10 October 2017
EMA/PDCO/622369/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 10-13 October 2017

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

10 October 2017, 14:00- 17:00, room 3A

11 October 2017, 08:30- 19:00, room 3A

12 October 2017, 08:30- 19:00, room 3A

13 October 2017, 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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Table of contents

1. Introductions

1.1. Welcome and declarations of interest of members, alternates and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PDCO plenary session to be held 10-13 October 2017. See October 2017 PDCO minutes (to be published post November 2017 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 10-13 October 2017.

1.3. Adoption of the minutes

PDCO minutes for 12-15 September 2017.

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. Omega-3-carboxylic acids - EMEA-001865-PIP02-16

Hypertriglyceridaemia or mixed dyslipidaemia to reduce the risk of atherosclerotic cardiovascular disease (ACVD), Mixed dyslipidaemia with persistent hypertriglyceridaemia.

Day 120 opinion

Action: For adoption

Cardiovascular Diseases

2.1.2. Synthetic double-stranded siRNA oligonucleotide directed against hydroxyacid oxidase 1 mRNA that is covalently linked to a ligand containing three N-acetylgalactosamine residues - Orphan - EMEA-002079-PIP01-16

Alnylam UK Limited; Treatment of Primary Hyperoxaluria Type 1

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.3. Iron hydroxyethyl amylopectin heptonate - EMEA-002094-PIP01-16

Iron deficiency anemia, Iron deficiency.

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.4. emapalumab - Orphan - EMEA-002031-PIP01-16

Novimmune B.V; Treatment of Haemophagocytic Lymphohistiocytosis

Day 120 opinion

Action: For adoption, Oral Explanation Meeting to be held on 12 October, 15:00-16:00

Immunology-Rheumatology-Transplantation

2.1.5. recombinant humanised IgG4 monoclonal antibody against MSRV-Envelope protein - EMEA-002127-PIP01-17

Treatment of Multiple Sclerosis / Treatment of patients from 10 to less than 18 years old with relapsing-remitting multiple sclerosis

Day 120 opinion

Action: For adoption

Neurology

2.1.6. ruxolitinib phosphate - EMEA-000901-PIP03-16

Acute graft versus host disease / Treatment of acute Graft vs Host Disease (GvHD) after allogeneic hematopoietic stem cell transplantation (alloSCT) in paediatric patients aged 28 days and above.

Day 120 opinion

Action: For adoption

Oncology

2.1.7. N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup A polysaccharide conjugated to tetanus toxoid - EMEA-001930-PIP01-16

Prevention of Meningococcal Disease

Day 120 opinion

Action: For adoption

Vaccines

2.1.8. ezetimibe / atorvastatin - EMEA-002207-PIP01-17

Treatment of hypercholesterolaemia

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.9. vonapanitase - Orphan - EMEA-002195-PIP01-17

Proteon Therapeutics Limited; prevention of arteriovenous fistula failure

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.10. Opicinumab - EMEA-002194-PIP01-17

Treatment of Multiple Sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.1.11. resminostat - Orphan - EMEA-002211-PIP01-17

4SC AG; Cutaneous T-Cell Lymphoma

Day 60 opinion

Action: For adoption

Oncology

2.1.12. - EMEA-002197-PIP01-17

Treatment of ocular melanoma

Day 60 opinion

Action: For adoption

Oncology

2.1.13. Tolonium chloride - EMEA-002170-PIP01-17

Dental and oral soft tissue infections

Day 60 opinion

Action: For adoption

Other

2.1.14. Human Neutrophil Elastase Inhibitor - EMEA-002196-PIP01-17

Treatment of Non Cystic Fibrosis Bronchiectasis

Day 60 opinion

Action: For adoption

Pneumology – Allergology

2.1.15. - EMEA-002215-PIP01-17

Disease caused by Streptococcus pneumoniae

Day 60 opinion

Action: For adoption

Vaccines

2.1.16. allopregnanolone - EMEA-002051-PIP02-16

Treatment of postpartum depression

Day 120 opinion

Action: For adoption

Psychiatry

2.2. Opinions on Compliance Check

The following compliance checks have been put up for discussion and the members of the PDCO have been invited to comment on issues of possible non-compliance

2.2.1. rivaroxaban - EMEA-C4-000430-PIP01-08-M10

Bayer AG; Treatment of thromboembolic events

Day 60 letter

Action: For adoption

Cardiovascular Diseases

2.2.2. rabeprazole (sodium) - EMEA-C-000055-PIP01-07-M05

Eisai Ltd.; Treatment of gastro-oesophageal reflux disease

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.2.3. turoctocog alfa pegol - EMEA-C1-001174-PIP02-12-M02

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

Day 60 letter

Action: For adoption

Haematology-Hemostaseology

2.2.4. Treosulfan - EMEA-C1-000883-PIP01-10-M04

medac Gesellschaft für klinische Spezialpräparate mbH; Conditioning treatment prior to haematopoietic progenitor cell transplantation

Day 60 letter

Action: For adoption

Immunology-Rheumatology-Transplantation / Oncology

2.2.5. Entolimob - EMEA-C2-002020-PIP01-16-M01

TMC Pharma Services Ltd.; Treatment of acute radiation syndrome

Day 1 letter

Action: For adoption

Other

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Azilsartan medoxomil - EMEA-000237-PIP01-08-M07

Takeda Development Centre (Europe) Ltd.; Treatment of hypertension / Essential (primary) hypertension, Secondary hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. Tolvaptan - EMEA-001231-PIP02-13-M05

Otsuka Pharmaceutical Europe Ltd.; Polycystic Kidney Disease (PKD), Dilutional hyponatraemia / Treatment of chronic (>48 hours) dilutional hyponatraemia resistant to fluid restriction (i.e., euvolemic 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

2.3.3. Teduglutide ([gly2] recombinant human glucagon-like peptide) - Orphan - EMEA-000482-PIP01-08-M04

Shire Pharmaceuticals Ireland Limited; ICD-9-CM Diagnosis 579.3 - Other and unspecified post surgical non absorption - Syndrome Short Bowel

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.4. Fc- and CDR-modified humanised monoclonal antibody against C5 - Orphan - EMEA-002077-PIP01-16-M01

Alexion Europe SAS; Treatment of Paroxysmal Nocturnal Haemoglobinuria

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.5. sarilumab - EMEA-001045-PIP01-10-M01

sanofi-aventis recherche et développement; Treatment of chronic idiopathic arthritis (including rheumatoid arthrtis, spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis)

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.6. Secukinumab - EMEA-000380-PIP01-08-M04

Novartis Europharm Ltd; Psoriasis / Moderate to severe plaque psoriasis in adults who are candidates for systemic therapy

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.7. Upadacitinib - EMEA-001741-PIP01-14-M01

AbbVie Ltd; Treatment of Chronic Idiopathic Arthritis / Treatment of Juvenile Idiopathic Arthritis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.8. Adalimumab - EMEA-000366-PIP02-09-M05

AbbVie Limited; Ulcerative Colitis / Treatment of Moderate to severe ulcerative colitis

Day 60 opinion

Action: For adoption

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

2.3.9. lumicitabine - EMEA-001758-PIP01-15-M02

Janssen-Cilag International NV; Treatment of lower respiratory tract disease caused by human respiratory syncytial virus

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.10. Telavancin hydrochloride - EMEA-000239-PIP01-08-M03

Theravance Biopharma Ireland Ltd.; Nosocomial Pneumonia (NP)

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.11. Thrombomodulin alfa - EMEA-001363-PIP01-12-M01

Asahi Kasei Pharma America Corporation; Treatment of sepsis / Treatment of patients with severe sepsis (respiratory failure and/or septic shock) with coagulopathy

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.12. Bumetanide - EMEA-001303-PIP01-12-M02

Les Laboratoires Servier; Treatment of Autism Spectrum Disorder

Day 60 opinion

Action: For adoption

Neurology

2.3.13. eculizumab - Orphan - EMEA-000876-PIP03-14-M01

Alexion Europe SAS; Neuromyelitis optica spectrum disorders / Treatment of Relapsing Neuromyelitis Optica Spectrum Disorders in the paediatric population

Day 60 opinion

Action: For adoption

Neurology

2.3.14. lacosamide - EMEA-000402-PIP03-17-M01

UCB Pharma S.A.; Treatment of Generalized Epilepsy and Epilepsy Syndromes: Epilepsy - generalized idiopathic epilepsy and epilepsy syndromes [G40.3] Epilepsy - Other generalized epilepsy and epileptic syndromes [G40.4] / Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures (PGTCS) in pediatric patients with idiopathic generalized epilepsy (IGE)(4 years to <18 years), Adjunctive therapy in the treatment of epileptic syndromes associated with generalized seizures in pediatric patients with epilepsy birth to <18 years (specific epileptic syndrome(s) to be based on future clinical development further to exploratory study results)

Day 60 opinion

Action: For adoption

Neurology

2.3.15. ozanimod - EMEA-001710-PIP02-14-M02

Celgene Europe Limited; Treatment of multiple sclerosis / Treatment of relapsing remitting forms of multiple sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.3.16. avelumab (recombinant human monoclonal IgG1 antibody directed against Programmed Death Ligand-1 (anti-PD-L1) - Orphan - EMEA-001849-PIP02-15-M01

Merck KGaA; Treatment of all conditions included in the category of solid malignant neoplasms (including central nervous system tumours and lymphoma)

Day 60 opinion

Action: For adoption

Oncology

2.3.17. Naltrexone HCl / Bupropion HCl - EMEA-001373-PIP01-12-M03

Orexigen Therapeutics Ireland Limited; Treatment of obesity

Day 60 opinion

Action: For adoption

Other

2.3.18. Palovarotene - Orphan - EMEA-001662-PIP01-14-M01

Clementia Pharmaceuticals Inc.; Treatment of Fibrodysplasia Ossificans Progressiva (FOP)

Day 60 opinion

Action: For adoption

Other

2.3.19. Tapentadol - EMEA-000018-PIP01-07-M14

Grünenthal GmbH; Treatment of acute pain

Day 60 opinion

Action: For adoption

Pain

2.3.20. mirabegron - EMEA-000597-PIP02-10-M06

Astellas Pharma Europe B.V.; Treatment of idiopathic overactive bladder / Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome

Day 60 opinion

Action: For adoption

Uro-nephrology

2.3.21. Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1)/Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2)/Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage)/Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) - EMEA-002068-PIP01-16-M01

Seqirus UK Limited; Prevention of influenza

Day 1 opinion

Action: For adoption

Vaccines

2.3.22. Lubiprostone - EMEA-000245-PIP01-08-M04

Sucampo AG; chronic idiopathic constipation

Day 30 opinion

Action: For adoption

Gastroenterology-Hepatology

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. Brazikumab - EMEA-001929-PIP01-16

Crohn's disease, Ulcerative colitis

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.2. Susoctocog alfa - EMEA-000753-PIP02-16

Congenital haemophilia A with antibodies (inhibitors) to human factor VIII / Peri-operative management in patients with congenital haemophilia A with antibodies (inhibitors) to human FVIII

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.3. Risankizumab - EMEA-001776-PIP02-17

Chronic Idiopathic Arthritis

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.4. trazodone hydrochloride - EMEA-002142-PIP01-17

Treatment of insomnia

Day 90 discussion

Action: For discussion

Neurology

3.1.5. carotuximab - Orphan - EMEA-002138-PIP01-17

TRACON Pharma Limited--Patricia Bitar; Treatment of soft tissue sarcoma

Day 90 discussion

Action: For discussion

Oncology

3.1.6. fully human monoclonal antibody (mAb) directed against the human PD-1 receptor - EMEA-002007-PIP02-17

Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue) / Treatment of newly diagnosed diffuse intrinsic pontine gliomas (DIPG), newly diagnosed and recurrent high-grade gliomas (HGG)

Day 90 discussion

Action: For discussion

Oncology

3.1.7. Vosoritide - Orphan - EMEA-002033-PIP01-16

BioMarin International Limited; Treatment of achondroplasia

Day 90 discussion

Action: For discussion

Other

3.1.8. Bupivacaine - EMEA-000877-PIP02-16

Postsurgical analgesia

Day 90 discussion

Action: For discussion

Pain

3.1.9. formoterol fumarate / glycopyrronium bromide / budesonide - EMEA-002063-PIP01-16

Asthma / For the regular treatment of asthma in children 6 to 11 years of age where use of a triple combination medicinal product (ICS, LAMA and LABA) is appropriate: • patients not adequately controlled with ICS and another controller such as a LABA or LAMA

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.10. - EMEA-002216-PIP01-17

Day 60 discussion

Action: For discussion

Dermatology

3.1.11. - EMEA-002208-PIP01-17

Treatment of psoriasis, Treatment of Crohn's disease, Treatment of ulcerative colitis / Treatment of moderate to severely active Crohn's disease in paediatric patients aged 2 to less than 18 years of age, Treatment of moderate to severely active ulcerative colitis in paediatric patients aged 2 to less than 18 years of age, Treatment of moderate-to-severe plaque psoriasis in paediatric patients aged 6 to less than 18 years of age.

Day 60 discussion

Action: For discussion

Dermatology / Gastroenterology-Hepatology

3.1.12. inclisiran sodium - EMEA-002214-PIP01-17

Treatment of elevated cholesterol / Inclisiran is indicated to lower LDL-C in adults and children aged 11 years old and older with heterozygous familial hypercholesterolemia in combination with other lipid lowering therapies., Inclisiran is indicated to lower LDL-C in adults and children aged 11 years old and older with homozygous familial hypercholesterolemia in combination with other lipid lowering therapies.

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.13. Anti-Mucosal Addressin Cell Adhesion Molecule Antibody - EMEA-002218-PIP01-17

Treatment of Ulcerative Colitis, Treatment of Crohn's Disease / Treatment of moderate to severe active Crohn's Disease, Treatment of moderate to severe active Ulcerative Colitis

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.14. Ibrutinib - Orphan - EMEA-001397-PIP04-17

Janssen-Cilag International N.V.; Treatment of cGVHD / indicated for the treatment of cGVHD in children 1 year of age and older.

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.15. Branaplam - EMEA-002204-PIP01-17

Spinal Muscular Atrophy

Day 60 discussion

Action: For discussion

Neurology

3.1.16. Glasdegib maleate - EMEA-002199-PIP01-17

Treatment of acute myeloid leukaemia (AML) / • Glasdegib as monotherapy for prevention of AML relapse in children aged 2 years up to <18 years with high risk for relapse post-alloSCT; • Glasdegib in combination with FLAG/DNX as reinduction treatment of R/R AML in children aged 2 years up to <18 years, followed by consolidation therapy with or without SCT, and finally single-agent glasdegib post-consolidation.

Day 60 discussion

Action: For discussion

Oncology

3.1.17. isatuximab - Orphan - EMEA-002205-PIP01-17

Sanofi-Aventis Recherche & Développement; Treatment of malignant neoplasms of the haematopoietic and lymphoid tissue / Treatment of relapsed, refractory acute lymphoblastic leukemia in combination with standard treatment in paediatric patients with no more than one prior salvage therapy, Treatment of relapsed, refractory acute myeloblastic leukemia in combination with standard treatment in paediatric patients with no more than one prior salvage therapy

Day 60 discussion

Action: For discussion

Oncology

3.1.18. Autologous cartilage derived cultured chondrocytes - EMEA-002217-PIP01-17

Treatment of cartilage disorders

Day 60 discussion

Action: For discussion

Other

3.1.19. - EMEA-001976-PIP01-16

Asthma / Once-daily maintenance treatment of asthma as prophylactic therapy in patients aged 12 years and older (and in age 5-11) where use of a maintenance anti-inflammatory medication is appropriate

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.20. Plant-derived Quadrivalent VLP Influenza vaccine - EMEA-002220-PIP01-17

Prophylaxis of seasonal influenza / For active immunization of persons six months of age and older for the prevention of disease caused by influenza A subtype viruses and type B viruses covered by the vaccine.

Day 60 discussion

Action: For discussion

Vaccines

3.1.21. - EMEA-001527-PIP02-17

Treatment of obesity.

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.22. Itacitinib - EMEA-002178-PIP01-17

Treatment of acute Graft versus Host Disease (D89.810, ICD-10-CM) / Treatment of steroid naïve paediatric population with acute graft versus host disease after allogeneic hematopoietic stem cell transplantation

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.23. tedizolid phosphate - EMEA-001379-PIP02-17

Treatment of Gram-positive bacterial pneumonia

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.24. fremanezumab - EMEA-001877-PIP03-17

Prevention of cluster headache

Day 30 discussion

Action: For discussion

Neurology

3.1.25. Setmelanotide - Orphan - EMEA-002209-PIP01-17

Rhythm Pharmaceuticals, Inc; Treatment of appetite and general nutrition disorders / Treatment of obesity and/or hyperphagia associated with genetic defects upstream of the MC4 receptor in the leptin-melanocortin pathway

Day 30 discussion

Action: For discussion

Nutrition

3.1.26. Afatinib - EMEA-001596-PIP02-17

Treatment of oropharyngeal, laryngeal or nasal epithelial carcinoma, Treatment of paediatric patients with tumours with known ErbB deregulations irrespective of tumour histology, Treatment of lung carcinoma, Treatment of urether and bladder carcinoma / Treatment of paediatric patients aged between ≥ 1 year and ≤ 18 years with recurrent or refractory tumours with known ErbB deregulation and irrespective of tumour histology, -

Day 30 discussion

Action: For discussion

Oncology

3.1.27. Synthetic double-stranded small interfering RNA (siRNA) oligonucleotide specific to the mRNA of the caspase 2 gene - EMEA-002224-PIP01-17

Treatment of optic nerve bleeding and vascular disorders / Treatment of ischaemic optic neuropathy

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.28. fosnetupitant / palonosetron - EMEA-001198-PIP03-17

Prevention of Chemotherapy-Induced Nausea and Vomiting

Day 30 discussion

Action: For discussion

Other

3.1.29. Sirolimus - Orphan - EMEA-002213-PIP01-17

Vascular Therapies, Inc.; Prevention of arteriovenous access dysfunction

Day 30 discussion

Action: For discussion

Other

3.1.30. - EMEA-002160-PIP01-17

Prevention of human immunodeficiency virus (HIV-1) infection / Prevention of HIV-1 infection in children from 9 to less than 18 years of age

Day 30 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.1.31. Clade C gp140 - EMEA-002221-PIP01-17

Prevention of human immunodeficiency virus (HIV-1) infection / Prevention of HIV-1 infection in children from 9 to less than 18 years of age

Day 30 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.1.32. Mosaic gp140 / Clade C gp140 - EMEA-002161-PIP01-17

Prevention of human immunodeficiency virus (HIV-1) infection / Prevention of HIV-1 infection in children from 9 to less than 18 years of age

Day 30 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.2. Discussions on Compliance Check

The following compliance checks have been put up for discussion and the members of the PDCO have been invited to comment on issues of possible non-compliance

3.2.1. avacopan - EMEA-C1-002023-PIP01-16-M01

ChemoCentryx, Ltd.; Treatment of antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.2. mepolizumab - EMEA-C-000069-PIP02-10-M08

GSK TRADING SERVICES LIMITED; Treatment of asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. recombinant human glutamic acid decarboxylase (rhGAD65) - EMEA-000609-PIP01-09-M01

Diamyd Medical AB; E10 Insulin-dependent diabetes mellitus / Treatment of type 1 Diabetes Mellitus of recent onset

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.2. sotagliflozin - EMEA-001517-PIP02-14-M02

sanofi-aventis R&D; Treatment of type 1 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.3. Eluxadoline - EMEA-001579-PIP01-13-M02

Allergan Limited; Irritable bowel syndrome with diarrhoea

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.4. Human coagulation factor X - Orphan - EMEA-000971-PIP01-10-M03

Bio Products Laboratory Limited; Treatment of hereditary factor X deficiency

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.5. avacopan - Orphan - EMEA-002023-PIP01-16-M02

ChemoCentryx, Ltd.; Treatment of ANCA-associated vasculitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.6. Human normal immunoglobulin for subcutaneous administration - EMEA-001853-PIP01-15-M01

Grifols Therapeutics Inc; Treatment for primary immunodeficiency

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.7. bezlotoxumab - EMEA-001645-PIP01-14-M02

Merck Sharp & Dohme (Europe), Inc.; Treatment of Clostridium difficile infection / indicated for the prevention of recurrence of Clostridium difficile infection (CDI) in paediatric patients at high risk for recurrence of CDI

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.8. ataluren - Orphan - EMEA-000115-PIP01-07-M09

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

3.3.9. Delta-9-tetrahydrocannabinol / Cannabidiol - EMEA-000181-PIP01-08-M04

GW Pharma Ltd; Spasticity / Intractable spasticity due to cerebral palsy or traumatic CNS injury

Day 30 discussion

Action: For discussion

Neurology

3.3.10. Blinatumomab - Orphan - EMEA-000574-PIP02-12-M02

Amgen Europe B.V.; Treatment of Acute Lymphoblastic Leukaemia / Treatment of Philadelphia chromosome-negative relapsed or refractory B-precursor acute lymphoblastic leukaemia (ALL) in patients 1 month and older.

Day 30 discussion

Action: For discussion

Oncology

3.3.11. ibrutinib - Orphan - EMEA-001397-PIP03-14-M03

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

Day 30 discussion

Action: For discussion

Oncology

3.3.12. inotuzumb ozogamicin - Orphan - EMEA-001429-PIP01-13-M02

Pfizer Ltd; Treatment of Acute Lymphoblastic Leukaemia / For the treatment of relapsed or refractory B cell precursor Acute Lymphoblastic Leukaemia

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.3.13. Human Thrombin / Human Fibrinogen - EMEA-001149-PIP01-11-M04

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 30 discussion

Action: For discussion

Other

3.3.14. Lanadelumab - Orphan - EMEA-001864-PIP01-15-M01

Shire Pharmaceuticals Ireland Limited; Treatment of hereditary angioedema

Day 30 discussion

Action: For discussion

Other

3.3.15. sildenafil - Orphan - EMEA-000671-PIP01-09-M09

Pfizer Limited; Treatment of Pulmonary Arterial Hypertension (PAH)

Day 30 discussion

Action: For discussion

Other

3.3.16. spheroids of human autologous matrix-associated chondrocytes - EMEA-001264-PIP01-12-M01

CO.DON AG; Treatment of symptomatic articular cartilage defects of the femoral condyle and the patella of the knee (International Cartilage Repair Society [ICRS] grade III or IV) with defect sizes up to 10 cm2

Day 30 discussion

Action: For discussion

Other

3.3.17. Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis pollen (Grasses-Mix) (1/5) each - EMEA-000794-PIP01-09-M01

LETI Pharma GmbH; J 30.1 Allergic rhinitis due to pollen, J 30.2 Other seasonal allergic rhinitis,, H10.1 Acute allergic conjunctivitis, J30.3 Other allergic rhinitis, J30.4 Allergic rhinitis, unspecified / Treatment of patients with allergic rhinitis with or without intermittent allergic asthma due to sensitisation against grass pollens (Gramineas family), Treatment of patients with allergic rhinoconjunctivitis with or without intermittent allergic asthma due to sensitisation against grass pollens (Gramineas family)

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.18. Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extract of Phleum pratense, Dactylis glomerata, Festuca elatior, Lolium perenne and Poa pratensis pollen (Grasses-Mix) and Secale cereale (Cultivated Rye) pollen (50/50) - EMEA-000792-PIP01-09-M01

LETI Pharma GmbH; J 30.1 Allergic rhinitis due to pollen, J 30.2 Other seasonal allergic rhinitis,, H10.1 Acute allergic conjunctivitis, J30.3 Other allergic rhinitis, J30.4 Allergic rhinitis, unspecified / Treatment of patients with allergic rhinitis with or without intermittent allergic asthma due to sensitisation against grass pollens (Gramineas family), Treatment of patients with allergic rhinoconjunctivitis with or without intermittent allergic asthma due to sensitisation against grass pollens (Gramineas family)

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.19. Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergic extract of Phleum pratense pollen - EMEA-000795-PIP01-09-M01

LETI Pharma GmbH; J 30.1 Allergic rhinitis due to pollen, J 30.2 Other seasonal allergic rhinitis,, H10.1 Acute allergic conjunctivitis, J30.3 Other allergic rhinitis, J30.4 Allergic rhinitis, unspecified / Treatment of patients with allergic rhinitis with or without intermittent allergic asthma due to sensitisation against grass pollens (Gramineas family), Treatment of patients with allergic rhinoconjunctivitis with or without intermittent allergic asthma due to sensitisation against grass pollens (Gramineas family)

Day 30 discussion

Action: For discussion

Pneumology - Allergology

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 3 January 2018 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. Ribavirin - EMEA-16-2017

GlaxoSmithKline Intellectual Property Development Limited; All classes of medicinal products for treatment of Chronic Pulmonary Obstructive Disease (COPD)/ reduction of the risk or severity of virally triggered COPD exacerbations in patients with COPD and a history of exacerbations

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. Rivaroxaban - EMEA-000430-PIP01-08-M10

Bayer AG; Prevention of thromboembolic events/ Prevention of stroke, myocardial infarction and cardiovascular death, and for the prevention of acute limb ischemia and mortality in adult patients with Coronary Artery Disease or Peripheral Artery Disease

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

None

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

Action: For information

Joint CHMP/PDCO session

Action: For discussion

9.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

9.3.1. Non-clinical Working Group: D30 Products identified

PDCO member: Karen Van Malderen

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.3.3. Reflection paper on the use of extrapolation in paediatric medicines development

PDCO member: Dirk Mentzer

Action: For adoption

9.3.4. Guideline on the development of new medicinal products for the treatment of Crohn's Disease and ulcerative colitis

PDCO member: Peter Szitanyi, Johannes Taminiau

Action: For adoption

9.3.5. Minutes - PCWP/HCPWP joint meeting held on 27-28 June 2017

Action: For information

9.3.6. Revision of the 'Guideline on recombinant and plasma-derived FVIII products'

Action: For information

9.4. Cooperation within the EU regulatory network

9.4.1. European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA)

Action: For information

9.5. Cooperation with International Regulators

9.5.1. ICH S11 and ICH S9 Questions and answers

PDCO Members: Karen van Malderen

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

9.7.1. Draft PDCO Work plan 2018

Action: For discussion

9.8. Planning and reporting

10. Any other business

10.1. AOB topic

10.1.1. Preparedness of the system and capacity increase

Action: For information

11. Breakout sessions

11.1.1. Paediatric oncology

Action: For discussion on Thursday, 14:00 - 15:00, room 3J

11.1.2. Neonatology

Action: For discussion on Thursday, 14:00 - 15:00, room 3L

11.1.3. Inventory

Action: For discussion on Thursday, 14:00 - 15:00, delegates' lounge

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/