



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 January 2016
EMA/PDCO/12664/2016
Procedure Management and Committees Support Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 27-29 January 2016

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

27 January 2016, 08:30- 19:00, room 3A

28 January 2016, 08:30- 19:00, room 3A

29 January 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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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 27-29 January 2016. See January 2016 PDCO minutes (to be published post February 2016 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 27-29 January 2016.

1.3. Adoption of the minutes

PDCO minutes for 9-11 December 2015.

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. Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) - EMEA-001830-PIP01-15

Prevention of influenza / Prophylaxis of influenza caused by Pandemic strain (as example A(H5N1v) is used)

Day 60 opinion

Action: For adoption

Vaccines

2.1.2. Tetracaine hydrochloride / Oxymetazoline hydrochloride - EMEA-001764-PIP03-15

Anesthesia

Day 60 opinion

Action: For adoption

Anaesthesiology

2.1.3. Levamisole (as Levamisole Hydrochloride) - Orphan - EMEA-001885-PIP01-15

ACE Pharmaceuticals BV; Glomerulonephritis and Nephrotic syndrome / Treatment of steroid sensitive nephrotic syndrome

Day 60 opinion

Action: For adoption

Uro-nephrology

2.1.4. EMEA-001749-PIP01-15

Atopic Dermatitis / Treatment of atopic dermatitis in children (3 months of age and older) and adults

Day 120 opinion

Action: For adoption; Oral Explanation Meeting to be held on 27 January 2016, 14:00-15:00

Dermatology

2.1.5. Sulfamethoxazole (CAS#: 723-46-6) / Miconazole (CAS#: 22916-47-8) / Azithromycin [monohydrate (CAS#: 121470-24-4) / dihydrate (CAS#: 117772-70-0)] - EMEA-001769-PIP01-15

Second-Degree Burns / Burn of second degree of ankle and foot, Burn of second degree of trunk, Burn of second degree of wrist and hand, Burn of second degree of hip and lower limb, except ankle and foot, Burn of second degree of shoulder and upper limb, except wrist and hand

Day 120 opinion

Action: For adoption

Dermatology

2.1.6. exenatide - EMEA-001755-PIP01-15

Treatment of type 2 diabetes mellitus / Treatment of type 2 diabetes mellitus in patients from 10 to less than 18 years old

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.7. romosozumab - EMEA-001075-PIP04-15

Treatment of osteoporosis / Treatment of osteogenesis imperfecta, Treatment of glucocorticoid induced osteoporosis

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.8. [Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with lentiviral vector that encodes for the human Wiskott Aldrich Syndrome \(WAS\) cDNA sequence - Orphan - EMEA-001792-PIP01-15](#)

GlaxoSmithKline Trading Services Limited; Wiskott Aldrich Syndrome / Treatment of Wiskott Aldrich Syndrome

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.9. [Eculizumab - Orphan - EMEA-000876-PIP05-15](#)

Alexion Europe SAS; Treatment of Myasthenia Gravis / Treatment of Refractory Generalised Myasthenia Gravis

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.10. [guselkumab - EMEA-001523-PIP02-14](#)

Treatment of psoriasis / Treatment of severe plaque psoriasis in children ≥ 6 to < 18 years of age who cannot be adequately controlled with topical agents and/or phototherapy

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.11. [Human normal immunoglobulin - EMEA-001797-PIP01-15](#)

Primary Immunodeficiency Diseases

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.12. [EMEA-001758-PIP01-15](#)

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

infection / The treatment of respiratory syncytial virus infection

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.13. Arimoclomol citrate - Orphan - EMEA-001748-PIP01-15

Orphazyme ApS; Treatment of Niemann-Pick Disease, Type C / Treatment of Niemann-Pick Disease, Type C

Day 120 opinion

Action: For adoption

Neurology

2.1.14. biotin - EMEA-001712-PIP02-15

Multiple sclerosis (MS)

Day 120 opinion

Action: For adoption

Neurology

2.1.15. binimetinib - EMEA-001454-PIP03-15

Treatment of Melanoma / Binimetinib in combination with encorafenib is indicated for the treatment of patients aged 12 years and older with unresectable or metastatic melanoma harboring BRAF V600 mutations.

Day 120 opinion

Action: For adoption

Oncology

2.1.16. encorafenib - EMEA-001588-PIP01-13

Treatment of Melanoma / Encorafenib in combination with binimetinib is indicated for the treatment of patients aged 12 years and older with unresectable or metastatic melanoma harboring BRAF V600 mutations.

Day 120 opinion

Action: For adoption

Oncology

2.1.17. nivolumab - EMEA-001407-PIP02-15

Treatment of malignant neoplasms of lymphoid tissue, Treatment of malignant neoplasms of the central nervous system / Treatment of paediatric patients with recurrent or progressive high grade primary central nervous system tumours in the age group from 6 months to < 18 years., Treatment of paediatric patients with relapsed or refractory Hodgkin lymphoma in the age group from 5 years to < 18 years.

Day 120 opinion

Action: For adoption

Oncology

2.1.18. Gemtuzumab linked to Ozogamicin - Orphan - EMEA-001733-PIP02-15

Pfizer Limited; Treatment of Acute Myeloid Leukaemia / indicated in combination with liposomal daunorubin/cytarabine or mitoxantrone/cytarabine paediatric induction regimens for the treatment of de novo and secondary Acute Myeloid Leukaemia in children aged 28 days up to 18 years.

Day 120 opinion

Action: For adoption

Oncology / Haematology-Hemostaseology

2.1.19. Rolapitant - EMEA-001768-PIP02-15

Prevention of chemotherapy induced nausea and vomiting

Day 120 opinion

Action: For adoption

Other

2.1.20. amlodipine / ramipril - EMEA-001871-PIP01-15

Treatment of hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.21. Omega-3-carboxylic acids - EMEA-001865-PIP01-15

Treatment of Hypertriglyceridaemia or Treatment of mixed dyslipidemia with persistent hypertriglyceridemia >200 mg/dL to reduce the risk of atherosclerotic cardiovascular disease (ACVD)

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.22. EMEA-001892-PIP01-15

Used for imaging in patients undergoing oncologic diagnostic procedures describing functions or diseases where increased expression of oestrogen receptors by specific tissues is the diagnostic target

Day 60 opinion

Action: For adoption

Diagnostic

2.1.23. Humanised IgG4 monoclonal antibody against extracellular tau - Orphan - EMEA-001867-PIP01-15

Bristol-Myers Squibb International Corporation; Treatment of progressive supranuclear palsy

Day 60 opinion

Action: For adoption

Neurology

2.1.24. recombinant human monoclonal antibody against growth differentiation factor 8 - EMEA-001859-PIP02-15

sporadic inclusion body myositis

Day 60 opinion

Action: For adoption

Neurology

2.1.25. Testosterone - EMEA-001873-PIP01-15

Treatment of dry eye disease

Day 60 opinion

Action: For adoption

Ophthalmology

2.1.26. Glycopyrronium bromide / Formoterol fumarate dihydrate / Beclometasone dipropionate - EMEA-001875-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. [velaglucerase alfa - EMEA-C-000556-PIP01-09-M02](#)

Shire Pharmaceuticals Ireland Limited; Treatment of Gaucher Disease, Types 1 and 3

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.2.2. [Ozenoxacin - EMEA-C-000981-PIP01-10-M04](#)

Ferrer Internacional, S.A.; Treatment of impetigo

Day 60 opinion

Action: For adoption

Infectious Diseases

2.2.3. [Everolimus - EMEA-C-000019-PIP02-07-M05](#)

Novartis Europharm Limited; Subependymal Giant Cell Astrocytoma

Day 30 opinion

Action: For adoption

Neurology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. [recombinant 10 kD culture filtrate protein / Recombinant dimer of 6 kD early secretory antigenic target - EMEA-001156-PIP01-11-M06](#)

Statens Serum Institut; Diagnosis of tuberculosis / To diagnose individuals suspected to be infected with Mycobacterium tuberculosis from 28 days of age

Day 60 opinion

Action: For adoption

2.3.2. Evolocumab - EMEA-001268-PIP01-12-M02

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 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.3. macitentan - Orphan - EMEA-001032-PIP01-10-M02

Actelion Registration Ltd.; Treatment of Idiopathic Pulmonary Fibrosis, Treatment of Pulmonary Arterial Hypertension, Treatment of Systemic Sclerosis / N.A., Treatment of Pulmonary Arterial Hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.4. dabigatran etexilate mesilate - EMEA-000081-PIP01-07-M08

Boehringer Ingelheim International GmbH; Treatment of thromboembolic events, Prevention of thromboembolic events / Treatment of venous thromboembolic events in paediatric patients (secondary venous thrombotic event prevention)

Day 60 opinion

Action: For adoption

Cardiovascular Diseases / Haematology-Hemostaseology

2.3.5. dupilumab - EMEA-001501-PIP01-13-M02

Regeneron Pharmaceuticals, Inc; Atopic Dermatitis / Atopic Dermatitis

Day 60 opinion

Action: For adoption

Dermatology

2.3.6. Bupropion Hydrochloride / Naltrexone Hydrochloride - EMEA-001373-PIP01-12-M01

Orexigen Therapeutics Ireland Limited; Treatment of obesity / Treatment of obesity

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.7. Dapagliflozin - EMEA-000694-PIP02-14-M01

AstraZeneca AB; Type 1 Diabetes Mellitus / As an adjunct to insulin treatment to improve glycaemic control in adults with type 1 diabetes mellitus when insulin alone does not provide adequate control

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.8. denosumab - EMEA-000145-PIP02-12-M01

Amgen Europe B.V.; Treatment of Osteoporosis / Treatment of osteogenesis imperfecta, Treatment of glucocorticoid induced osteoporosis

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.9. saxagliptin - EMEA-000200-PIP01-08-M06

AstraZeneca AB; E11 Type 2 Diabetes / Treatment of Type 2 Diabetes

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.10. Tolvaptan - EMEA-001231-PIP02-13-M02

Otsuka Pharmaceutical Europe Ltd.; Polycystic Kidney Disease (PKD), Dilutional hyponatraemia / Treatment of chronic (>48 hours) dilutional hyponatraemia resistant to fluid restriction (i.e., euvoletic and hypervolemic hyponatremia) associated with heart failure, cirrhosis or SIADH., Treatment of progression of ADPKD, Treatment of progression of ARPKD

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.11. ferric maltol - EMEA-001195-PIP01-11-M01

Iron Therapeutics (UK) Ltd.; Iron deficiency anaemia (IDA) / Treatment of Iron deficiency anaemia (IDA)

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.12. [Trenonacog alfa \(Coagulation Factor IX \(Recombinant\)\) - EMEA-000661-PIP01-09-M07](#)

Cangene Europe Limited; Hereditary Factor IX Deficiency (Haemophilia B) / Replacement therapy or prophylaxis in patients with hereditary Factor IX Deficiency/ Haemophilia B

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.13. [rituximab - EMEA-000308-PIP02-11-M01](#)

Roche Registration Limited; Granulomatosis with polyangiitis (Wegener's) and microscopic polyangiitis; ANCA associated vasculidities / Treatment of granulomatosis with polyangiitis (Wegener's), Treatment of microscopic polyangiitis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.14. [Aztreonam - Orphan - EMEA-000827-PIP01-09-M04](#)

Gilead Sciences International Limited; E84.0 Cystic Fibrosis with pulmonary manifestations / Treatment of initial Pseudomonas aeruginosa pulmonary infection/ colonisation in patients with Cystic Fibrosis., Treatment of chronic Pseudomonas aeruginosa pulmonary infection/ colonisation in patients with Cystic Fibrosis.

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.15. [dalbavancin - EMEA-000016-PIP01-07-M05](#)

Durata Therapeutics International B.V; skin and soft tissue skin infections

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.16. Meropenem - EMEA-000898-PIP01-10-M02

NeoMero Consortium; Bacterial sepsis, Bacterial meningitis / Treatment of bacterial meningitis in neonates and infants below 3 months of age, Treatment of bacterial sepsis in neonates and infants below 3 months of age

Day 60 opinion

Action: For adoption

Neonatology - Paediatric Intensive Care / Infectious Diseases

2.3.17. Rufinamide - Orphan - EMEA-000709-PIP01-09-M04

Eisai Limited; Lennox-Gastaut Syndrome

Day 60 opinion

Action: For adoption

Neurology

2.3.18. Tasimelteon - Orphan - EMEA-001531-PIP01-13-M02

Vanda Pharmaceuticals Ltd.; ICD9 - 327.34 Circadian rhythm sleep disorder, free-running type / Non-24-Hour Sleep-Wake Disorder (Non-24) in the totally blind

Day 60 opinion

Action: For adoption

Neurology

2.3.19. midostaurin - Orphan - EMEA-000780-PIP01-09-M02

Novartis Europharm Ltd; C92.0 Acute myeloid leukaemia, C94.3 Mast cell leukaemia, C96.2 Malignant mastocytosis / Treatment of paediatric patients with FLT3 mutated AML, newly diagnosed or in first relapse, A waiver is in place for this condition.

Day 60 opinion

Action: For adoption

Oncology

2.3.20. pazopanib - EMEA-000601-PIP01-09-M03

Novartis Europharm Limited; Ewing sarcoma family of tumours, Rhabdomyosarcoma, Non-rhabdomyosarcoma soft tissue sarcoma / Treatment of pediatric patients with rhabdomyosarcoma, Treatment of pediatric patients with Ewing sarcoma family of tumours, Treatment of pediatric patients with non-rhabdomyosarcoma soft tissue sarcoma

Day 60 opinion

Action: For adoption

Oncology / Uro-nephrology

2.3.21. Human Thrombin / Human Fibrinogen - EMEA-001149-PIP01-11-M03

Omrix Biopharmaceuticals N.V.; Treatment of cerebrospinal fluid leakage resulting from a surgical procedure., Treatment of haemorrhage resulting from a surgical procedure. / indicated for suture line sealing in dura mater closure, indicated for supportive treatment in surgery where standard surgical techniques are insufficient, for improvement of haemostasis. indicated for supportive treatment in surgery where standard surgical techniques are insufficient, for improvement of haemostasis.

Day 60 opinion

Action: For adoption

Other

2.3.22. zoledronic acid - EMEA-000057-PIP01-07-M06

Novartis Europharm Limited; Osteoporosis / Glucocorticoid-induced osteoporosis

Day 60 opinion

Action: For adoption

Other

2.3.23. Tapentadol - EMEA-000325-PIP01-08-M04

Grünenthal GmbH; Chronic pain / Treatment of chronic pain

Day 60 opinion

Action: For adoption

Pain

2.3.24. Tapentadol - EMEA-000485-PIP01-08-M04

Grünenthal GmbH; Chronic pain / Treatment of chronic pain

Day 60 opinion

Action: For adoption

Pain

2.3.25. Tapentadol - EMEA-000486-PIP01-08-M04

Grünenthal GmbH; Chronic pain / Treatment of chronic pain

Day 60 opinion

Action: For adoption

Pain

2.3.26. naloxone hydrochloride - EMEA-001567-PIP01-13-M02

Develco Pharma GmbH; Opioid-induced constipation / Treatment of opioid-induced constipation

Day 60 opinion

Action: For adoption

Pain / Gastroenterology-Hepatology

2.3.27. Basmisanil - EMEA-001506-PIP02-14-M01

Roche Registration Ltd; Treatment of Down syndrome / Treatment of intellectual disability associated with Down syndrome

Day 60 opinion

Action: For adoption

Psychiatry

2.3.28. Cariprazine hydrochloride - EMEA-001652-PIP01-14-M01

Gedeon Richter Plc.; F20 Schizophrenia

Day 60 opinion

Action: For adoption

Psychiatry

2.3.29. Etelcalcetide - EMEA-001554-PIP01-13-M01

Amgen Europe B.V.; Hyperparathyroid disorders / Hyperparathyroidism Secondary

Day 60 opinion

Action: For adoption

Uro-nephrology

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. certolizumab pegol - EMEA-001071-PIP03-14

Treatment of psoriasis / treatment of severe chronic plaque psoriasis

Day 90 discussion

Action: For discussion

Dermatology

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

Treatment of Fabry disease

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

Treatment of primary immunodeficiency

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

Pfizer Limited; Duchenne Muscular Dystrophy

Day 90 discussion

Action: For discussion

Neurology

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

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

Day 90 discussion

Action: For discussion

Oto-rhino-laryngology

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

ICD10: R52 Pain, unspecified

Day 90 discussion

Action: For discussion

Pain

3.1.7. Ularitide acetate - EMEA-001863-PIP01-15

Treatment of acute heart failure

Day 60 discussion

Action: For discussion

Cardiovascular Diseases

3.1.8. White soft paraffin / Liquid paraffin - EMEA-001789-PIP02-15

Prevention of atopic dermatitis / Prevention of atopic dermatitis in neonates and infants at risk to develop the disease

Day 60 discussion

Action: For discussion

Dermatology

3.1.9. Recombinant Fusion Protein Linking Coagulation Factor VIIa with Albumin - Orphan - EMEA-001886-PIP01-15

CSL Behring GmbH; Treatment of congenital Haemophilia A or B

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.10. Recombinant Fusion Protein Linking Coagulation Factor VIIa with Albumin - Orphan - EMEA-001886-PIP02-15

CSL Behring GmbH; Treatment of congenital Factor VII Deficiency

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.11. Bivalent anti-human myostatin adnectin recombinant human IgG1-Fc fusion protein - EMEA-001793-PIP01-15

Treatment of Duchenne Muscular Dystrophy / Treatment of Duchenne Muscular Dystrophy in patients aged ≥ 6 months to < 18 years

Day 60 discussion

Action: For discussion

Neurology

3.1.12. copanlisib - EMEA-001757-PIP02-15

Treatment of all conditions included in the category of malignant neoplasms (except hematopoietic and lymphoid tissue), Treatment of mature B-cell neoplasms / Treatment of children with neuroblastoma, Ewing's sarcoma, osteosarcoma or rhabdomyosarcoma who failed one or more prior lines of therapy.

Day 60 discussion

Action: For discussion

Oncology

3.1.13. Carfilzomib - Orphan - EMEA-001806-PIP02-15

Amgen Europe B.V.; Treatment of acute lymphoblastic leukemia / Treatment of paediatric patients (≥ 28 days to ≤ 18 years of age, and young adults ≤ 21 years at the time of their initial diagnosis) with early first relapse (< 36 months from initial diagnosis), multiple relapses, or refractory ALL, with or without extramedullary disease.

Day 60 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.1.14. bempedoic acid - EMEA-001872-PIP01-15

Primary Hypercholesterolemia / Treatment of heterozygous familial hypercholesterolaemia

Day 60 discussion

Action: For discussion

Other / Cardiovascular Diseases

3.1.15. 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 Hemangiomas [PVOD/PCH] / , Treatment of PAH in pediatric patients aged 1 to <18 years of age.

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.16. Finasteride - EMEA-001878-PIP01-15

Treatment of androgenetic alopecia

Day 30 discussion

Action: For discussion

Dermatology

3.1.17. 2-hydroxypropyl- β -cyclodextrin - Orphan - EMEA-001866-PIP01-15

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

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.18. 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 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases

3.1.19. 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 / 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 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.20. 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 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.21. Recombinant human monoclonal antibody to GM-CSF - 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 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.22. Immunoglobulin G2, anti-(human α -calcitonin gene-related peptide/ β -calcitonin gene-related peptide) - EMEA-001877-PIP01-15

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

Day 30 discussion

Action: For discussion

Neurology

3.1.23. acalabrutinib - EMEA-001796-PIP02-15

Treatment of lymphoplasmacytic lymphoma, Treatment of mantle cell lymphoma

Day 30 discussion

Action: For discussion

Oncology

3.1.24. pidilizumab - EMEA-001891-PIP01-15

Treatment of Diffuse Large B-Cell Lymphoma

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.1.25. 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 30 discussion

Action: For discussion

Other

3.1.26. Gallium68 chloride - 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 30 discussion

Action: For discussion

Other

3.1.27. 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 30 discussion

Action: For discussion

Other

3.1.28. 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 30 discussion

Action: For discussion

Pneumology - Allergology

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

Treatment of asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.30. 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 30 discussion

Action: For discussion

Pneumology - Allergology

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

Novartis Europharm Ltd.; Treatment of hyperimmunoglobulin D syndrome

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

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

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.3. Human normal immunoglobulin - EMEA-C-000830-PIP02-10-M02

Bio Products Laboratory Limited; Treatment of idiopathic thrombocytopenic purpura as model for immunomodulation

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology

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

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

Day 30 discussion

Action: For discussion

Neurology

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

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

Day 30 discussion

Action: For discussion

Oncology

3.2.6. mirabegron - EMEA-C1-000597-PIP02-10-M04

Astellas Pharma Europe B.V.; Treatment of Idiopathic overactive bladder

Day 30 discussion

Action: For discussion

Uro-nephrology

3.2.7. mirabegron - EMEA-C1-000597-PIP03-15-M01

Astellas Pharma Europe B.V.; Treatment of neurogenic detrusor overactivity

Day 30 discussion

Action: For discussion

Uro-nephrology

3.2.8. 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 30 discussion

Action: For discussion

Vaccines

3.2.9. 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 30 discussion

Action: For discussion

Vaccines

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

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

uniQure biopharma B.V.; Hyperchylomicronaemia / 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 30 discussion

Action: For discussion

Cardiovascular Diseases

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

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

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.3. 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 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. 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 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. 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 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.6. 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 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.7. 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 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

AbbVie Limited; Non-infectious uveitis

Day 30 discussion

Action: For discussion

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

3.3.9. 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 30 discussion

Action: For discussion

Infectious Diseases

3.3.10. 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 30 discussion

Action: For discussion

Infectious Diseases

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

Roche Registration Limited; Spinal Muscular Atrophy

Day 30 discussion

Action: For discussion

Neurology

3.3.12. Talimogene laherparepvec / Talimogene laherparepvec - EMEA-001251-PIP01-11-M01

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

Day 30 discussion

Action: For discussion

Oncology

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

Grünenthal GmbH; Acute pain / Treatment of acute pain

Day 30 discussion

Action: For discussion

Pain

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

Grünenthal GmbH; Acute pain / Treatment of acute pain

Day 30 discussion

Action: For discussion

Pain

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

Grünenthal GmbH; Acute pain / Treatment of acute pain

Day 30 discussion

Action: For discussion

Pain

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

NOVARTIS EUROPHARM LTD.; Treatment of asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.17. [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 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.18. [Loxapine - EMEA-001115-PIP01-10-M04](#)

Ferrer Internacional, S.A.; Bipolar Disorder, Schizophrenia / For rapid control of agitation in patients with schizopherenia, For rapid control of agitation in patients with schizophrenia

Day 30 discussion

Action: For discussion

Psychiatry

3.3.19. [potassium hydrogen carbonate / potassium citrate monohydrated - EMEA-001357-PIP01-12-M01](#)

Advicenne Pharma; Treatment of renal tubular acidosis

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3.20. [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 30 discussion

Action: For discussion

Uro-nephrology / 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 April 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. Nomination of PDCO members for 10 year report for creation of review 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. Relugolix - EMEA-52-2015

Classes of androgen receptor modulator, of oestrogen receptor modulator, of growth and sex hormone as well as their releasing or inhibiting factors, and of sex hormone metabolism modulator medicinal products for treatment of breast malignant neoplasms, prostate malignant neoplasms and neuroendocrine malignant neoplasms/ Treatment of hormone-sensitive advanced prostate cancer

Action: For adoption

6.1.2. Brolucizumab - EMEA-53-2015

Treatment of age-related macular degeneration/ Treatment of neovascular (wet) age-related macular degeneration in adults

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

7.1.1. linagliptin (base) - EMEA-000498-PIP01-08

Action: For adoption

7.1.2. linagliptin/metformin - EMEA-000699-PIP01-09

Action: For adoption

8. Annual reports on deferrals

8.1.1. Alogliptin benzoate - EMEA-000496-PIP01-08-M04

Takeda Global Research and Development Centre (Europe) Ltd.

Difficulties progressing the PIP? No

Action: For information

8.1.2. clevidipine butyrate - EMEA-000282-PIP01-08-M02

The Medicines Company

Difficulties progressing the PIP? Yes

Action: For information

8.1.3. Dextran, 3 [(2-aminoethyl)thio]propyl 17-carboxy-10,13,16-tris(carboxymethyl)-8-oxo-4-thia-7,10,13,16-tetraazaheptadec-1-yl 3-[[2-[[1-imino-2-(D-mannopyranosylthio)ethyl]amino]ethyl]thio]propyl ether - EMEA-001255-PIP01-11

Navidea Biopharmaceuticals Limited

Difficulties progressing the PIP? Yes

Action: For information

8.1.4. Lu AA21004 - EMEA-000455-PIP02-10-M03

H. Lundbeck A/S

Difficulties progressing the PIP? No

Action: For information

8.1.5. Macitentan - EMEA-001032-PIP01-10-M01

Actelion Registration Ltd

Difficulties progressing the PIP? Yes

Action: For information

8.1.6. mirabegron - EMEA-000597-PIP03-M01

Astellas Pharma Europe B.V.

Difficulties progressing the PIP? No

Action: For information

8.1.7. mirabegron - EMEA-000597-PIP02-10-M04

Astellas Pharma Europe B.V.

Difficulties progressing the PIP? No

Action: For information

8.1.8. Nonacog alfa (recombinant coagulation factor IX) - EMEA-001139-PIP01-11-M01

BAXTER Innovations GmbH

Difficulties progressing the PIP? No

Action: For information

8.1.9. raltegravir - EMEA-000279-PIP01-08-M04

Merck Sharp & Dohme (Europe), Inc.

Difficulties progressing the PIP? Yes

Action: For information

8.1.10. rilpivirine (as hydrochloride) / emtricitabine / tenofovir disoproxil (as fumarate) - EMEA-000774-PIP01-09-M02

Gilead Sciences International Limited

Difficulties progressing the PIP? No

Action: For information

8.1.11. Solifenacin (succinate) - EMEA-000573-PIP02-13-M03

Astellas Pharma Europe B.V.

Difficulties progressing the PIP? No

Action: For information

8.1.12. Ticagrelor - EMEA-000480-PIP01-08-M08

AstraZeneca AB

Difficulties progressing the PIP? Yes

Action: For information

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. Deferrals in paediatric-only development

PDCO member: Karl-Heinz Huemer

Action: For discussion

9.1.2. Procedure of assignment of PDCO expert for centralised procedures of relevance (including Art. 46 procedures)

Action: For discussion

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. Reflection paper on extrapolation of efficacy and safety in paediatric medicine development

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

9.4. Cooperation within the EU regulatory network

None

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

None

9.7. PDCO work plan

9.7.1. PDCO Work Plan 2016

Action: For adoption

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 Agenda for 13 January 2016

Action: For information

9.9.2. PDCO ORGAM Draft Minutes for 2 December 2015

Action: For adoption

10. Any other business

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 3H

11.1.4. Deferrals in paediatric-only development

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

11.1.5. Ethics

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

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/