19 July 2016
EMA/PDCO/452922/2016
Procedure Management and Committees Support Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 20-22 July 2016

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

20 July 2016, 08:30- 19:00, room 3A

21 July 2016, 08:30- 19:00, room 3A

22 July 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 20-22 July 2016. See July 2016 PDCO minutes (to be published post August 2016 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 20-22 July 2016.

1.3. Adoption of the minutes

PDCO minutes for 22-24 June 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. 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 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.2. 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 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.3. 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 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

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

Treatment of Catecholamine-resistant hypotension associated with distributive shock

Day 120 opinion

Action: For adoption

Other

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

Treatment of cartilage disorders

Day 120 opinion

Action: For adoption

Other

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

Treatment of schizophrenia / Cognitive Impairment Associated with Schizophrenia

Day 120 opinion

Action: For adoption

Psychiatry

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

Treatment of hypercholesterolaemia

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

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

Treatment of essential hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

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

Venous therapeutic procedures

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

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

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

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.11. 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 60 opinion

Action: For adoption

Cardiovascular Diseases / Haematology-Hemostaseology

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

Pregnancy / Prevention of pregnancy

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

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

Hyperuricaemia associated with gout

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.14. Allogeneic human neural stem cells genetically modified to express c-MycERTAM, a c-Myc and modified oestrogen receptor fusion protein - EMEA-001969-PIP01-16

Sequelae of cerebral infarction

Day 60 opinion

Action: For adoption

Neurology

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

No items.

2.2.1. Levamisole Hydrochloride – EMEA-C-001885-PIP01-15-M01

ACE Pharmaceuticals BV; Treatment of glomerulonephritis and nephrotic syndrome

Day 0 opinion

Action: For adoption

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. 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 60 opinion

Action: For adoption

Cardiovascular Diseases

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

Allergan Pharmaceuticals International Limited; Functional Constipation / in children

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

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

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

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

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

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

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.5. 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 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.6. 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 60 opinion

Action: For adoption

Infectious Diseases

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

Novartis Europharm Limited; Multiple Sclerosis / Multiple Sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.3.8. 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 60 opinion

Action: For adoption

Psychiatry

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

Shire Pharmaceutical Contracts Ltd; Hyperphosphataemia / No indication in the paediatric population is proposed

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. 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 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.2. 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 ≥2 years to <18 years

Day 90 discussion

Action: For discussion

Neurology

3.1.3. GIVINOSTAT - Orphan - EMEA-000551-PIP02-14

Italfarmaco S.p.A.; Duchenne Muscular Dystrophy / Improvement of symptoms and improvement of disability in DMD affected patients

Day 90 discussion

Action: For discussion

Neurology

3.1.4. copanlisib dihydrochloride - 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 90 discussion

Action: For discussion

Oncology

3.1.5. Guadecitabine - EMEA-001730-PIP02-15

Treatment of acute myeloid leukemia / Adults with Previously Untreated Acute Myeloid Leukemia (AML) Who Are Not Considered Candidates or unfit for Intensive Remission Induction Chemotherapy, Treatment of pediatric subjects age 3 months or older to less than 18 years with relapsed refractory AML after failure of intensive remission induction chemotherapy

Day 90 discussion

Action: For discussion

Oncology

3.1.6. Orphan - EMEA-001794-PIP01-15

ReveraGen BioPharma Ltd; Treatment of duchenne muscular dystrophy / Treatment of duchenne muscular dystrophy

Day 90 discussion

Action: For discussion

Other

3.1.7. 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 90 discussion

Action: For discussion

Other

3.1.8. 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 90 discussion

Action: For discussion

Pneumology - Allergology

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

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

Day 60 discussion

Action: For discussion

Dermatology

3.1.10. 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 60 discussion

Action: For discussion

Diagnostic

3.1.11. 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 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.12. Seletalisib - EMEA-001938-PIP01-16

Primary Immunodeficiency syndrome

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.13. 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 60 discussion

Action: For discussion

Infectious Diseases

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

GW Research Ltd; Treatment of Seizures

Day 60 discussion

Action: For discussion

Neurology

3.1.15. Human bone marrow-derived allogeneic mesenchymal precursor cells (MPCs) - EMEA-001827-PIP02-16

Chronic heart failure

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.16. fluoromisonidazolum (18F) - EMEA-001977-PIP02-16

Imaging of hypoxic tissue in Non-small Cell Lung Cancer (NSCLC) for diagnostic purposes, Imaging of hypoxic tissue in Renal Cell Carcinoma (RCC) for diagnostic purposes, Imaging of hypoxic tissue in Gliomas for diagnostic purposes, Imaging of hypoxic tissue in Head and Neck Squamous Cell Carcinoma (HNSCC) for diagnostic purposes

Day 30 discussion

Action: For discussion

Diagnostic / Oncology

3.1.17. Allogeneic, non-expanded, umbilical Cord blood-derived, hematopoietic mature myeloid and lymphoid cells (NF) / Allogeneic, ex vivo expanded, umbilical Cord blood-derived, hematopoietic CD34+ progenitor cells (CF) - Orphan - EMEA-001913-PIP01-15

Gamida Cell Limited; acute lymphoblastic leukaemia, myelodysplastic syndrome, acute myeloid leukaemia, chronic myeloid leukaemia / haematopoietic reconstitution of patients who are medically indicated for allogeneic haematopoietic stem cell transplantation

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.18. EMEA-001741-PIP02-16

Treatment of Ulcerative Colitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.19. Autologous CD34+ hematopoietic stem cells transduced ex vivo with EFS lentiviral vector encoding for the human ADA gene - Orphan - EMEA-001974-PIP01-16

Pr Bobby Gaspar; Severe combined immunodeficiency disorder due to adenosine deaminase deficiency [ADA-SCID] / Treatment of severe combined immunodeficiency disorder due to adenosine deaminase deficiency [ADA-SCID]

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.20. blisibimod - EMEA-001972-PIP01-16

systemic lupus erythematosus

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.21. tocilizumab - EMEA-000309-PIP03-16

Systemic Sclerosis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.22. T-lymphocytes enriched leukocyte preparation depleted ex vivo of host host-alloreactive T cells using photodynamic treatment - Orphan - EMEA-001980-PIP01-16

Kiadis Pharma Netherlands B.V.; Adjunctive treatment in haematopoietic stem cell transplantation for a malignant disease / Adjunctive treatment to a haploidentical haematopoietic stem cell transplantation with CD34+ selected cells, in patients with a haematological malignancy, for the reduction of morbidity (i.e. incidences and severity of graft versus host disease) and mortality due to infection and relapse.

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Oncology

3.1.23. EMEA-001975-PIP01-16

Treatment of influenza

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.24. Recombinant Respiratory Syncytial Virus Vaccine with adjuvant - EMEA-001966-PIP01-16

Prevention of RSV disease

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.25. EMEA-001970-PIP01-16

ICD10 code A04.7: Enterocolitis due to Clostridium difficile / indicated as a treatment, at the completion of antibiotic therapy, of paediatric patients with active recurrent Clostridium difficile infection to prevent further recurrence

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.26. lifitegrast - EMEA-001979-PIP01-16

Treatment of dry eye disease

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.27. paracetamol / ibuprofen - EMEA-002002-PIP01-16

Treatment of pain

Day 30 discussion

Action: For discussion

Pain

3.1.28. Fevipiprant - EMEA-001315-PIP02-16

Asthma / Treatment of moderate to severe asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.29. olodaterol hydrochloride - EMEA-001965-PIP01-16

Treatment of cystic fibrosis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.30. Live attenuated, chimeric dengue virus, serotype 4 / Live, attenuated, chimeric dengue virus, serotype 3 / Live, attenuated dengue virus, serotype 2 / Live, attenuated, chimeric dengue virus, serotype 1 - EMEA-001888-PIP01-15

Prevention of dengue fever

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. Pitavastatin calcium - EMEA-C-000054-PIP01-07-M04

Kowa Pharmaceutical Europe Co. Ltd.; Treatment of disorders of lipoprotein metabolism and other lipidaemias

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.2. Pitavastatin calcium - EMEA-C-000300-PIP01-08-M04

Kowa Pharmaceutical Europe Co. Ltd.; Treatment of disorders of lipoprotein metabolism and other lipidaemias

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.3. icatibant - EMEA-C-000408-PIP01-08-M05

Shire Orphan Therapies GmbH; Treatment of hereditary angioedema (HAE)

Day 30 discussion

Action: For discussion

Other

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. apixaban - EMEA-000183-PIP01-08-M04

Bristol-Myers Squibb / Pfizer EEIG; Prevention of arterial thromboembolism, Prevention of venous thromboembolism / Prevention of venous thromboembolism (VTE) in paediatric subjects (1 to <18 years old) with a newly diagnosed acute lymphoblastic leukemia (ALL) or lymphoma (T or B cell), a functioning central venous access device (CVAD) and receiving PEG L-asparaginase during chemotherapy induction., Prevention of TE in paediatric patients (birth to below 18 years old) with cardiac disease.

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. selepressin - EMEA-000506-PIP01-08-M02

Ferring Pharmaceuticals A/S; Septic shock / Vasopressor-dependent Septic Shock

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.3. Humanised monoclonal antibody IgG2 recognising the interleukin-31 receptor A (IL-31RA) - EMEA-001624-PIP01-14-M01

CHUGAI PHARMA EUROPE LTD; Atopic Dermatitis / Atopic Dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.3.4. albiglutide - EMEA-001175-PIP01-11-M04

Glaxo Group Limited; Non-insulin dependent diabetes mellitus / type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. Alogliptin benzoate (as alogliptin) - EMEA-000496-PIP01-08-M05

Takeda Development Centre Europe Ltd; Type 2 diabetes melitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. Sapropterin Dihydrochloride - Orphan - EMEA-001476-PIP01-13-M01

BioMarin International Limited; Hyperphenylalaninemia / BH4 deficiency, Phenylketonuria

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.7. eftrenonacog alfa - Orphan - EMEA-000914-PIP01-10-M03

Biogen Idec Ltd; Hereditary Factor IX Deficiency - D67

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.8. Autologous CD34+ cells transduced with lentiviral vector containing the human Wiskott Aldrich Syndrom Protein gene. - Orphan - EMEA-000786-PIP01-09-M02

Genethon; Treatment of Wiskott-Aldrich syndrome

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.9. Delamanid - Orphan - EMEA-001113-PIP01-10-M05

Otsuka Europe Development and Commercialisation Ltd.; Treatment of multi drug resistant tuberculosis / Treatment of multi drug resistant tuberculosis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.10. Elvitegravir - EMEA-000968-PIP02-11-M05

Gilead Sciences International Ltd; Human immunodeficiency virus [HIV] disease resulting in other conditions [ICD-10: B23] / Vitekta is indicated for use with a pharmacoenhancer and other antiretroviral agents for the treatment of HIV-1 infection in paediatric patients aged < 18 years.

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.11. Tedizolid phosphate - EMEA-001379-PIP01-12-M02

Merck Sharp & Dohme (Europe), Inc.; Treatment of complicated skin and soft tissue infections / Treatment of complicated skin and soft tissue infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.12. nusinersen - Orphan - EMEA-001448-PIP01-13-M02

Ionis Pharmaceuticals, Inc.; Spinal muscular atrophy

Day 30 discussion

Action: For discussion

Neurology

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

BioMarin International Limited; Neuronal Ceroid Lipofuscinosis Type 2 (NCL2) / Treatment of Neuronal Ceroid Lipofuscinosis Type 2 (NCL2)

Day 30 discussion

Action: For discussion

Neurology

3.3.14. zuretinol acetate - Orphan - EMEA-001453-PIP01-13-M01

QLT Ophthalmics (UK), Ltd.; Retinitis Pigmentosa, Leber Congenital Amaurosis / Treatment of patients with Inherited Retinal Disease who have been phenotypically diagnosed as LCA or RP caused by mutations in retinal pigment epithelium protein 65 (RPE65) or lecithin:retinol acyltransferase (LRAT) genes

Day 30 discussion

Action: For discussion

Ophthalmology

3.3.15. Human recombinant IgG1 monoclonal antibody targeting fibroblast growth factor 23 (FGF23) - Orphan - EMEA-001659-PIP01-15-M01

Ultragenyx Pharmaceutical Inc.; X-linked Hypophosphatemia

Day 30 discussion

Action: For discussion

Other

3.3.16. Human Thrombin (component 2) / Human Fibrinogen (component 1) - EMEA-001598-PIP01-13-M02

Instituto Grifols, S.A.; Treatment of haemorrhage resulting from a surgical procedure / Supportive treatment in surgery where standard surgical techniques are insufficient for improvement of haemostasis, and as a suture support in vascular surgery

Day 30 discussion

Action: For discussion

Other

3.3.17. CONCENTRATE OF PROTEOLYTIC ENZYMES ENRICHED IN BROMELAIN - Orphan - EMEA-000142-PIP02-09-M04

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

Day 30 discussion

Action: For discussion

Other / Dermatology

3.3.18. mepolizumab - Orphan - EMEA-000069-PIP02-10-M06

GSK Trading Services Limited; treatment of asthma / add-on treatment for severe refractory eosinophilic asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.19. Peanut flour - EMEA-001734-PIP01-14-M01

Aimmune Therapeutics; Peanut Allergy / Peanut oral immunotherapy for the reduction in clinical reactivity to accidental exposure in peanut allergic children and adults

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.20. Reslizumab - EMEA-001202-PIP02-13-M01

Teva Pharmaceuticals Europe; Treatment of asthma / CINQAERO is indicated as add- on treatment in adult patients with severe eosinophilic asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.21. EMEA-000431-PIP01-08-M09

Glaxo Group Limited; Mixed Asthma / Treatment of asthma where use of a combination product (long acting beta agonist and inhaled corticosteroid) is appropriate

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.22. L-Seryl-L-arginyl-L-valyl-L-leucyl-L-aspartyl-glycyl-L-leucyl-L-valyl-L-methionyl-L-threonyl-L-threonyl-L-isoleucyl-L-seryl-L-seryl-L-seryl-L-lysine, acetate salt / L-Threonyl-L-alanyl-L-methionyl-L-lysyl-L-lysyl-L-isoleucyl-L-glutaminyl-L-aspartyl-L-cysteinyl-L-tyrosyl-L-valyl-L-glutamyl-L-asparaginyl-glycyl-L-leucyl-L-isoleucine, acetate salt / L-Lysyl-L-glutamyl-L-asparaginyl-L-alanyl-L-leucyl-L-seryl-L-leucyl-L-leucyl-L-aspartyl-L-lysyl-L-isoleucyl-L-tyrosyl-L-threonyl-L-seryl-L-prolyl-L-leucine, acetate salt / L-Arginyl-L-isoleucyl-L-leucyl-L-lysyl-L-asparaginyl-L-cysteinyl-L-valyl-L-aspartyl-L-alanyl-L-lysyl-L-methionyl-L-threonyl-L-glutamyl-L-glutamyl-L-aspartyl-L-lysyl-L-glutamic acid, acetate salt / L-Lysyl-L-alanyl-L-leucyl-L-prolyl-L-valyl-L-valyl-L-leucyl-L-glutamyl-L-asparaginyl-L-alanyl-L-arginyl-L-isoleucyl-L-leucyl-L-lysyl-L-asparaginyl-L-cysteinyl-L-valine, acetate salt / L-Glutamyl-L-glutaminyl-L-valyl-L-alanyl-L-glutaminyl-L-tyrosyl-L-lysyl-L-alanyl-L-leucyl-L-prolyl-L-valyl-L-valyl-L-leucyl-L-glutamyl-L-asparaginyl-L-alanine, acetate salt / L-Cysteinyl-L-prolyl-L-alanyl-L-valyl-L-lysyl-L-arginyl-L-aspartyl-L-valyl-L-aspartyl-L-leucyl-L-phenylalanyl-L-leucyl-L-threonine, hydrochloride salt - EMEA-001054-PIP01-10-M04

Circassia Limited; Treatment of perennial allergic rhinitis / Treatment of cat allergen induced rhino-conjunctivitis in patients with clinically relevant symptoms

Day 30 discussion

Action: For discussion

Pneumology - Allergology / Oto-rhino-laryngology

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 13 September 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. Appointment of PDCO representation at EnprEMA drafting group to work for clinical trial preparedness

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. Seribantumab - EMEA-20-2016

Treatment of lung carcinoma (small cell and non-small cell carcinoma)/ Seribantumab is indicated in combination with docetaxel or pemetrexed for the treatment of patients with heregulin positive non-small cell lung cancer following prior therapy with a PD-1 or PD-L1 blocking antibody for locally advanced or metastatic disease

Action: For adoption

6.1.2. Avelumab - EMEA-21-2016

Treatment of ureter and bladder carcinoma,Treatment of kidney and renal pelvis carcinoma (excluding nephroblastoma, nephroblastomatosis, clear cell sarcoma, mesoblastic nephroma, renal medullary carcinoma and rhabdoid tumour of the kidney)/ Treatment of urothelial cancer

Action: For adoption

6.1.3. Danirixin - EMEA-22-2016

All classes of medicinal products for treatment of chronic obstructive pulmonary disease

(COPD) (excluding chronic lung diseases associated with long-term airflow limitation, such as asthma, bronchopulmonary dysplasia, primary cilia dyskinesia, obstructive lung disease related to graft-versus-host disease after [bone-marrow] transplantation)/ Maintenance treatment to relieve symptoms of COPD in adult patients

Action: For adoption

6.1.4. EMEA-23-2016

Treatment of Alzheimer's disease / slowing of disease progression in patients with early Alzheimer's disease (defined as the continuum of Mild Cognitive Impairment due to Alzheimer's disease and mild dementia of the Alzheimer's type)

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. Semaglutide - EMEA-001441-PIP01-13

Novo Nordisk A/S; Reduction of the risk of major cardiovascular adverse events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and high cardiovascular risk/ Treatment of type 2 diabetes mellitus

Action: For adoption

7.1.2. Brentuximab vedotin - EMEA-000980-PIP01-10-M04

Takeda Pharma A/S; Anaplastic large cell lymphoma to cover adult T - cell leukaemia/lymphoma, hepatosplenic T - cell lymphoma, angiocentric lymphoma, angio-immunoblastic T - cell lymphoma, T - cell lymphoma/leukaemia, intestinal T - cell lymphomas

Action: For adoption

7.1.3. Liraglutide - EMEA-000128-PIP01-07-M07

Novo Nordisk A/S; Treatment of type 2 diabetes/Prevention of major adverse cardiovascular events (MACE) in adults with type 2 diabetes mellitus and high cardiovascular risk as an adjunct to standard of care therapy.

Action: For adoption

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. Proposals for optimisation of PDCO plenary meetings

PDCO Chair: Dirk Mentzer

Action: For discussion

9.1.2. PDCO work plan 216 mid-year report and draft PDCO work plan 2017

PDCO Chair: Dirk Mentzer

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. 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. Strategic Review and Leaning Meeting to be held in Brussels on 19-21 October 2016 –registration opened

PDCO Chair: Koenraad Norga

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

9.3.3. Juvenile animal studies with anti-cancer medicines

PDCO member: Jacqueline Carleer

Action: For discussion

9.3.4. Guideline on influenza vaccines

Action: For information, guideline was adopted via written procedure on 8 July 2016

9.4. Cooperation within the EU regulatory network

9.4.1. European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA) representation at PDCO plenary meetings

Action: For information

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

10. Any other business

10.1.1. Templates for the summaries of the PDCO opinions

Action: For discussion

10.1.2. Survey to Committee members, alternates and concerned NCA staff on the service / support provided by Committee Secretariats

Action: For information

10.1.3. Training for PDCO alternate

PDCO member: Jorrit Gerritsen

Action: For information

11. Breakout sessions

11.1.1. Paediatric oncology

Action: For discussion on Thursday, 18:00 - 19:00, room 3M

11.1.2. Neonatology

Action: For discussion on Thursday, 18:00 - 19:00, room 3L

11.1.3. Paediatric inventories

Action: For discussion on Thursday, 18:00 - 19:00, room 3K

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/