23 February 2016
EMA/PDCO/100838/2016
Procedure Management and Committees Support Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 24-26 February 2016

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

24 February 2016, 08:30- 19:00, room 3E

25 February 2016, 08:30- 19:00, room 3E

26 February 2016, 08:30- 13:00, room 3E

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 24-26 February 2016. See February 2016 PDCO minutes (to be published post March 2016 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 24-26 February 2016.

1.3. Adoption of the minutes

PDCO minutes for 27-29 January 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. certolizumab pegol - EMEA-001071-PIP03-14

Treatment of psoriasis / treatment of severe chronic plaque psoriasis

Day 120 opinion

Action: For adoption

Dermatology

2.1.2. Recombinant Human alpha-galactosidase A - EMEA-001828-PIP01-15

Treatment of Fabry disease

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

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

Treatment of primary immunodeficiency

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.4. Humanised monoclonal antibody against myostatin - Orphan - EMEA-001763-PIP01-15

Pfizer Limited; Duchenne Muscular Dystrophy

Day 120 opinion

Action: For adoption

Neurology

2.1.5. Octenidine dihydrochloride - EMEA-001514-PIP01-13

Treatment of upper respiratory tract infections / Treatment of sore-throat due to infectious pharyngitis

Day 120 opinion

Action: For adoption

Oto-rhino-laryngology

2.1.6. Ketamine / Sufentanil - EMEA-001739-PIP01-14

ICD10: R52 Pain, unspecified

Day 120 opinion

Action: For adoption

Pain

2.1.7. Finasteride - EMEA-001878-PIP01-15

Treatment of androgenetic alopecia

Day 60 opinion

Action: For adoption

Dermatology

2.1.8. Perindopril arginine / Atorvastatin - EMEA-001876-PIP01-15

Treatment of cardiovascular diseases, Treatment of ischaemic coronary artery disorders, Treatment of hypertension, Treatment of elevated cholesterol

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases

2.1.9. acalabrutinib - EMEA-001796-PIP02-15

Treatment of lymphoplasmacytic lymphoma, Treatment of mantle cell lymphoma

Day 60 opinion

Action: For adoption

Oncology

2.1.10. Gallium68 chloride (Ga68Cl3) - EMEA-001842-PIP02-15

This medicinal product is not intended for direct use in patients. Visualisation of function and/or specific organs or lesions in the body, depending on the carrier molecule used.

Day 60 opinion

Action: For adoption

Other

2.1.11. Levocetirizine dihydrochloride / Montelukast sodium - EMEA-001908-PIP01-15

Treatment of asthma

Day 60 opinion

Action: For adoption

Pneumology - Allergology

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. Canakinumab - EMEA-C-000060-PIP04-14-M01

Novartis Europharm Ltd.; Treatment of hyperimmunoglobulin D syndrome

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.2.2. Canakinumab - EMEA-C-000060-PIP05-14-M01

Novartis Europharm Ltd.; Treatment of tumour necrosis factor receptor associated periodic syndrome

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.2.3. Recombinant Human TriPeptidyl Peptidase 1 (rhTPP1) - EMEA-C1-001362-PIP01-12-M02

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

Day 60 opinion

Action: For adoption

Neurology

2.2.4. Bevacizumab - EMEA-C-000056-PIP01-07-M02

F.Hoffmann-La Roche Ltd; Treatment of non-rhabdomyosarcoma soft tissue sarcoma

Day 60 opinion

Action: For adoption

Oncology

2.2.5. Japanese-encephalitis virus, inactivated (attenuated strain SA14-14-2 grown in vero cells) - EMEA-C-000559-PIP01-09-M03

Valneva Austria GmbH; Prevention of Japanese encephalitis

Day 60 opinion

Action: For adoption

Vaccines

2.2.6. Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily A) / Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily B) - EMEA-C1-001037-PIP02-11-M03

Pfizer Ltd.; Prevention of invasive meningococcal disease caused by N. meningitidis serogroup B

Day 60 opinion

Action: For adoption

Vaccines

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Alipogene Tiparvovec - Orphan - EMEA-000292-PIP01-08-M02

uniQure biopharma B.V.; Hyperchylomicronaemia / Glybera is indicated for patients aged 2 or above diagnosed with familial lipoprotein lipase deficiency (LPLD) and suffering from severe or multiple pancreatitis attacks despite dietary fat restrictions. The diagnosis of LPLD has to be confirmed by genetic testing. The indication is restricted to patients with detectable levels of LPL protein.

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. Alirocumab - EMEA-001169-PIP01-11-M01

Sanofi-aventis Recherche & développement; Treatment of elevated cholesterol / Treatment of heterozygous and homozygous familial hypercholesterolemia

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.3. Pitavastatin - EMEA-000054-PIP01-07-M04

Kowa Pharmaceutical Europe Company Ltd; Endocrine, nutritional and metabolic diseases - Metabolic disorders - Disorders of lipoprotein metabolism and other lipidaemias E78 / Treatment of high-risk hyperlipidaemia (excluding homozygous familial hypercholesterolaemia) in children and adolescents who are not controlled on diet.

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.4. Pitavastatin - EMEA-000300-PIP01-08-M04

Kowa Pharmaceutical Europe Company Ltd; Endocrine, nutritional and metabolic diseases - Metabolic disorders - Disorders of lipoprotein metabolism and other lipidaemias E78 / Treatment of high-risk hyperlipidaemia (excluding homozygous familial hypercholesterolaemia) in children and adolescents who are not controlled on diet.

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.5. Heterologous Human Adult Liver-derived Progenitor Cells (HHAPLC) - Orphan - EMEA-001155-PIP01-11-M03

Promethera Biosciences; Urea Cycle Disorders, Crigler-Najjar Syndrome / Treatment of inborn errors of liver metabolism

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.6. Coagulation Factor VIIa (Recombinant) - EMEA-001203-PIP02-14-M01

LFB SA; Treatment of congenital coagulation disorders, Treatment of acquired haemophilia / Treatment of bleeding and prevention of bleeding in those undergoing surgery or invasive procedures in patients with haemophilia A or B with inhibitors to Factors VIII or IX, Treatment of bleeding and prevention of bleeding in those undergoing surgery or invasive procedures in patients with acquired haemophilia

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.7. ixekizumab - EMEA-001050-PIP01-10-M01

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 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.8. Adalimumab - EMEA-000366-PIP05-12-M01

AbbVie Limited; Non-infectious uveitis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Ophthalmology / Dermatology /

Gastroenterology-Hepatology

2.3.9. boceprevir - EMEA-000583-PIP01-09-M07

Merck Sharp & Dohme Ltd; Treatment of chronic viral hepatitis C / Treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alpha and ribavirin, in children and adolescents from 3 years to less than 18 years of age with compensated liver disease who are previously untreated or who have failed previous therapy.

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.10. Fidaxomicin - EMEA-000636-PIP01-09-M04

Astellas Pharma Europe B.V.; Treatment of enterocolitis caused by clostridium difficile / Treatment of Clostridium difficile infections (CDI) also known as C. difficile-associated diarrhoea (CDAD).

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.11. Olesoxime - Orphan - EMEA-001414-PIP01-12-M01

Roche Registration Limited; Spinal Muscular Atrophy

Day 60 opinion

Action: For adoption

Neurology

2.3.12. Talimogene laherparepvec - EMEA-001251-PIP01-11-M01

Amgen Europe B.V.; Treatment of melanoma in adults / Treatment of solid malignant non-CNS tumours

Day 60 opinion

Action: For adoption

Oncology

2.3.13. Tapentadol - EMEA-000018-PIP01-07-M10

Grünenthal GmbH; Acute pain / Treatment of acute pain

Day 60 opinion

Action: For adoption

Pain

2.3.14. Tapentadol - EMEA-000494-PIP01-08-M09

Grünenthal GmbH; Acute pain / Treatment of acute pain

Day 60 opinion

Action: For adoption

Pain

2.3.15. Tapentadol - EMEA-000495-PIP01-08-M09

Grünenthal GmbH; Acute pain / Treatment of acute pain

Day 60 opinion

Action: For adoption

Pain

2.3.16. mometasone furoate / indacaterol acetate (dose expressed as free base) - EMEA-001217-PIP01-11-M02

NOVARTIS EUROPHARM LTD.; Treatment of asthma

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.17. tralokinumab - EMEA-000782-PIP01-09-M03

MedImmune Ltd; Asthma / Treatment of adults and adolescents whose asthma is inadequately controlled with medium or high-dose inhaled corticosteroids (ICS) and at least one additional controller medication

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.18. potassium hydrogen carbonate / potassium citrate monohydrated - EMEA-001357-PIP01-12-M01

Advicenne Pharma; Treatment of renal tubular acidosis

Day 60 opinion

Action: For adoption

Uro-nephrology

2.3.19. Everolimus - Orphan - EMEA-000019-PIP08-12-M02

Novartis Europharm Limited; Tuberous Sclerosis Complex (TSC) / Treatment of refractory epilepsy associated with tuberous sclerosis complex (TSC)

Day 60 opinion

Action: For adoption

Uro-nephrology / Neurology

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. KEOC liquid extract ethanolic 30 per cent (w/w) of Allium cepa L. (fresh bulb) and Citrus lemon (L.) Burm. (fresh fruit), Paullinia cupana Kunth, Theobroma cacao L. - EMEA-001835-PIP01-15

Treatment of alopecia

Day 90 discussion

Action: For discussion

Dermatology

3.1.2. A derivative of (2S,3S,4R)-3-ethyl-4-hydroxypyrrolidine-2-carboxylic acid / A derivative of (S)-methyl (2-(2-(1H-imidazol-2-yl)pyrrolidin-1-yl)-2-oxoethyl)carbamate / Sofosbuvir - EMEA-001822-PIP01-15

Treatment of chronic hepatitis C / Treatment of chronic Hepatitis C in adolescents and children 3 years of age and older

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.3. Anti-respiratory syncytial virus human IgG1κ monoclonal antibody (MEDI8897) - EMEA-001784-PIP01-15

Prevention of respiratory syncytial viral infections

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.4. doravirine - EMEA-001676-PIP01-14

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 90 discussion

Action: For discussion

Infectious Diseases

3.1.5. tenofovir alafenamide / emtricitabine / cobicistat / darunavir - EMEA-001825-PIP01-15

Treatment of human immunodeficiency virus type-1 (HIV-1) infection / Treatment of HIV-1 infection in adolescents aged from 12 years to <18 years, and weighing 40 kg or more

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.6. tenofovir disoproxil fumarate / lamivudine / doravirine - EMEA-001695-PIP01-14

Treatment of human immunodeficiency virus-1 (HIV-1) infection / Antiretroviral combination therapy, for the treatment of HIV-1 infection in adults and in children aged 2 to 18 years

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.7. Human recombinant IgG1 monoclonal antibody targeting fibroblast growth factor 23 (FGF23) - Orphan - EMEA-001659-PIP01-15

Ultragenyx Pharmaceutical Inc.; X-linked Hypophosphatemia

Day 90 discussion

Action: For discussion

Other

3.1.8. 5-(4-Cyclopropyl-1H-imidazol-1-yl)-2-fluoro-4-methyl-N-{6-[4-(propan-2-yl)-4H-1,2,4-triazol-3-yl]pyridin-2-yl}benzamide - EMEA-001868-PIP01-15

Treatment of Persistent Pulmonary Hypertension of the Newborn [PPHN], Treatment of Pulmonary Arterial Hypertension (PAH), Treatment of Pulmonary Veno-Occlusive Disease and Pulmonary Capillary Hemangiomatosis [PVOD/PCH] / , Treatment of PAH in pediatric patients aged 1 to <18 years of age.

Day 60 discussion

Action: For discussion

Cardiovascular Diseases

3.1.9. 2-hydroxypropyl-ß-cyclodextrin (HP-ß-CD) - Orphan - EMEA-001866-PIP01-15

Vtesse Europe Ltd; Treatment of Niemann-Pick disease, type C

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.10. 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

Alnylam UK Limited; Treatment of Haemophilia B, Treatment of Haemophilia A / ALN-AT3SC is indicated 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, ALN-AT3SC is indicated 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

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.11. 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 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.12. Recombinant human monoclonal antibody to GM-CSF (GSK3196165). - EMEA-001882-PIP01-15

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 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.13. Immunoglobulin G2, anti-(human α-calcitonin gene-related peptide/β-calcitonin gene-related peptide) (human-Mus musculus monoclonal TEV-48125 heavy chain), disulphide with human-Mus musculus monoclonal TEV-48125 light chain, dimer - EMEA-001877-PIP01-15

Migraine / Prophylaxis of headache in children aged 6 to 18 years with episodic and chronic migraine

Day 60 discussion

Action: For discussion

Neurology

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

Prevention of factor Xa inhibitor associated haemorrhage, Treatment of factor Xa inhibitor associatedhaemorrhage / (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 60 discussion

Action: For discussion

Other

3.1.15. Recombinant, CHO cell expressed, fully human IgG1, kappa light chain, monoclonal antibody - Orphan - EMEA-001864-PIP01-15

Dyax Corp.; Hereditary angioedema / Treatment of hereditary angioedema

Day 60 discussion

Action: For discussion

Other

3.1.16. Birch pollen extract (Betula verrucosa) - EMEA-001879-PIP01-15

J30.1 Allergic rhinitis due to pollen / Treatment of tree pollen allergic rhinitis and/or conjunctivitis

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.17. Ragweed pollen extract (Ambrosia artemisiifolia) - EMEA-001881-PIP01-15

Treatment of allergic rhinitis and/or conjunctivitis / treatment of ragweed pollen allergic rhinitis and/or conjunctivitis

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.18. Hydrogen Peroxide - EMEA-001884-PIP02-15

Treatment of seborrhoeic keratosis / Treatment of seborrhoeic keratosis

Day 30 discussion

Action: For discussion

Dermatology

3.1.19. tralokinumab - EMEA-001900-PIP01-15

Atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.1.20. 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 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.21. Naldemedine Tosylate - EMEA-001893-PIP01-15

Opioid-induced constipation (OIC) / Opioid-induced constipation (OIC)

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.22. 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 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.23. Expanded donor-derived allogenic T cells transduced with the retroviral vector expressing the transgenes for inducible caspase9 and the truncated CD19 selectable marker - EMEA-001869-PIP01-15

ICD-9 code 279.10 Immunodeficiency with predominant T-cell defect, unspecified / Non-malignant disorders amenable to cure by haematopoietic stem cell transplant (HSCT)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.24. Rimiducid - EMEA-001870-PIP01-15

Treatment of Graft Versus Host Disease (ICD 279.50) / Treatment of Graft Versus Host Disease (GvHD) in paediatric patients with non-malignant conditions who received BPX-501 T cell replacement

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.25. Omadacycline - EMEA-000560-PIP02-15

Infections of the skin and subcutaneous tissue

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.26. Omadacycline - EMEA-000560-PIP03-15

Bacterial pneumonia

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.27. Humanised, affinity-optimised, afucosylated immunoglobulin G1 kappa monoclonal antibody - EMEA-001911-PIP01-15

Treatment of Neuromyelitis Optica (NMO) and Neuromyelitis Optica Spectrum Disorders (NMOSD)

Day 30 discussion

Action: For discussion

Neurology

3.1.28. Humanized monoclonal calcitonin gene-related peptide neutralizing antibody (LY2951742) - EMEA-001860-PIP03-16

Prophylactic treatment of migraine headache

Day 30 discussion

Action: For discussion

Neurology

3.1.29. Levodopa - EMEA-001874-PIP01-15

Parkinson's Disease

Day 30 discussion

Action: For discussion

Neurology

3.1.30. Humanised chimeric antibody with a humanised H chain and a chimeric (mouse V-domain, human C-domain) L chain against epidermal growth factor receptor conjugated to maleimidocaproyl monomethylauristatin F - Orphan - EMEA-001732-PIP02-15

AbbVie Ltd; Treatment of high-grade glioma. / Treatment of high-grade glioma.

Day 30 discussion

Action: For discussion

Oncology

3.1.31. Sapacitabine - Orphan - EMEA-001901-PIP01-15

Cyclacel Limited; Treatment of acute myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.1.32. Angiotensin II (LJPC-501) - EMEA-001912-PIP01-15

Treatment of Catecholamine-resistant hypotension associated with distributive shock.

Day 30 discussion

Action: For discussion

Other

3.1.33. Diclofenac sodium / Capsaicin - EMEA-001861-PIP01-15

Treatment of pain

Day 30 discussion

Action: For discussion

Pain

3.1.34. Anti IL-4 and IL-13 humanized bispecific monoclonal antibody (SAR156597) - EMEA-001804-PIP02-15

Interstitial Lung Diseases

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.35. esketamine hydrochloride (2S)-2-(2-chlorophenyl)-2-(methylamino) cyclohexanone hydrochloride - EMEA-001428-PIP03-15

Major Depressive Disorder (MDD)

Day 30 discussion

Action: For discussion

Psychiatry

3.1.36. Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) - EMEA-001894-PIP01-15

Prevention of influenza

Day 30 discussion

Action: For discussion

Vaccines

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. rurioctocog alfa pegol - EMEA-C1-001296-PIP01-12-M03

Baxalta Innovations GmbH; Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.2.2. C1inhibitor (human) - EMEA-C-000568-PIP01-09-M06

NPS Pharma Holdings Limited (now part of Shire); Treatment of C1 inhibitor deficiency

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.3. Tofacitinib citrate - EMEA-C3-000576-PIP01-09-M05

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

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.4. Adalimumab - EMEA-C-000366-PIP04-12

AbbVie Ltd; Treatment of hidradenitis suppurativa

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Dermatology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. rivaroxaban - EMEA-000430-PIP01-08-M09

Bayer Pharma AG; Treatment of thromboembolic events, Prevention of thromboembolic events / , Treatment (secondary prevention) of venous thromboembolism

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. Tadalafil - EMEA-000452-PIP02-10-M04

Eli Lilly and Company Ltd; Pulmonary arterial hypertension (already approved in adults) / Treatment of Persistent Pulmonary Hypertension of the Newborn, Treatment of Pulmonary Arterial Hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.3. vorapaxar sulfate - EMEA-000778-PIP02-12-M01

Merck Sharp & Dohme (Europe), Inc.; Prevention of Thromboembolism / Prevention of thromboemboloc events in paediatric patients

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.4. exenatide - EMEA-000689-PIP01-09-M06

AstraZeneca AB; Non insulin dependant diabetes mellitus (treatment including thiazolidinediones), Non insulin dependant diabetes mellitus (excluding treatment with thiazolidinediones) / Treatment of type 2 Diabetes Mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. Lixisenatide - EMEA-000916-PIP01-10-M05

sanofi-aventis R&D; Type 2 diabetes mellitus / Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. sitagliptin phosphate - EMEA-000471-PIP01-08-M02

Merck Sharp and Dohme (Europe), Inc.; Type 2 diabetes mellitus / Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.7. sitagliptin phosphate - EMEA-000472-PIP01-08-M02

Merck Sharp and Dohme (Europe), Inc.; Type 2 diabetes mellitus / Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.8. Denosumab - EMEA-000145-PIP01-07-M08

Amgen Europe B.V.; Prevention of skeletal related events in patients with bone metastases, Treatment of hypercalcaemia of malignancy, Treatment of bone loss associated with sex hormone ablative therapy, Treatment of giant cell tumour of bone / Treatment of giant cell tumour of bone in children (12-17 years old), None (i.e. product-specific waiver across all paediatric subsets already granted by the EMA for this condition), None (i.e. product-specific waiver across all paediatric subsets is being proposed for this indication)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Endocrinology-Gynaecology-Fertility-Metabolism / Oncology

3.3.9. solithromycin - EMEA-001581-PIP01-13-M02

Triskel EU Services, Ltd; Treatment of community acquired pneumoniae, Treatment of

infection by Francisella tularaensis (tularaemia), Treatment of infection by Bacillus anthracis (anthrax) / Treatment of community acquired pneumoniae, Treatment of inhalation tularaemia following exposure to Francisella tularaensis, Treatment of inhalation anthrax following exposure to Bacillus anthracis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.10. ataluren - Orphan - EMEA-000115-PIP01-07-M07

PTC Therapeutics International Limited; Treatment of dystrophinopathy ICD-10: G71.0 Muscular dystrophy [of Duchenne and Becker] / Treatment of nonsense-mutation dystrophinopathy

Day 30 discussion

Action: For discussion

Neurology

3.3.11. Dimethyl fumarate - EMEA-000832-PIP01-10-M03

Biogen Idec Ltd; Multiple Sclerosis / Treatment of relapsing remitting forms of multiple sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.3.12. Perampanel - EMEA-000467-PIP01-08-M07

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

3.3.13. Pitolisant - Orphan - EMEA-001176-PIP01-11-M02

BIOPROJET PHARMA; Narcolepsy / Treatment of narcolepsy with or without cataplexy

Day 30 discussion

Action: For discussion

Neurology

3.3.14. Cabozantinib - Orphan - EMEA-001143-PIP01-11-M01

Exelixis Inc; Cancer

Day 30 discussion

Action: For discussion

Oncology

3.3.15. Selumetinib - EMEA-001585-PIP01-13-M01

AstraZeneca AB; Treatment of Neurofibromatosis-Type 1, Treatment of Thyroid cancer, Treatment of lung carcinoma / , Selumetinib is indicated for the treatment of inoperable NF1 related plexiform neurofibroma in children and adolescents, Selumetinib in combination with adjuvant radioactive iodine therapy is indicated for the treatment of adolescents newly diagnosed with differentiated thyroid cancer who are at high risk of primary treatment failure.

Day 30 discussion

Action: For discussion

Oncology

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 May 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

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. Duvelisib - EMEA-54-2015

Treatment of chronic lymphocytic leukaemia/ treatment of adult patients with chronic lymphocytic leukaemia who have received at least one prior treatment

Action: For adoption

6.1.2. Duvelisib - EMEA-55-2015

Treatment of follicular lymphoma/ treatment of adult patients with follicular lymphoma who have received at least two prior treatments

Action: For adoption

6.1.3. Mesmulogene ancovacivec - EMEA-56-2015

Treatment of lung carcinoma (small cell and non-small cell carcinoma)/ Treatment of advanced non-squamous non-small cell lung cancer

Action: For adoption

6.1.4. Crenezumab - EMEA-57-2015

Treatment of Alzheimer's Disease/ Treatment of prodromal Alzheimer's Disease to mild dementia of the Alzheimer's type

Action: For adoption

6.1.5. In vitro transcribed (IVT) ribonucleic acid (RNA)-electroporated and cultured autologous mature dendritic cells (DCs) - EMEA-01-2016

Treatment of kidney and renal pelvis carcinoma (excluding nephroblastoma, nephroblastomatosis, clear cell sarcoma, mesoblastic nephroma, renal medullary carcinoma and rhabdoid tumour of the kidney) - All medicines for treatment of kidney and renal pelvis carcinoma/ Treatment of advanced renal cell carcinoma

Action: For adoption

6.1.6. Pegpleranib - EMEA-02-2016

All classes of medicinal products for treatment of age-related macular degeneration and diabetic macular oedema/ Treatment of neovascular age related macular degeneration

(nAMD) in combination with anti-VEGF agents

Action: For adoption

6.1.7. Masitinib - EMEA-03-2016

Treatment of amyotrophic lateral sclerosis/ Treatment of amyotrophic lateral sclerosis

Action: For adoption

6.1.8. Paracetamol - EMEA-04-2016

Treatment of primary and secondary osteoarthrosis/ Relief of pain associated with osteoarthritis

Action: For adoption

6.1.9. Plitidepsin - EMEA-05-2016

Treatment of multiple myeloma/ Plitidepsin in combination with dexamethasone, is indicated in adults for the treatment of relapsed/refractory multiple myeloma who have received at least three prior regimens including bortezomib, and either lenalidomide or thalidomide

Action: For adoption

6.1.10. Recombinant human anti-human VEGF-A and anti-human Ang-2 mAb (RO6867461) - EMEA-06-2016

All classes of medicinal products for treatment of age-related macular degeneration and diabetic macular oedema/ Treatment of diabetic macular edema

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

8.1.1. (S)-Isopropyl 2-((S)-(((2R,3R,4R,5R)-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl)-4-fluoro-3-hydroxy-4-methyltetrahydrofuran-2-yl)methoxy)(phenoxy)phosphorylamino)-Propanoate (GS-7977) - EMEA-001276-PIP01-12-M01

Gilead Sciences International Ltd.

Difficulties progressing the PIP? No

Action: For information

8.1.2. 3-[[[6-Deoxy-4-O-(3,5-dichloro-2-ethyl-4,6-dihydroxybenzoyl)-2-O-methyl-β-D-mannopyranosyl]oxy]-methyl]-12(R)-[[6-deoxy-5-C-methyl-4-O-(2-methyl-1-oxopropyl)-β-D-l lyxo-hexopyranosyl]oxy]-11(S)-ethyl-8(S)-hydroxy-18(S)-(1(R)-hydroxyethyl)-9,13,15-trimethyloxacyclooctadeca-3,5,9,13,15-pentene-2-one - EMEA-00636-PIP01-09-M03

Astellas Pharma Europe B.V.

Difficulties progressing the PIP? Yes

Action: For information

8.1.3. Aciclovir - EMEA-001066-PIP02-11-M01

BioAlliance Pharma

Difficulties progressing the PIP? No

Action: For information

8.1.4. AGOMELATINE - EMEA-001181-PIP-11- M02

Les Laboratoires Servier

Difficulties progressing the PIP? Yes

Action: For information

8.1.5. Apremilast - EMEA-000715-PIP03-11-M03

Celgene Europe Limited

Difficulties progressing the PIP? No

Action: For information

8.1.6. Apremilast - EMEA-000715/PIP02-11-M02

Celgene Europe Limited

Difficulties progressing the PIP? No

Action: For information

8.1.7. apremilast - Orphan - EMEA-000715/PIP05-13

Celgene Europe Limited

Difficulties progressing the PIP? No

Action: For information

8.1.8. corifollitropin alfa - EMEA-000306-PIP01-08-M02

N.V. Organon

Difficulties progressing the PIP? Yes

Action: For information

8.1.9. Dimethyl fumarate - EMEA-000832-PIP01-10

Biogen Idec Ltd.

Difficulties progressing the PIP? Yes

Action: For information

8.1.10. Eliglustat (tartrate) - Orphan - EMEA-000461-PIP02-11

Genzyme Europe B.V.

Difficulties progressing the PIP? No

Action: For information

8.1.11. N.meningitidis Outer Membrane Vesicles (OMV) from NZ 98/254 strain / N.meningitidis936-741 purified antigen / N.meningitidis 961c purified antigen / N.meningitidis 287-953 purified antigen - EMEA-00139-PIP01-07

Novartis Vaccines and Diagnostics S.r.l.

Difficulties progressing the PIP? No

Action: For information

8.1.12. Nanoparticle albumin-bound paclitaxel - Orphan - EMEA-001308-PIP01-12

Celgene Europe Limited

Difficulties progressing the PIP? No

Action: For information

8.1.13. Natalizumab - 001095-PIP02-12

Biogen Idec Limited

Difficulties progressing the PIP? No

Action: For information

8.1.14. pegylated human interferon beta-1a - EMEA-001129-PIP01-11-M01

Biogen Idec Ltd.

Difficulties progressing the PIP? No

Action: For information

8.1.15. Potassium sulphate / Magnesium sulphate, heptahydrate / Sodium sulphate, anhydrous - EMEA-000816-PIP02-10

Ipsen Pharma

Difficulties progressing the PIP? Yes

Action: For information

8.1.16. Recombinant human monoclonal antibody to human interleukin-17A of the IgG1/kappa-class (secukinumab) - EMEA-000380-PIP01-08-M03

Novartis Europharm Ltd

Difficulties progressing the PIP? No

Action: For information

8.1.17. Recombinant human monoclonal antibody to human interleukin-17A of the IgG1/kappa-class (secukinumab) - Orphan - EMEA-000380-PIP02-09-M02

Novartis Europharm Limited

Difficulties progressing the PIP? No

Action: For information

8.1.18. Romiplostim - Orphan - EMEA-000653-PIP01-09-M04

Amgen Europe B.V

Difficulties progressing the PIP? Yes

Action: For information

8.1.19. rufinamide - Orphan - EMEA-000709-PIP01-09-M03

Eisai Ltd.

Difficulties progressing the PIP? No

Action: For information

8.1.20. Sodium (4R,9aS)-5-Hydroxy-4-methyl-6,10-dioxo-3,4,6,9,9a,10-hexahydro-2H-1-oxa-4a,8a-diaza-anthracene-7-carboxylic acid 2,4-difluoro-benzylamide - EMEA-000409-PIP01-08-M03

GlaxoSmithKline Trading Services Ltd.

Difficulties progressing the PIP? No

Action: For information

8.1.21. Tenofovir disoproxil (as fumarate) - EMEA-000533-PIP01-08-M06

Gilead Sciences International Limited

Difficulties progressing the PIP? No

Action: For information

8.1.22. ustekinumab - EMEA-000311-PIP01-08

Janssen-Cilag International NV

Difficulties progressing the PIP? No

Action: For information

8.1.23. ustekinumab - EMEA-000311-PIP04-13

Janssen-Cilag International NV

Difficulties progressing the PIP? No

Action: For information

8.1.24. vorapaxar - EMEA-000778-PIP02-12

Merck Sharp & Dohme (Europe), Inc

Difficulties progressing the PIP? No

Action: For information

8.1.25. zanamivir - EMEA-001318-PIP01-12-M01

GlaxoSmithKline Trading Services Limited

Difficulties progressing the PIP? No

Action: For information

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. Follow-up actions - PDCO members training 26 January 2016

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

9.3. 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

9.4. Cooperation within the EU regulatory network

9.4.1. The Innovative Medicines Initiative (IMI) Workshop on Paediatric Clinical trials to be held on 5 April 2016 in Brussels, Belgium

PDCO Chair: Dirk Mentzer

Action: For information

9.5. Cooperation with International Regulators

9.5.1. Draft Programme of EMA Extrapolation Workshop

Action: For information

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

None

9.7. PDCO work plan

None

9.8. Planning and reporting

9.8.1. Report on the 'Data Gathering Initiative'

Action: For information

9.9. PDCO ORGAM

9.9.1. PDCO ORGAM Draft Minutes for 17 February 2016

Action: For adoption

10. Any other business

10.1. None.

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

11.1.3. Inventory

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

11.1.4. 10-Year Report Drafting Group

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

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/