23 June 2016
EMA/PDCO/316468/2016
Procedure Management and Committees Support Division

Paediatric Committee (PDCO)

Agenda for the meeting on 22-24 June 2016

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

22 June 2016, 08:30- 19:00, room 3A

23 June 2016, 08:30- 19:00, room 3A

24 June 2016, 08:30- 13:00, room 3A

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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Table of contents

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 22-24 June 2016. See June 2016 PDCO minutes (to be published post July 2016 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 22-24 June 2016.

1.3. Adoption of the minutes

PDCO minutes for 25-27 May 2016.

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. betrixaban - EMEA-001834-PIP01-15

Prevention of venous thromboembolism / adults and children

Day 120 opinion

Action: For adoption

Cardiovascular Diseases

2.1.2. Semaglutide - EMEA-001441-PIP02-15

Treatment of Type 2 Diabetes Mellitus / Treatment of Type 2 Diabetes Mellitus

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.3. Eculizumab - Orphan - EMEA-000876-PIP06-15

Alexion Europe SAS; Prevention of graft rejection following solid organ transplantation / Prevention of acute antibody-mediated rejection in sensitized recipients after kidney transplantation

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.4. EMEA-001776-PIP01-15

Treatment of Active Psoriatic Arthritis, Treatment of Crohn's disease, Treatment of plaque psoriasis, Treatment of Ankylosing Spondylitis, Treatment of Asthma / not available at present, Treatment of moderate to severe plaque psoriasis in children and adolescents from the age of 6 years, who are candidates for systemic therapies

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Dermatology / Pneumology - Allergology / Gastroenterology-Hepatology

2.1.5. EMEA-001838-PIP01-15

Treatment of respiratory tract disease caused by human respiratory syncytial virus (RSV) / Treatment of respiratory tract disease caused by human RSV

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.6. Cabotegravir - EMEA-001418-PIP02-15

Prevention of human immunodeficiency virus (HIV-1) infection / Cabotegravir is to be indicated in combination with safer sex practices for PrEP to reduce the risk of HIV-1 acquisition in sexually active adolescents at high risk, from 12 to < 18 years of age

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.7. Peramivir - EMEA-001856-PIP01-15

Treatment of influenza / Treatment of influenza

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.8. Quizartinib - Orphan - EMEA-001821-PIP01-15

Daiichi Sankyo Europe GmbH; Acute myeloid leukaemia / For the treatment of paediatric patients aged from 1 month to less than 18 years of age with newly diagnosed FLT3-ITD(+) AML, For the treatment of paediatric patients aged from 1 month to less than 18 years of age with relapsed or refractory FLT3-ITD(+) AML after failure of front line intensive chemotherapy regimen, in combination with standard chemotherapy

Day 120 opinion

Action: For adoption

Oncology

2.1.9. andexanet alfa - EMEA-001902-PIP01-15

Prevention of factor Xa inhibitor associated haemorrhage, Treatment of factor Xa inhibitor associated haemorrhage / (as above), For the reversal of anticoagulation due to direct and indirect factor Xa inhibitors in patients experiencing an acute major bleeding event or requiring urgent surgery

Day 120 opinion

Action: For adoption

Other

2.1.10. 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

GlaxoSmithKline Trading Services Limited; Metachromatic leukodystrophy (MLD) / For the treatment of metachromatic leukodystrophy (MLD)

Day 120 opinion

Action: For adoption

Other

2.1.11. Hydrochlorothiazide / Amlodipine / Ramipril - EMEA-001942-PIP01-16

Treatment of hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.12. Rosuvastatin / Amlodipine - EMEA-001935-PIP01-16

Treatment of angina and dyslipidaemia, Treatment of concomitant hypertension and dyslipidemia, Treatment of essential hypertension in patients who are estimated to have a high risk for a first cardiovascular event

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.13. Lusutrombopag - EMEA-001905-PIP01-15

Treatment of thrombocytopenia

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.14. Lenalidomide - Orphan - EMEA-000371-PIP03-15

Celgene Europe Limited; Marginal zone lymphoma, Multiple Myeloma, Follicular Lymphoma, Diffuse Large B-cell Lymphoma, Myelodysplastic syndrome, Mantle Cell Lymphoma

Day 60 opinion

Action: For adoption

Oncology

2.1.15. Pembrolizumab - EMEA-001474-PIP02-16 – early adoption of opinion

Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoietic and lymphoid tissue), Treatment of Hodgkin Lymphoma / Treatment of relapsed or refractory classical Hodgkin Lymphoma in children from 5 years to less than 18 years of age, Treatment of advanced, untreated or previously treated, malignant melanoma in children from 12 year old to less than 18 years of age/ Treatment as monotherapy of a PD-L1 positive paediatric malignant solid tumor in children from 6 months to less than 18 years of age

Day 60 opinion

Action: For opinion

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. Human Fibrinogen - EMEA-C1-001208-PIP01-11-M02

Octapharma Pharamzeutika Produktionsges.m.b.H; Treatment of congenital fibrinogen deficiency

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.2.2. Everolimus - EMEA-C1-000019-PIP08-12-M02

Novartis Europharm Limited; Treatment of Tuberous Sclerosis Complex

Day 0 opinion

Action: For information

Neurology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Recombinant human beta-glucuronidase - Orphan - EMEA-001540-PIP01-13-M01

Ultragenyx UK Limited; ICD-10: E76.2, Mucopolysaccharidosis type 7 (MPS 7) / Treatment of Mucopolysaccharidosis 7 (MPS 7)

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.2. elobixibat - EMEA-001484-PIP01-13-M01

Elobix AB; Constipation

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.3. turoctocog alfa - EMEA-000428-PIP01-08-M03

Novo Nordisk A/S; Hereditary Factor VIII Deficiency / Treatment and prophylaxis of bleeding in patients with Haemophilia A (congenital Factor VIII deficiency)

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.4. Adalimumab - EMEA-000366-PIP05-12-M02

AbbVie Limited; Non-infectious uveitis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Ophthalmology / Dermatology / Gastroenterology-Hepatology

2.3.5. (3-((4-Benzoyl-1-piperazinyl)(oxo)acetyl)-4-methoxy-7-(3-methyl-1H-1,2,4-triazol-1-yl)-1H-pyrrolo[2,3-c]pyridin-1-yl)methyl dihydrogen phosphate, 2-amino-2-(hydroxymethyl)-1,3-propanediol (1:1) - EMEA-001687-PIP01-14-M01

Bristol-Myers Squibb International Corporation; Treatment of human immunodeficiency virus [HIV-1] infection / Treatment of multi-drug resistant HIV-1 infection as part of a combination therapy in paediatric patients aged 2 years to <18 years, who have no more than 2 remaining available fully active antiretroviral therapies

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.6. Anidulafungin - EMEA-000469-PIP01-08-M06

Pfizer Limited; Treatment of invasive candidiasis

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.7. rilpivirine (as hydrochloride) - EMEA-000317-PIP01-08-M09

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 60 opinion

Action: For adoption

Infectious Diseases

2.3.8. Tenofovir alafenamide (as fumarate) - EMEA-001584-PIP01-13-M01

Gilead Sciences International Ltd.; Treatment of chronic hepatitis B / indicated for the treatment of chronic hepatitis B infection in paediatric patients aged 2 years and above

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.9. Dobutamine - EMEA-001262-PIP01-12-M01

Proveca Limited; Circulatory impairment / haemodynamic insufficiency

Day 60 opinion

Action: For adoption

Neonatology - Paediatric Intensive Care / Cardiovascular Diseases

2.3.10. Brentuximab vedotin - Orphan - EMEA-000980-PIP01-10-M04

Takeda Pharma A/S; Treatment of Hodgkin lymphoma, Treatment of anaplastic large cell lymphoma / Treatment of paediatric patients with newly diagnosed, relapsed or refractory Hodgkin lymphoma (from 5 years of age), Treatment of paediatric patients with first and subsequent relapse or refractory systemic anaplastic large cell lymphoma (from 2 years of age)

Day 60 opinion

Action: For adoption

Oncology

2.3.11. Dinutuximab - Orphan - EMEA-001285-PIP01-12-M02

United Therapeutics Europe Limited; Neuroblastoma / Treatment of patients with high-risk neuroblastoma following myeloablative therapy and autologous stem cell rescue in combination with GM-CSF, IL-2, and isotretinoin

Day 60 opinion

Action: For adoption

Oncology

2.3.12. vemurafenib (propane-1-sulfonic acid {3-[5-(4-chlorophenyl)-1H-pyrrolo[2,3-b]pyridine-3-carbonyl]-2,4-difluorophenyl}-amide - EMEA-000978-PIP01-10-M01

Roche Registration Limited; Treatment of melanoma

Day 60 opinion

Action: For adoption

Oncology

2.3.13. ivacaftor / lumacaftor - EMEA-001582-PIP01-13-M04

Vertex Pharmaceuticals (Europe) Limited; cystic fibrosis / Treatment of cystic fibrosis

Day 60 opinion

Action: For adoption

Other

2.3.14. Benralizumab - EMEA-001214-PIP01-11-M05

AstraZeneca AB; Asthma / Treatment of asthma

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.15. budesonide - EMEA-001087-PIP02-12-M02

Vectura Limited; treatment of asthma

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.16. lurasidone hydrochloride - EMEA-001230-PIP01-11-M02

Sunovion Pharmaceuticals Ltd.; schizophrenia / schizophrenia

Day 60 opinion

Action: For adoption

Psychiatry

2.3.17. Pneumococcal polysaccharide serotype 23F conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 19F conjugated to diphtheria toxoid / Pneumococcal polysaccharide serotype 18C conjugated to tetanus toxoid / Pneumococcal polysaccharide serotype 14 conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 9V conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 7F conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 6B conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 5 conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 1 conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal

polysaccharide serotype 4 conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein - EMEA-000673-PIP01-09-M09

GlaxoSmithKline Biologicals S.A.; Disease caused by Streptococcus pneumoniae, Acute Otitis Media caused by Non-typeable Haemophilus influenzae / Disease caused by Streptococcus pneumoniae, Acute Otitis Media caused by Non-typeable Haemophilus influenzae

Day 60 opinion

Action: For adoption

Vaccines

2.3.18. Levamisole Hydrochloride – EMEA-001885-PIP01-15-M01

ACE Pharmaceuticals BV; Treatment of glomerulonephritis and nephrotic syndrome

Day 0 opinion

Action: For adoption

Uro-nephrology

2.3.19. Solithromycin – EMEA-001581-PIP01-13-M03

Triskel EU Services, Ltd; Treatment of bacterial pneumonia/Treatment of tularaemia/ Treatment of anthrax

Day 0 opinion

Action: For adoption

2.3.20. dupilumab - EMEA-001501-PIP01-13-M03 – early adoption of opinion

Regeneron Pharmaceuticals, Inc; Atopic Dermatitis / Atopic Dermatitis

Day 30 opinion

Action: For adoption

Dermatology

2.4. Opinions on Re-examinations

No items.

2.5. Finalisation and adoption of opinions

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. Cathine hydrochloride (D-Norpseudoephedrine hydrochloride) - EMEA-001909-PIP01-15

Treatment of obesity / Adjunct therapy for patients with obesity and a body mass index (BMI) of at least 30 for adults and above the 97th percentile for children who failed to achieve adequate therapeutic response with comprehensive weight loss measures alone

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.2. Elafibranor - EMEA-001857-PIP01-15

Treatment of non-alcoholic fatty liver disease (NAFLD), Treatment of non-alcoholic steatohepatitis (NASH) / Treatment of non-alcoholic fatty liver disease (NAFLD)

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.3. Eculizumab - Orphan - EMEA-000876-PIP07-15

Alexion Europe SAS; Prevention of delayed graft function after solid organ transplantation / Prevention of delayed graft function after kidney transplantation in patients at increased risk of delayed graft function

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.4. Angiotensin II - EMEA-001912-PIP01-15

Treatment of Catecholamine-resistant hypotension associated with distributive shock

Day 90 discussion

Action: For discussion

Other

3.1.5. Autologous cartilage derived cultured chondrocytes - EMEA-001823-PIP01-15

Treatment of cartilage disorders

Day 90 discussion

Action: For discussion

Other

3.1.6. derivative of 4H-pyrazolo[3,4-d]pyrimidin-4-one - EMEA-001742-PIP01-14

Treatment of schizophrenia / Cognitive Impairment Associated with Schizophrenia

Day 90 discussion

Action: For discussion

Psychiatry

3.1.7. pegvaliase - Orphan - EMEA-001951-PIP01-16

BioMarin International Limited; For the treatment of hyperphenylalaninaemia / For the treatment of hyperphenylalaninaemia in paediatric patients of all ages with phenylketonuria

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.8. EMEA-001929-PIP01-16

Crohn's disease, Ulcerative colitis / Treatment of children 4 to 17 years of age with moderately to severely active Crohn's disease who have had an inadequate response with, lost response to, or were intolerant to treatment with a tumour necrosis factor-alpha inhibitor; or immunomodulator, or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids., Treatment of children 4 to 17 years of age with moderately to severely active ulcerative colitis who have had an inadequate response with, lost response to, or were intolerant to treatment with a tumour necrosis factor-alpha inhibitor; or immunomodulator, or had an inadequate response with, were intolerant to, or demonstrated dependence on corticosteroids

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.9. Autologous CD34+ cells transduced with lentiviral vector encoding the human beta-globin gene - EMEA-001933-PIP01-16

Beta-thalassemia major and intermedia / Treatment of Beta thalassemia major and intermedia

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.10. EMEA-001944-PIP01-16

Anaemia secondary to chronic kidney disease / Treatment of anaemia secondary to chronic kidney disease

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.11. EMEA-001923-PIP01-15

Chronic idiopathic arthritis, including rheumatoid arthritis, axial spondyloarthritis, psoriatic arthritis and juvenile idiopathic arthritis (pJIA indication), Chronic idiopathic arthritis, including rheumatoid arthritis, axial spondyloarthritis, psoriatic arthritis and juvenile idiopathic arthritis (sJIA indication) / Treatment of systemic Juvenile Idiopathic Arthritis (sJIA), Treatment of polyarticular-course Juvenile Idiopathic Arthritis (pJIA)

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.12. Dolutegravir (DTG) / Lamivudine (3TC) - EMEA-001940-PIP01-16

Treatment of human immunodeficiency virus (HIV-1) infection / Treatment of human immunodeficiency virus (HIV-1) infection

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.13. Anti-(human calcitonin gene-related peptide receptor) human monoclonal antibody - EMEA-001664-PIP02-15

Migraine headaches / Prophylaxis of migraine

Day 60 discussion

Action: For discussion

Neurology

3.1.14. Humanized monoclonal calcitonin gene-related peptide neutralizing antibody - EMEA-001860-PIP04-16

Prophylactic treatment of cluster headache

Day 60 discussion

Action: For discussion

Neurology

3.1.15. Recombinant human monoclonal IgG1 antibody directed against Programmed Death Ligand-1 (anti-PD-L1) [MSB0010718C] - Orphan - EMEA-001849-PIP02-15

Merck KGaA; The treatment of solid malignant neoplasms

Day 60 discussion

Action: For discussion

Oncology

3.1.16. Dexamethasone / Povidone-Iodine - EMEA-001936-PIP01-16

Treatment of Infectious conjunctivitis (adenoviral and bacterial)

Day 60 discussion

Action: For discussion

Ophthalmology

Grass pollen-induced allergic rhinitis/rhinoconjunctivitis / Treatment of grass pollen-induced allergic rhinitis, with or without conjunctivitis (AR/C)

Day 60 discussion

Action: For discussion

Pneumology - Allergology / Oto-rhino-laryngology

3.1.17. Ezetimibe / Rosuvastatin (calcium) - EMEA-001941-PIP01-16

Treatment of hypercholesterolaemia

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.18. Indapamid / Amlodipine besylate / Perindopril erbumine - EMEA-001948-PIP01-16

Treatment of essential hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.19. Lauromacrogol 400 - EMEA-001704-PIP03-16

Venous therapeutic procedures

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.20. tadalafil / macitentan - EMEA-001961-PIP01-16

I27.0: Primary pulmonary hypertension / Treatment of Pulmonary Arterial Hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.21. Humanized IgG1, kappa anti-serum amyloid A and anti-AL amyloid antibody - Orphan - EMEA-001962-PIP01-16

Prothena Therapeutics Limited; Treatment of Light Chain (AL) Amyloidosis

Day 30 discussion

Action: For discussion

Cardiovascular Diseases / Haematology-Hemostaseology

3.1.22. Birch bark extract - Orphan - EMEA-001299-PIP02-16

Birken AG; Treatment of epidermolysis bullosa / Treatment of epidermolysis bullosa

Day 30 discussion

Action: For discussion

Dermatology

3.1.23. Gadolinium - EMEA-001949-PIP01-16

Detection and visualisation of areas with disruption of the blood brain barrier and/or abnormal vascularity for diagnostic purposes

Day 30 discussion

Action: For discussion

Diagnostic

3.1.24. (S)-lactic acid - EMEA-001953-PIP01-16

Pregnancy / Prevention of pregnancy

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.25. Recombinant human alpha-glucosidase conjugated with multiple copies of synthetic bismannose-6-phosphate-tetra-mannose glycan - Orphan - EMEA-001945-PIP01-16

Genzyme Europe B.V.; ICD-10: E74.0; Glycogen storage disease (Pompe disease) / Long-term use as an ERT for the treatment of patients with a confirmed diagnosis of Pompe disease (acid α-glucosidase deficiency)

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.26. allopurinol / lesinurad - EMEA-001952-PIP01-16

hyperuricaemia associated with gout

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.27. Seletalisib - EMEA-001938-PIP01-16

Primary Immunodeficiency syndrome

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.28. EMEA-001981-PIP01-16

Treatment of Chronic Hepatitis C Virus Infection / Treatment of chronic hepatitis C infection of genotypes 1 to 6 with the combination regimen of MK-3682, MK 5172 and MK-8408 in children and adolescents from 3 years to < 18 years of age

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.29. Cannabidiol - Orphan - EMEA-001964-PIP01-16

GW Research Ltd; Treatment of Seizures

Day 30 discussion

Action: For discussion

Neurology

3.1.30. CTX0E03 human neural stem cells (allogeneic) - EMEA-001969-PIP01-16

Sequelae of cerebral infarction

Day 30 discussion

Action: For discussion

Neurology

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. semaglutide - EMEA-C1-001441-PIP01-13

Novo Nordisk A/S; Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.2. solithromycin - EMEA-C1-001581-PIP01-13-M02

Triskel EU Services, Ltd; Treatment of bacterial pneumoniae

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.3. Octenidine Dihydrochloride - EMEA-C1-001514-PIP01-13

Cassella-med GmbH & Co. KG; Treatment of upper respiratory tract infections

Day 30 discussion

Action: For discussion

Oto-rhino-laryngology

3.2.4. Aripiprazole - EMEA-C-000235-PIP02-10-M02

Otsuka Pharmaceutical Europe Ltd.; Treatment of bipolar affective disorder

Day 30 discussion

Action: For discussion

Psychiatry

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Evolocumab - EMEA-001268-PIP01-12-M03

Amgen Europe B.V.; Treatment of mixed dyslipidaemia, Treatment of elevated cholesterol / Heterozygous Familial Hypercholesterolaemia (HeFH) and Homozygous Familial Hypercholesterolaemia (HoFH) after Prior Lipid-Lowering Therapy in paediatric subjects aged 10 years and above

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. Linaclotide - EMEA-000927-PIP01-10-M03

Allergan Pharmaceuticals International Limited; Functional Constipation / in children

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.3. Lubiprostone - EMEA-000245-PIP01-08-M03

Sucampo Pharma Europe Ltd.; chronic idiopathic constipation / chronic idiopathic constipation

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.4. vedolizumab - EMEA-000645-PIP01-09-M04

Takeda Pharma A/S; ulcerative colitis, Crohn's disease

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.5. ixekizumab - EMEA-001050-PIP01-10-M02

Eli Lilly & Company Limited; Treatment of psoriasis vulgaris, Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis) / Treatment of moderate to severe chronic plaque psoriasis in paediatric patients from the age of 6 years who are not adequately controlled by topical therapies., Treatment of JIA (including polyarticular arthritis, extended oligoarticular arthritis, sJIA without active systemic features, and ERA including JoAS and JPsA) in paediatric patients from the age of 2 years and for the treatment of sJIA with active systemic features in paediatric patients from the age of 1 year

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.6. piperaquine tetraphosphate / dihydroartemisinin - EMEA-000153-PIP01-07-M04

Sigma-Tau SpA; Uncomplicated malaria caused by Plasmodium falciparum (ICD-10 code B50) / Treatment of uncomplicated malaria caused by Plasmodium falciparum

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.7. Fingolimod hydrochloride - EMEA-000087-PIP01-07-M04

Novartis Europharm Limited; Multiple Sclerosis / Multiple Sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.3.8. Brexpiprazole - EMEA-001185-PIP01-11-M03

Otsuka Europe Development and Commercialisation Ltd, Zweigniederlassung Frankfurt am Main; Schizophrenia / Treatment of schizophrenia in adolescents 13 to 17 years of age

Day 30 discussion

Action: For discussion

Psychiatry

3.3.9. Lanthanum carbonate hydrate - EMEA-000637-PIP02-10-M05

Shire Pharmaceutical Contracts Ltd; Hyperphosphataemia

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3.10. Recombinant Human TriPeptidyl Peptidase 1 (rhTPP1) - EMEA-001362-PIP01-12-M03

BioMarin International Limited; Treatment of Neuronal Ceroid Lipofuscinosis Type 2 (CLN2)

Day 0 discussion

Action: For discussion

Neurology

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 16 August 2016 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

4.3.1. Call for expression of interest to become PDCO representative in Enpr-EMA Coordinating Group

Scope: Replacement of Christoph Male

Action: For adoption

4.3.2. Appointment of PDCO representative at the SAWP

Scope: Re-appointment of Karl-Heinz Huemer/appointment of another PDCO member

Action: For adoption

4.3.3. Appointment of alternate at Formulation Working Group

Scope: Appointment of Daniela Reins as alternate to member Andreas Grummel at PDCO Formulation Working Group

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.

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. {2-amino-8-[4-(pyrrolidinylcarbonyl)phenyl]-(3H-benzo[f]azepin-4-yl)}-N,N-dipropylcarboxamide –Orphan – EMEA-18-2016

VentiRx Pharmaceuticals, Inc.; Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours), Treatment of Fallopian tube carcinoma (excluding rhabdomyosarcoma and germ cell tumours), Treatment of peritoneal carcinoma (excluding blastomas and sarcomas) / Treatment in combination with pegylated liposomal doxorubicin for advanced ovarian cancer

Action: For adoption

6.1.2. Glycopyrronium bromide/Formoterol fumarate dihydrate - EMEA-19-2016

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)/ long-term, maintenance bronchodilator treatment of airflow obstruction in patients with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema

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

None

8. Annual reports on deferrals

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

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. PDCO meeting dates 2016, 2017 and 2018

PDCO Chair: Dirk Mentzer

Action: For adoption

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. Recommendations on eligibility to PRIME – report from CHMP

Action: For information

Disclosure of information related to priority medicines cannot be released at present time as these contain commercially confidential information.

9.2.3. Report from the Strategic Review and Learning Meeting held on 1-3 June 2016, Utrecht

PDCO Chair: Dirk Mentzer

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: Jacqueline Carleer

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.3.3. Paediatric Addendum to the Guideline on clinical investigation of medicinal products for the treatment of acute heart failure | Updated draft following public consultation and discussion at CVS WP May 2016 meeting

PDCO member: Christoph Male

Action: For discussion and adoption

9.3.4. Revision of the Guideline on the clinical investigation of human normal immunoglobulin for intravenous administration (IVIg)

Action: For discussion and adoption

9.4. Cooperation within the EU regulatory network

9.4.1. European Commission (EC) 10-year report on Paediatric Regulation: draft economic impact study

Action: For discussion

9.5. Cooperation with International Regulators

None

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

9.6.1. Recommendations for Pharmacological Clinical Trials in Children with Irritable Bowel Syndrome (IBS) from the Rome Foundation Paediatric Subcommittee on Clinical Trials

PDCO Member: Johannes Taminiau

Action: For information

9.7. PDCO work plan

None

9.8. Planning and reporting

None

9.9. PDCO ORGAM

None

10. Any other business

10.1.1. Templates for the summaries of the PDCO opinions

Action: For discussion

10.1.2. Requests for participation at scientific/regulatory meetings of EMA staff – PDCO members

Action: For discussion

10.1.3. Overview of PIPs for HIV

Action: For discussion

11. Breakout sessions

11.1.1. Paediatric oncology

Action: For discussion on Thursday, 18:30 - 19:30, room 3M

11.1.2. Neonatology

Action: For discussion on Thursday, 18:30 - 19:30, room 3L

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/