illness (MA-LRTI) and/or RSV associated severe MA-LRTI in neonates and infants by active immunisation of pregnant adolescents

Day 30 discussion

Action: For discussion

Vaccines

3.1.62. EMEA-002771-PIP01-20

Prevention of influenza disease

Day 30 discussion

Action: For discussion

Vaccines / Infectious Diseases

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. Secukinumab - EMEA-C2-000380-PIP01-08-M04

Novartis Europharm Ltd; Treatment of psoriasis

Day 30 discussion

Action: For discussion

Dermatology

3.2.2. Eptinezumab - EMEA-C1-002243-PIP01-17

H. Lundbeck A/S; Prevention of migraine headaches

Day 30 discussion

Action: For discussion

Neurology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Crisaborole - EMEA-002065-PIP01-16-M03

Pfizer Europe MA EEIG; Mild to moderate atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.3.2. Epeglenatide - EMEA-001903-PIP01-15-M01

Sanofi-aventis recherche et développement; Type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.3. Glucagon - EMEA-001657-PIP01-14-M01

Eli Lilly and Company; Treatment of severe hypoglycaemia

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. Ladarixin - EMEA-002642-PIP01-19-M01

Dompé farmaceutici S.p.A; Treatment of type 1 diabetes / Treatment of new-onset type 1 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. Pegvaliase - Orphan - EMEA-001951-PIP01-16-M01

BioMarin International Limited; Treatment of hyperphenylalaninaemia in paediatric patients with phenylketonuria

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. Recombinant human glutamic acid dexarboxylase - EMEA-000609-PIP01-09-M02

Diamyd Medical AB; Treatment of type 1 diabetes / Treatment of type 1 diabetes

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.7. Ozanimod hydrochloride - EMEA-001710-PIP04-17-M01

Celgene Europe B.V.; Treatment of Crohn's disease

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.8. Ustekinumab - EMEA-000311-PIP04-13-M03

Janssen-Cilag International NV; Treatment of Crohn's Disease

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.9. Ustekinumab - EMEA-000311-PIP05-17-M01

Janssen-Cilag International NV; Treatment of ulcerative colitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.10. Synthetic double-stranded siRNA oligonucleotide directed against antithrombin mRNA and covalently linked to a ligand containing three N-acetylgalactosamine residues - Orphan - EMEA-001855-PIP01-15-M02

Genzyme Europe B.V.; Treatment of Haemophilia B / Treatment of Haemophilia A / For routine prophylaxis to prevent or reduce the frequency of bleeding episodes in children aged ≥ 1 year with severe Haemophilia B, including patients who express neutralizing antibodies to exogenous factor IX substitution / For routine prophylaxis to prevent or reduce the frequency of bleeding episodes in children aged ≥ 1 year with severe haemophilia A, including patients who express neutralizing antibodies to exogenous factor VIII substitution

Day 30 discussion

Action: For discussion

Haematology-Haemostaseology

3.3.11. Anifrolumab - EMEA-001435-PIP02-16-M01

AstraZeneca AB; Treatment of systemic lupus erythematosus

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.12. Belatacept - EMEA-000157-PIP01-07-M05

Bristol-Myers Squibb Pharma EEIG; Prevention of rejection of transplanted kidney / In combination with corticosteroids and a mycophenolic acid (MPA), for prophylaxis of graft rejection in pediatric patients at least 12 years of age and with a stable renal transplant for at least 6 months, who convert to a CNI-free maintenance immunosuppressive regimen.

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.13. Brincidofovir - Orphan - EMEA-001904-PIP03-18-M01

Chimerix IRL Limited; Treatment of smallpox

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.14. Ceftobiprole medocaril sodium - EMEA-000205-PIP02-11-M04

Basilea Pharmaceutica International Ltd.; Bacterial pneumoniae / Pneumonia due to Streptococcus pneumoniae / Pneumonia due to Hemophilus influenzae / Treatment of nosocomial pneumonia / Treatment of community acquired pneumonia

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.15. Dasabuvir sodium - EMEA-001439-PIP01-13-M03

AbbVie Ltd; Treatment of chronic hepatitis C / Treatment of children and adolescents aged from 3 years to less than 18 years of age with genotype I chronic HCV infection and without liver decompensation, in combination with ombitasvir/paritaprevir/ritonavir

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.16. Relebactam monohydrate / cilastatin sodium / imipenem monohydrate - EMEA-001809-PIP01-15-M02

Merck Sharp & Dohme (Europe), Inc.; Treatment of infections caused by Gram-negative organisms / Treatment of hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP) / Treatment of serious bacterial infections caused by aerobic Gram-negative organisms in patients with limited treatment options

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.17. Rilpivirine (hydrochloride) - EMEA-000317-PIP01-08-M12

Janssen-Cilag International NV; Treatment of human immunodeficiency virus (HIV-1) infection / Rilpivirine is indicated in combination with other antiretroviral (ARV) medicinal products, for the treatment of human immunodeficiency virus (HIV-1) infection in ARV-naïve paediatric patients from 2 to less than 18 years with a baseline viral load below 100,000 HIV-1 RNA copies/mL.

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.18. Ritonavir / paritaprevir / ombitasvir - EMEA-001440-PIP01-13-M03

AbbVie Ltd; Treatment of chronic Hepatitis C (HCV) infection / Treatment of children and adolescents from ≥ 3 years to < 18 years of age with chronic HCV infection with compensated cirrhosis or without compensated cirrhosis in combination with other medicinal products

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.19. Lasmiditan - EMEA-002166-PIP01-17-M04

Eli Lilly and Company Limited; Migraine with and without aura

Day 30 discussion

Action: For discussion

Neurology

3.3.20. Olenasufigene relduparvovec - Orphan - EMEA-002122-PIP02-17-M01

LYSOGENE; Mucopolysaccharidosis type IIIA / Treatment of children with Sanfilippo type A syndrome

Day 30 discussion

Action: For discussion

Neurology

3.3.21. Perampanel - EMEA-000467-PIP01-08-M14

Eisai Europe Limited; Treatment of treatment-resistant epilepsies / Adjunctive therapy in patients with other paediatric epilepsies / Adjunctive therapy in patients with refractory partial onset seizures including secondarily generalised seizures

Day 30 discussion

Action: For discussion

Neurology

3.3.22. Pitolisant - Orphan - EMEA-001176-PIP01-11-M05

BIOPROJET PHARMA; Narcolepsy / Narcolepsy with or without cataplexy

Day 30 discussion

Action: For discussion

Neurology

3.3.23. Concentrate of proteolytic enzyme enriched in bromelain - Orphan - EMEA-000142-PIP02-09-M09

MediWound Germany GmbH; Treatment of burns of external body surfaces / Removal of eschar in deep partial and/or full thickness burns

Day 30 discussion

Action: For discussion

Other

3.3.24. Palonosetron / fosnetupitant - EMEA-001198-PIP03-17-M04

Helsinn Birex Pharmaceuticals Limited; Prevention of chemotherapy-induced nausea and vomiting

Day 30 discussion

Action: For discussion

Other

3.3.25. [Dermatophagoides pteronyssinus / Dermatophagoides farinae - EMEA-001258-PIP01-11-M06](#)

ALK-Abelló A/S; Treatment of allergic rhinitis / Treatment of asthma / In house dust mite allergic asthma / In house dust mite allergic rhinitis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.26. [Glycopyrronium bromide / Formoterol fumarate dihydrate / Beclometasone dipropionate - EMEA-001875-PIP02-18-M02](#)

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

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.27. [Reslizumab - EMEA-001202-PIP02-13-M04](#)

Teva Pharmaceuticals Europe; Treatment of asthma / Add on treatment to reduce exacerbations, relieve symptoms and improve lung function in paediatric patients from 6 to less than 18 years of age with inadequately controlled severe asthma who have a blood eosinophil count greater than equal to 300 microlitre

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.28. [Derivative of 4H-pyrazolo\[3,4-d\]pyrimidin-4-one - EMEA-001742-PIP01-14-M01](#)

Boehringer Ingelheim International GmbH; Treatment of schizophrenia / Adjunctive therapy to antipsychotic treatment for the prevention of relapse in patients with schizophrenia 13 to <18 years of age

Day 30 discussion

Action: For discussion

Psychiatry

3.3.29. Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live) - EMEA-001786-PIP01-15-M01

Merck Sharp & Dohme (Europe), Inc.; Prevention of Ebola disease / Active immunization of individuals from 1 year of age to less than 18 years of age to protect against Ebola virus disease (EVD) caused by Zaire Ebola virus

Day 30 discussion

Action: For discussion

Vaccines

3.3.30. Purified rabies virus, WISTAR PM/WI 38-1503-3M strain (inactivated) - EMEA-002234-PIP01-17-M01

Sanofi Pasteur; Prevention of rabies disease / treatment of exposure to rabies virus

Day 30 discussion

Action: For discussion

Vaccines

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 item

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

6.1.1. EMEA-05-2020

AstraZeneca AB; All classes of medicinal products for treatment of chronic obstructive pulmonary disease (COPD) (excluding chronic lung diseases associated with long-term airflow limitation, such as asthma, bronchopulmonary dysplasia, primary cilia dyskinesia, obstructive lung disease related to graft-versus-host disease after [bone-marrow] transplantation) / Maintenance treatment of COPD

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 Annex B.

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

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 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

9.4.1. European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA): Severe Paediatric Asthma Collaborative in Europe (SPACE)

Action: For information

9.5. Cooperation with International Regulators

No item

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

9.6.1. Meeting Summary from the PCWP/HCPWP Joint meeting on 3-4 March 2020

Action: For information

9.7. PDCO work plan

No item

9.8. Planning and reporting

No item

10. Any other business

10.1. Covid-19 update

Action: For information

11. Breakout sessions

11.1. Paediatric oncology

Action: For discussion

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/