16 April 2019
EMA/PDCO/209562/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 23-26 April 2019

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

23 April 2019, 14:00- 19:30, room 2D

24 April 2019, 08:30- 19:30, room 2D

25 April 2019, 08:30- 19:30, room 2D

26 April 2019, 08:30- 13:00, room 2D

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 23-26 April 2019. See 23-26 April 2019 PDCO minutes (to be published post 27-29 May 2019 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 23-26 April 2019

1.3. Adoption of the minutes

PDCO minutes for 26-29 March 2019

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. Adeno-associated viral vector serotype 5 containing a B domain deleted variant of human coagulation factor VIII gene - Orphan - EMEA-002427-PIP01-18

BioMarin International Limited; Treatment of patients with haemophilia A

Day 120 Opinion

Action: For adoption

Haematology-Hemostaseology

2.1.2. Dexamethasone - EMEA-002423-PIP01-18

ICD10 H59.9 Post-procedural disorder of eye and adnexa

Day 120 Opinion

Action: For adoption

Ophthalmology

2.1.3. Lentiviral vector containing the human ABCA4 gene for treatment of Stargardt's disease - Orphan - EMEA-002407-PIP01-18

Sanofi-Aventis Recherche & Développement; Treatment of inherited retinal disorders

Day 120 Opinion

Action: For adoption

Ophthalmology

2.1.4. Ramipril / bisoprolol - EMEA-002531-PIP01-18

Treatment of chronic (systolic) heart failure (ICD10: I50.22) / Treatment of coronary artery disease (ICD10: I25-1) / Treatment of essential hypertension (ICD10: I10) / Treatment of hypertension with stable coronary artery disease and those with stable chronic heart failure with reduced systolic left ventricular function in adult patients adequately controlled with bisoprolol and ramipril given concurrently at the same dose level (substitution indication)

Day 60 Opinion

Action: For adoption

Cardiovascular Diseases

2.1.5. Sutimlimab - Orphan - EMEA-002542-PIP01-18

Bioverativ Inc; Treatment of primary cold agglutinin disease

Day 60 Opinion

Action: For adoption

Haematology-Hemostaseology

2.1.6. Abemaciclib - EMEA-002342-PIP03-18

Treatment of breast cancer

Day 60 Opinion

Action: For adoption

Oncology

2.1.7. Capivasertib - EMEA-002551-PIP01-18

Prostate cancer / Breast cancer

Day 60 Opinion

Action: For adoption

Oncology

2.1.8. Tisotumab vedotin - EMEA-002522-PIP01-18

Treatment of cervical cancer

Day 60 Opinion

Action: For adoption

Oncology

2.1.9. EMEA-002503-PIP01-18

Biochemical recurrence of prostate cancer

Day 60 Opinion

Action: For adoption

Oncology / Uro-nephrology

2.1.10. Emiplacel - EMEA-002539-PIP01-18

Treatment of peripheral ischaemia

Day 60 Opinion

Action: For adoption

Other

2.1.11. EMEA-002519-PIP02-18

Treatment of schizophrenia

Day 60 Opinion

Action: For adoption

Psychiatry

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. Emicizumab - EMEA-C-001839-PIP01-15

Roche Registration GmbH; Treatment of hereditary Factor VIII deficiency

Day 60 Opinion

Action: For adoption

Haematology-Hemostaseology

2.2.2. Turoctocog alfa - EMEA-C-000428-PIP01-08-M03

Novo Nordisk A/S; Treatment of hereditary Factor VIII deficiency

Day 60 Opinion

Action: For adoption

Haematology-Hemostaseology

2.2.3. Split influenza virus, inactivated containing antigen equivalent to A/ California/7/2009(H1N1)-like strain (A/California/7/2009), adjuvanted - EMEA-C-000669-PIP01-09-M02

Sanofi Pasteur SA; Influenza

Day 60 Opinion

Action: For adoption

Vaccines

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Semaglutide - EMEA-001441-PIP02-15-M02

Novo Nordisk; Type 2 diabetes mellitus

Day 60 Opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.2. Obeticholic Acid - Orphan - EMEA-001304-PIP02-13-M04

Intercept Pharma Ltd.; Primary biliary cholangitis (PBC) / Biliary atresia

Day 60 Opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.3. Potassium chloride / sodium chloride / ascorbic acid / sodium ascorbate / sodium sulfate / polyethylene glycol 3350 - EMEA-001705-PIP02-15-M02

Norgine Limited; Bowel cleansing prior to clinical procedures

Day 60 Opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.4. Rilpivirine - EMEA-000317-PIP01-08-M11

Janssen-Cilag International NV; Treatment of human immunodeficiency virus type 1 (HIV-1) infection / Rilpivirine is indicated in combination with other antiretroviral (ARV) medicinal products, for the treatment of human immunodeficiency virus type 1 (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 60 Opinion

Action: For adoption

Infectious Diseases

2.3.5. Perampanel - EMEA-000467-PIP01-08-M11

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 60 Opinion

Action: For adoption

Neurology

2.3.6. Atezolizumab - EMEA-001638-PIP01-14-M02

Roche Registration GmbH; Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours, haematopoietic and lymphoid tissue neoplasms) / Treatment of paediatric patients from birth to less than 18 years old with a PD-L1 positive paediatric solid tumour as part of the first line treatment

Day 60 Opinion

Action: For adoption

Oncology

2.3.7. Autologous CD4+ and CD8+ T cells Expressing a CD19-Specific Chimeric Antigen Receptor (lisocabtagene maraleucel) - Orphan - EMEA-001995-PIP01-16-M02

Celgene Europe B.V.; Treatment of B-lymphoblastic leukemia/lymphoma / Treatment of mature B-cell neoplasms / Treatment of paediatric patients with CD19+ relapsed or refractory B-cell acute lymphoblastic leukaemia / Treatment of paediatric patients with CD19+ relapsed or refractory diffuse-large B-cell lymphoma, Burkitt lymphoma or primary mediastinal large B-cell lymphoma

Day 60 Opinion

Action: For adoption

Oncology

2.3.8. Daratumumab - Orphan - EMEA-002152-PIP01-17-M01

Janssen-Cilag International NV; Treatment of lymphoid malignancies (except mature B-cell neoplasms) / Treatment of paediatric patients from birth to less than 18 years of age with a lymphoid malignancy (except mature B-cell neoplasms)

Day 60 Opinion

Action: For adoption

Oncology

2.3.9. Ibrutinib - Orphan - EMEA-001397-PIP03-14-M04

Janssen-Cilag International N.V.; Treatment of mature B-cell neoplasm / Treatment of children from 1 year to less than 18 years of age with newly-diagnosed and relapsed/refractory mature B-cell lymphoma, that is, diffuse large B-cell lymphoma or Burkitt and Burkitt-like lymphoma

Day 60 Opinion

Action: For adoption

Oncology

2.3.10. Isatuximab - Orphan - EMEA-002205-PIP01-17-M01

Sanofi-Aventis Recherche & Développement; Treatment of malignant neoplasms of the haematopoietic and lymphoid tissue / Treatment of relapsed, refractory and newly-diagnosed acute lymphoblastic leukemia in combination with standard treatment in paediatric patients from 28 days to less than 18 years of age / Treatment of relapsed, refractory and newly-diagnosed acute myeloid leukemia in combination with standard treatment in paediatric patients from 28 days to less than 18 years of age

Day 60 Opinion

Action: For adoption

Oncology

2.3.11. Lenvatinib - EMEA-001119-PIP02-12-M05

Eisai Europe Ltd; Treatment of papillary thyroid carcinoma / Treatment of osteosarcoma, Treatment of follicular thyroid carcinoma / Treatment of refractory or relapsed osteosarcoma in children and adolescents / Treatment of progressive, radioiodine-refractory differentiated thyroid cancer in children and adolescents

Day 60 Opinion

Action: For adoption

Oncology

2.3.12. Palbociclib - EMEA-002146-PIP01-17-M01

Pfizer Europe MA EEIG; Treatment of Ewing sarcoma / Treatment of refractory or recurrent Ewing sarcoma

Day 60 Opinion

Action: For adoption

Oncology

2.3.13. Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with lentiviral vector that encodes for the human ARSA cDNA sequence - Orphan - EMEA-001765-PIP02-15-M03

Orchard Therapeutics (Europe) Ltd; Metachromatic leukodystrophy (MLD) / For the Treatment of metachromatic leukodystrophy (MLD)

Day 60 Opinion

Action: For adoption

Other

2.3.14. Aqueous extracts of Dermatophagoides pteronyssinus and Dermatophagoides farinae - EMEA-000815-PIP01-09-M01

Allergy Therapeutics (UK) Ltd; Allergic rhinitis and acute atopic conjunctivitis due to house dust mites / allergic rhinitis / allergic conjunctivitis

Day 60 Opinion

Action: For adoption

Pneumology - Allergology

2.3.15. Birch, Hazel and Alder Pollen Extract - EMEA-000808-PIP01-09-M01

Allergy Therapeutics (UK) Ltd; J.30.1 Allergic rhinitis due to pollen H10.1 Acute atopic conjunctivitis / Allergic rhinitis / Allergic conjuctivitis

Day 60 Opinion

Action: For adoption

Pneumology - Allergology

2.3.16. Fc- and CDR-modified humanized monoclonal antibody against C5 - Orphan - EMEA-001943-PIP01-16-M02

Alexion Europe SAS; Atypical Haemolytic Uremic Syndrome / Treatment of atypical haemolytic uremic syndrome

Day 60 Opinion

Action: For adoption

Uro-nephrology / Haematology-Hemostaseology

2.4. Opinions on Re-examinations

2.4.1. Neisseria meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / Neisseria meningitidis serogroup W-135 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-M01

Sanofi Pasteur; Prevention of meningococcal disease

Opinion

Action: For adoption

Vaccines

2.4.2. Ofatumumab - EMEA-002397-PIP01-18

Novartis Europharm Limited; Treatment of multiple sclerosis / Treatment of relapsing remitting multiple sclerosis

Opinion

Action: For adoption

Neurology

2.5. Opinions on Review of Granted Waivers

No items

2.6. Finalisation and adoption of Opinions

No items

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.

No items

2.7.1. Mometasone (furoate) / indacaterol (acetate) - EMEA-C2-001217-PIP01-11-M05

Novartis Europharm Limited; Treatment of asthma

Day 1 letter

Action: For information

Pneumology - Allergology

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. Emricasan - EMEA-002457-PIP01-18

Non-alcoholic steatohepatitis (NASH) / Treatment of NASH with moderate to severe liver fibrosis (F2-F4) in patients aged 8 to less than 18 years old

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.2. Tropifexor - EMEA-002471-PIP01-18

Non-alcoholic steatohepatitis (NASH) / Treatment of NASH with moderate to severe liver fibrosis (F2/F3) in paediatric patients from 8 to less than 18 years of age

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.3. Autologous CD34+ haematopoietic stem cells transduced with lentiviral vector encoding the human βA-T87Q-globin gene - Orphan - EMEA-001665-PIP02-17

bluebird bio France; Sickle cell disease

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.4. Fidanacogene elaparvovec - Orphan - EMEA-002362-PIP01-18

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

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.5. Allogeneic Epstein-Barr virus specific cytotoxic T lymphocytes - Orphan - EMEA-002025-PIP02-16

Atara Biotherapeutics, Inc.; Treatment of Epstein-Barr virus associated post-transplant lymphoproliferative disorder / Treatment of solid organ transplant (SOT) patients with Epstein-Barr virus associated post-transplant lymphoproliferative disease (EBV+ PTLD), who have failed prior therapy with rituximab / Treatment of allogeneic haematopoietic cell transplant (alloHCT) patients with Epstein-Barr virus associated post-transplant lymphoproliferative disease (EBV+ PTLD) who have failed prior therapy with rituximab

Day 90 discussion

Action: For discussion

Oncology

3.1.6. Rapastinel - EMEA-002357-PIP01-18

Major depressive disorder

Day 90 discussion

Action: For discussion

Psychiatry

3.1.7. EMEA-002310-PIP02-17

Treatment of C3 glomerulopathy

Day 90 discussion

Action: For discussion

Uro-nephrology

3.1.8. Genetically modified replication-incompetent herpes simplex virus-1 expressing collagen VII - Orphan - EMEA-002472-PIP02-19

Krystal Biotech, Inc.; Dystrophic epidermolysis bullosa

Day 60 discussion

Action: For discussion

Dermatology

3.1.9. Human monoclonal IgG2 antibody against tissue factor pathway inhibitor - Orphan - EMEA-002498-PIP01-18

Bayer AG; Treatment of haemophilia A /Treatment of haemophilia B

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.10. Iclaprim mesylate - EMEA-002391-PIP02-19

Infection with gram-positive bacteria

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.11. 1-[4-bromo-5-[1-ethyl-7-(methylamino)-2-oxo-1,2-dihydro-1,6-naphthyridin-3-yl]-2-fluorophenyl]-3-phenylurea - Orphan - EMEA-002526-PIP02-19

Deciphera Pharmaceuticals LLC; Treatment of gastrointestinal stromal tumours

Day 60 discussion

Action: For discussion

Oncology

3.1.12. Trilaciclib - EMEA-002534-PIP02-19

Prevention of chemotherapy induced myelosuppression

Day 60 discussion

Action: For discussion

Oncology

3.1.13. Human immunoglobulin G2 isotype antibody to IL-33R - EMEA-002515-PIP01-18

Treatment of asthma / Add-on therapy for the maintenance treatment for moderate-severe asthma

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.14. Bisoprolol fumarate / ramipril - EMEA-002560-PIP01-19

Adults: treatment of essential hypertension /Adults: treatment of heart failure

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.15. Ezetimibe / rosuvastatin calcium - EMEA-002541-PIP01-18

Elevated cholesterol

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.16. Heparin sodium - EMEA-002557-PIP01-19

Prevention of thromboembolic events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.17. EMEA-002327-PIP02-19

Treatment and prevention of oral mucositis

Day 30 discussion

Action: For discussion

Dermatology

3.1.18. Tezepelumab - EMEA-002579-PIP01-18

Atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.1.19. EMEA-002552-PIP01-19

Treatment of non-alcoholic steatohepatitis (NASH)

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.20. Hematopoietic stem cells modified with a lentiviral vector encoding for the human Beta 2 Integrin/CD18 gene - Orphan - EMEA-002562-PIP01-19

Rocket Pharmaceuticals, Inc.; Severe leukocyte adhesion deficiency type I (LAD-I)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.21. Obinutuzumab - Orphan - EMEA-001207-PIP02-19

Roche Registration GmbH; Systemic lupus erythemathosus

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.22. Ritonavir / darunavir - EMEA-002537-PIP01-18

Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.23. EMEA-002563-PIP01-19

Treatment of focal epilepsy

Day 30 discussion

Action: For discussion

Neurology

3.1.24. EMEA-002318-PIP03-19

Treatment of malignant melanoma

Day 30 discussion

Action: For discussion

Oncology

3.1.25. 6-(2-hydroxy-2-methylpropoxy)-4-(6-(6-((6-methoxypyridin-3-yl)methyl)-3,6-diazabicyclo[3.1.1]heptan-3-yl)pyridin-3-yl)pyrazolo[1,5-a]pyridine-3-carbonitrile - Orphan - EMEA-002544-PIP01-18

Loxo Oncology, Inc.; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms) / Treatment of paediatric patients from ≥6 months to <18 years of age with RET-altered, locally advanced or metastatic, solid tumours or primary central nervous system (CNS) tumours.

Day 30 discussion

Action: For discussion

Oncology

3.1.26. Humanized antibody targeting B cell maturation antigen conjugated with maleimidocaproyl monomethyl auristatin F - Orphan - EMEA-002468-PIP03-19

GlaxoSmithKline Trading Services; Treatment of mature B-Cell neoplasms / Treatment for adult patients with BCMA-expressing mature B-cell neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.1.27. Momelotinib - Orphan - EMEA-001656-PIP02-19

Sierra Oncology Inc.; Treatment of primary myelofibrosis

Day 30 discussion

Action: For discussion

Oncology

3.1.28. Moxetumomab pasudotox - Orphan - EMEA-002525-PIP01-18

AstraZeneca AB; Chronic lymphocytic leukaemias

Day 30 discussion

Action: For discussion

Oncology

3.1.29. Carfilzomib - Orphan - EMEA-001806-PIP04-19

Amgen Europe BV; Treatment of acute lymphoblastic leukemia (ALL) / Treatment of paediatric patients aged 1 year or older and young adult patients up to 21 years of age with bone marrow relapse of T-cell ALL treated with at least 1 prior therapy or B-cell ALL treated with at least 2 prior therapies, with or without extramedullary disease

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.1.30. Atropine sulphate - EMEA-002538-PIP01-18

Treatment of myopia

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.31. Brimonidine tartrate - EMEA-002558-PIP01-19

Conjunctival hyperaemia due to minor eye irritation

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.32. Lonafarnib - Orphan - EMEA-002516-PIP01-18

Eiger BioPharmaceuticals Europe Limited; progeroid laminopathies, Hutchinson-Gilford Progeria Syndrome (HGPS)

Day 30 discussion

Action: For discussion

Other

3.1.33. Bempedoic acid - EMEA-001872-PIP02-19

Treatment of mixed dyslipidaemia

Day 30 discussion

Action: For discussion

Other / Cardiovascular Diseases

3.1.34. Ezetimibe / bempedoic acid - EMEA-002200-PIP02-19

Treatment of mixed dyslipidaemia

Day 30 discussion

Action: For discussion

Other / Cardiovascular Diseases

3.1.35. Dexamethasone sodium phosphate / levofloxacin - EMEA-002375-PIP02-18

Acute Otitis Externa / Treatment of acute otitis externa

Day 30 discussion

Action: For discussion

Oto-rhino-laryngology

3.1.36. Dexamethasone sodium phosphate / levofloxacin - EMEA-002375-PIP03-18

Acute Otitis Media with spontaneous tympanic membrane perforation / Treatment of acute otitis media with spontaneous tympanic membrane perforation

Day 30 discussion

Action: For discussion

Oto-rhino-laryngology

3.1.37. Selonsertib - EMEA-001868-PIP04-18

Chronic Kidney Disease / Treatment of patients with progressive chronic kidney disease (CKD) resulting from congenital anomalies of the kidney and urinary track (CAKUT) aged 3 to less than 18 years

Day 30 discussion

Action: For discussion

Uro-nephrology

3.1.38. Bordetella pertussis antigen: pertactin / Bordetella pertussis antigen: filamentous haemagglutinin / Bordetella pertussis antigen: pertussis toxoid / tetanus toxoid / diphtheria toxoid - EMEA-002343-PIP01-18

ICD10: A36 (diphtheria), ICD10: A37 (whooping cough), ICD10: A35 (other tetanus) / Active booster immunization

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. Filgotinib - EMEA-C1-001619-PIP04-17-M01

Gilead Sciences International Ltd.; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis, and juvenile idiopathic arthritis)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.2. Anidulafungin - EMEA-C-000469-PIP01-08-M07

Pfizer Limited; Treatment of invasive candidiasis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.3. Lefamulin - EMEA-C1-002075-PIP01-16-M01

Nabriva Therapeutics AG; Treatment of community-acquired pneumonia

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.4. Sofosbuvir - EMEA-C-001276-PIP01-12-M02

Gilead Sciences Ireland UC; Treatment of chronic hepatitis C

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.5. Sofosbuvir / ledipasvir - EMEA-C-001411-PIP01-12-M04

Gilead Sciences Ireland UC; Treatment of chronic hepatitis C

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.6. Lipegfilgrastim - EMEA-C-001019-PIP01-10-M04

UAB ”Sicor Biotech“; Prevention of chemotherapy-induced febrile neutropenia

Day 30 discussion

Action: For discussion

Oncology

3.2.7. Beclometasone dipropionate / formoterol fumarate dihydrate - EMEA-C-000548-PIP01-09-M08

Chiesi Farmaceutici S.p.A.; Maintenance therapy of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate:

patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting beta2-agonist or patients already adequately controlled on both inhaled corticosteroids and long-acting beta2-agonists in adults, as well as in children aged 5 to 11 years and in adolescents aged 12 to 17 years.

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.2.8. N.meningitidis serogroup A polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup W135 polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid - EMEA-C-000429-PIP01-08-M04

Pfizer Europe MA EEIG; Prevention of meningococcal disease

Day 30 discussion

Action: For discussion

Vaccines

3.2.9. Recombinant Influenza Hemagglutinin-strain B (Victoria lineage) / Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype) / Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) / Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype) - EMEA-C1-002418-PIP01-18

Sanofi Pasteur; Prevention of influenza infection

Day 30 discussion

Action: For discussion

Vaccines

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Baricitinib - EMEA-001220-PIP03-16-M01

Eli Lilly and Company Limited; Treatment of atopic dermatitis / Treatment of patients with moderate to severe atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.3.2. Terbinafine hydrochloride - EMEA-001259-PIP02-13-M02

Polichem, S.A.; Treatment of onychomycosis

Day 30 discussion

Action: For discussion

Dermatology

3.3.3. Testosterone - EMEA-001529-PIP02-14-M02

Acerus Biopharma Inc.; Male hypogonadism / Treatment of male hypogonadism

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. Human normal immunoglobulin for subcutaneous administration - EMEA-001853-PIP01-15-M02

Grifols Therapeutics LLC; Treatment for primary immunodeficiency

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.5. Tocilizumab - EMEA-000309-PIP04-17-M02

Roche Registration GmbH; Cytokine release syndrome / Treatment of chimeric antigen receptor (CAR) T cell-induced severe or life-threatening cytokine release syndrome (CRS) in adults and paediatric patients 2 years of age and older

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.6. Eravacycline - EMEA-001555-PIP01-13-M03

Tetraphase Pharmaceuticals, Inc.; Complicated intra-abdominal infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.7. Posaconazole - EMEA-000468-PIP02-12-M05

Merck Sharp & Dohme (Europe), Inc.; Prevention of invasive fungal infections / Treatment

of invasive fungal infections / For treatment of invasive fungal infections in the following paediatric patients: Invasive aspergillosis in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products; Treatment of Invasive Aspergillosis / Patients receiving remission-induction chemotherapy for acute myelogenous leukemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high risk of developing invasive fungal infections / Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease and who are at high risk of developing invasive fungal infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.8. Tedizolid phospate - EMEA-001379-PIP01-12-M04

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.9. Balovaptan - EMEA-001918-PIP01-15-M02

Roche Registration GmbH; ICD1O F84: Treatment of autism spectrum disorder / Treatment of core social and communication deficits in people with autism spectrum disorder aged 2 years or older

Day 30 discussion

Action: For discussion

Neurology

3.3.10. Eculizumab - Orphan - EMEA-000876-PIP03-14-M03

Alexion Europe SAS; Neuromyelitis optica spectrum disorders / Treatment of paediatric patients with relapsing neuromyelitis optica spectrum disorders

Day 30 discussion

Action: For discussion

Neurology

3.3.11. Galcanezumab - EMEA-001860-PIP03-16-M03

Eli Lilly and Company Limited; Prevention of migraine headaches

Day 30 discussion

Action: For discussion

Neurology

3.3.12. Humanised anti-IL-6 receptor (IL-6R) monoclonal antibody - Orphan - EMEA-001625-PIP01-14-M03

Roche Registration GmbH; Treatment of neuromyelitis optica

Day 30 discussion

Action: For discussion

Neurology

3.3.13. Afatinib - EMEA-001596-PIP02-17-M01

Boehringer Ingelheim International GmbH; Treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lymphoid tissue neoplasms) / Treatment of malignant neoplasms of the central nervous system

Day 30 discussion

Action: For discussion

Oncology

3.3.14. Durvalumab - EMEA-002028-PIP01-16-M01

AstraZeneca AB; Treatment of malignant neoplasms of haematopoietic and lymphoid tissue / Treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lyphoid tissue) / Treatment of paediatric patients from birth to less than 18 years old with a paediatric haematological malignancy / Treatment of paediatric patients from birth to less than 18 years old with a paediatric solid tumour.

Day 30 discussion

Action: For discussion

Oncology

3.3.15. Tremelimumab - EMEA-002029-PIP01-16-M01

AstraZeneca AB; Treatment of malignant neoplasms of haematopoietic and lymphoid tissue /Treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lyphoid tissue) / Treatment of paediatric patients from birth to less than 18 years old with a paediatric haematological malignancy / Treatment of paediatric patients from birth to less than 18 years old with a paediatric solid tumour.

Day 30 discussion

Action: For discussion

Oncology

3.3.16. Venetoclax - Orphan - EMEA-002018-PIP02-16-M02

AbbVie Ltd; Treatment of haematopoietic and lymphoid malignant neoplasms / Treatment of solid tumour malignant neoplasms / Treatment of a specific paediatric hematopoietic and lymphoid malignant neoplasm or of a solid malignant neoplasm in patients from 1 month to 18 years of age

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.3.17. Concentrate of proteolytic enzyme enriched in bromelain - Orphan - EMEA-000142-PIP02-09-M08

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

3.3.18. Lanadelumab - Orphan - EMEA-001864-PIP01-15-M04

Shire Pharmaceuticals Ireland Limited (an indirect wholly owned subsidiary of Shire plc"); Hereditary angioedema / Treatment of hereditary angioedema

Day 30 discussion

Action: For discussion

Other

3.3.19. Fentanyl hydrochloride - EMEA-001509-PIP01-13-M02

Incline Therapeutics Europe Ltd. (a wholly owned subsidiary of The Medicines Company); Treatment of acute pain

Day 30 discussion

Action: For discussion

Pain

3.3.20. Ivacaftor / tezacaftor - Orphan - EMEA-001640-PIP01-14-M05

Vertex Pharmaceuticals (Europe) Ltd.; Cystic fibrosis / Treatment of cystic fibrosis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.21. EMEA-001428-PIP03-15-M01

Janssen-Cilag International NV; Major depressive disorder (MDD)

Day 30 discussion

Action: For discussion

Psychiatry

3.3.22. Pneumococcal Polysaccharide Serotype 33F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 22F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 18C – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 14 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 9V – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6B – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 5 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 4 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 1 – Diphtheria CRM197 Conjugate - EMEA-002215-PIP01-17-M02

Merck Sharp & Dohme (Europe), Inc.; Prevention of disease caused by streptococcus pneumoniae / Active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by streptococcus pneumoniae in infants, children and adolescents from 6 weeks to less than 18 years of age.

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 25 June 2019 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 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

6.1. Discussions on the applicability of class waiver for products

6.1.1. EMEA-03-2019

KaNDy Therapeutics Limited; All classes of medicinal products for treatment of climacteric symptoms associated with decreased oestrogen levels, as occurring at menopause / Treatment of menopausal-related symptoms

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 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

Update on PDCO member(s)/alternate(s) mandate status

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

Action: For information

9.2.2. Coordination group for mutual recognition and decentralised procedures – Human (CMDh) – Paediatric subgroup

Action: For discussion

9.2.3. Concept paper on the need for revision of the guideline on the investigation of medicinal products in the term and preterm neonate - comments received during public consultation

Action: For discussion

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

9.3.3. Healthcare Professionals Working Party (HCPWP) and Patients and Consumers Working Party (PCWP) - Nomination of PDCO representative(s)

Action: For discussion

9.3.4. Healthcare Professionals Working Party (HCPWP) and Patients and Consumers Working Party (PCWP) - Proposal to increase the current membership of the PCWP and HCPWP from 20 to 22 organisation members each

Action: For discussion

9.4. Cooperation within the EU regulatory network

9.4.1. European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA) – draft letter to Innovative Therapies for Children with Cancer (ITCC) on foster age inclusive research

Action: For information

9.4.2. Multi-stakeholder Meeting on Allergen Immuno-therapy (AIT) for Children – minutes from the meeting

Action: For adoption

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

9.6.1. Cardiac Safety Research Consortium Think Tank: Non-vitamin K antagonist oral anticoagulants (NOAC) Use in the Pediatric Population: Defining the Path Forward - ACC Heart House - Washington, DC – Feedback

PDCO: Dirk Mentzer (Chair)

Action: For information

9.7. PDCO work plan

No items

9.8. Planning and reporting

9.8.1. Marketing authorisation applications (MAA) forecast for 2019 – planning update dated Q1 2019

Action: For information

9.8.2. Strategic Review and Learning Meeting (SRLM) under the Romanian Presidency to be held in Malta on 13-14 June 2019

PDCO members: Dana Gabriela Marin, John Joseph Borg

Action: For information

10. Any other business

No items

11. Breakout sessions

11.1.1. Paediatric oncology

Action: For discussion on Thursday, 12:30 - 13:30, room NL-0E

11.1.2. Neonatology

Action: For discussion on Thursday, 12:30 - 13:30, room NL-0F

11.1.3. Inventory

Action: For discussion on Thursday, 12:30 - 13:30, room NL-1B

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/