20 February 2017
EMA/PDCO/72697/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 21-24 February 2017

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

21 February 2017, 14:00 - 18:00, room 3A

22 February 2017, 08:30 - 19:00, room 3A

23 February 2017, 08:30 - 19:00, room 3A

24 February 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).

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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 21-24 February 2017. See 21-24 February 2017 PDCO minutes (to be published post March 2017 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 21-24 February 2017 meeting.

1.3. Adoption of the minutes

PDCO minutes for 24-27 January 2017 meeting.

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. Macimorelin - EMEA-001988-PIP01-16

Growth hormone deficiency / Diagnosis of growth hormone deficiency

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism / Diagnostic

2.1.2. Human fibrinogen concentrate - EMEA-001931-PIP01-16

Treatment of congenital fibrinogen deficiency

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.3. EMEA-001923-PIP01-15

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

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.4. Entolimod - Orphan - EMEA-002020-PIP01-16

Cleveland BioLabs Inc; Treatment of acute Radiation Syndrome / Entolimod is indicated for reducing the risk of death following exposure to potentially lethal irradiation occurring as the results of a radiation disaster

Day 120 opinion

Action: For adoption

Other

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

Treatment of primary hypercholesterolemia / Treatment of heterozygous familial hypercholesterolaemia

Day 120 opinion

Action: For adoption

Other / Cardiovascular Diseases

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

Treatment of cystic fibrosis

Day 120 opinion

Action: For adoption

Pneumology - Allergology

2.1.7. Baclofen - EMEA-001549-PIP02-14

Alcohol use disorders (DSM-5) / Reduction of alcohol consumption as a second line treatment after psychosocial intervention, in 15-17 years adolescents with alcohol use disorders according to DSM 5

Day 120 opinion

Action: For adoption

Psychiatry

2.1.8. rVSVΔG-ZEBOV-GP - EMEA-001786-PIP01-15

Prevention of Ebola disease

Day 120 opinion

Action: For adoption

Vaccines

2.1.9. Acetylsalicylic acid / Prasugrel HCl - EMEA-002071-PIP01-16

Prevention of atherosclerosis, thrombosis and thromboembolic events

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.10. Amlodipine / Candesartan - EMEA-002090-PIP01-16

Treatment of hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.11. Amlodipine / Perindopril - EMEA-002091-PIP01-16

Treatment of hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.12. Alicaforsen - Orphan - EMEA-002060-PIP01-16

Atlantic Pharmaceuticals Ltd; Treatment of gastrointestinal procedural complications / Treatment of active episodes of antibiotic refractory pouchitis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.13. Tobramycin - Orphan - EMEA-000184-PIP03-16

Novartis Europharm Limited; Treatment of Pseudomonas aeruginosa pulmonary colonisation in patients with bronchiectasis

Day 60 opinion

Action: For adoption

Infectious Diseases

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. Beclometasone dipropionate / Formoterol fumarate dihydrate - EMEA-C5-000548-PIP01-09-M06

Chiesi Farmaceutici S.p.A.; Treatment of asthma

Day 30 opinion

Action: For adoption

2.2.2. brexpiprazole - EMEA-C2-001185-PIP01-11-M03 – Day 0 adoption

Otsuka Pharmaceutical Europe Ltd.; Treatment of schizophrenia

Day 0 opinion

Action: For adoption

2.2.3. Ivacaftor / Lumacaftor - EMEA-C4-001582-PIP01-13-M04 – Day 30 adoption

Vertex Pharmaceuticals (Europe) Limited; Treatment of cystic fibrosis

Day 30 opinion

Action: For adoption

Other

Pneumology – Allergology

2.2.4. ipilimumab - EMEA-C-000117-PIP02-10-M07 – Day 30 adoption

Bristol-Myers Squibb Pharma EEIG; Treatment of melanoma

Day 30 opinion

Action: For adoption

Oncology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Evolocumab - EMEA-001268-PIP01-12-M04

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. Trifarotene - EMEA-001492-PIP01-13-M01

GALDERMA R&D; Treatment of acne vulgaris

Day 60 opinion

Action: For adoption

Dermatology

2.3.3. Recombinant human N-acetylglucosaminidase (rhNAGLU) - Orphan - EMEA-001653-PIP01-14-M02

Alexion Europe SAS; Treatment of Mucopolysaccharidosis IIIB (Sanfilippo B)

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.4. ferric maltol - EMEA-001195-PIP01-11-M02

Shield TX (UK) Limited; Treatment for iron deficiency anaemia (IDA)

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.5. ustekinumab - EMEA-000311-PIP03-11-M02

Janssen-Cilag International NV; Treatment of chronic idiopathic arthritis (including

rheumatoid arthritis, spondyloarthritis, PsA and juvenile idiopathic arthritis [JIA]) / Treatment of juvenile idiopathic arthritis (jPsA and ERA)

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.6. rituximab - EMEA-000308-PIP01-08-M03

Roche Registration Limited; Treatment of diffuse large B-cell lymphoma, Treatment of autoimmune arthritis / Treatment of mature B-cell malignancies, that is, diffuse large B-cell lymphoma, Burkitt and Burkitt-like lymphoma/leukaemia.

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Oncology

2.3.7. letermovir - Orphan - EMEA-001631-PIP01-14-M02

Merck Sharp & Dohme (Europe), Inc.; Prevention of cytomegalovirus infection / Prevention of CMV viremia and/or disease in at-risk patients having undergone an allogeneic HSCT or SOT

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.8. Oseltamivir phosphate - EMEA-000365-PIP01-08-M08

Roche Registration Limited; Treatment and prevention of influenza / Treatment and prevention of influenza in healthy and immunocompromised patients from 0 to less than 18 years of age

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.9. posaconazole - EMEA-000468-PIP02-12-M03

Merck Sharp & Dohme (Europe), Inc.; Prevention of invasive fungal infections, Treatment of invasive fungal infections / For treatment of invasive fungal infections in the following paediatric patients: -Invasive aspergillosis in patients with disease that is refractroy to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products;, Treatment of invasive aspergillosis, -Patients receiving remission-induction chemotherapy for acute myelogenous leukemia (AML) or myelodysplastic syndromes (MDS)

expected to result in prolonged neutropenia and who are at high risk of developing invasive fungal infections; - Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease and who are at high risk of developing invasive fungal infections.

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.10. telaprevir - EMEA-000196-PIP01-08-M04

Janssen-Cilag International NV; Treatment of chronic viral hepatitis C

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.11. Oritavancin diphosphate - EMEA-001270-PIP01-12-M01

The Medicines Company; Treatment of acute bacterial skin and skin structure infections

Day 60 opinion

Action: For adoption

Infectious Diseases / Dermatology

2.3.12. Bivalent anti-human myostatin adnectin recombinant human IgG1-Fc fusion protein - EMEA-001793-PIP01-15-M01

Bristol-Myers Squibb International Corporation; Treatment of Duchenne Muscular Dystrophy / Treatment of Duchenne Muscular Dystrophy in patients from 2 to less than 18 years of age

Day 60 opinion

Action: For adoption

Neurology

2.3.13. Siponimod hemifumarate - EMEA-000716-PIP01-09-M02

Novartis Europharm Limited; Multiple Sclerosis / Treatment of children/adolescent patients (10-18 years old) with relapsing forms of multiple sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.3.14. HSV-1/ICP34.5-/ICP47-/hGM-CSF - EMEA-001251-PIP01-11-M03

Amgen Europe B.V.; Treatment of solid malignant non-CNS tumours

Day 60 opinion

Action: For adoption

Oncology

2.3.15. ibrutinib - Orphan - EMEA-001397-PIP03-14-M02

Janssen-Cilag International N.V.; Treatment of mature B-cell neoplasm / 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 60 opinion

Action: For adoption

Oncology

2.3.16. Lenvatinib - Orphan - EMEA-001119-PIP02-12-M03

Eisai Europe Ltd; Treatment of papillary thyroid carcinoma, Treatment of Osteosarcoma, Treatment of follicular thyroid carcinoma / Treatment of refractory or relapsed osteosarcoma in children and adolescents, Treatment of progressive, radioiodine-refractory differentiated thyroid cancer in children and adolescents

Day 60 opinion

Action: For adoption

Oncology

2.3.17. Regorafenib - EMEA-001178-PIP01-11-M03

Bayer Pharma; Treatment of all conditions contained in the category of malignant neoplasms (except haematopoietic and lymphoid tissue) / Treatment of paediatric patients with a solid malignant tumour(s) integrated with anti-cancer therapy

Day 60 opinion

Action: For adoption

Oncology

2.3.18. ivacaftor / lumacaftor - EMEA-001582-PIP01-13-M05

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

Day 60 opinion

Action: For adoption

Other

2.3.19. Dermatophagoides pteronyssinus/ Dermatophagoides farinae (50%/50%) - EMEA-001258-PIP01-11-M02

ALK-Abelló A/S; Treatment of allergic rhinitis, Treatment of asthma / allergic rhinitis, allergic asthma

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.4. Opinions on Re-examinations

2.4.1. Methoxy polyethylene glycol- epoetin beta - EMEA-000172-PIP01-07-M02

Roche Registration Limited; Treatment of anaemia associated with chronic kidney disease

Day 30 opinion

Action: For adoption, Oral Explanation Meeting to be held on 23 February 2017, 11:00-12:00

Haematology-Hemostaseology

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. EMEA-001983-PIP01-16

Monitoring of renal function

Day 90 discussion

Action: For discussion

Diagnostic / Uro-nephrology

3.1.2. avacopan - Orphan - EMEA-002023-PIP01-16

ChemoCentryx, Ltd.; Treatment of ANCA-associated vasculitis

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.3. Tetrofosmin - Orphan - EMEA-002019-PIP02-16

proACTINA SA; Diagnosis of malignant Glioma

Day 60 discussion

Action: For discussion

Diagnostic

3.1.4. Levoglutamide - Orphan - EMEA-001996-PIP02-16

Emmaus Medical Europe Ltd.; Sickle cell disease / Levoglutamide is indicated for the prevention of sickle cell crises in adults, adolescents and children older than 5 years suffering from Sickle Cell Disease

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.5. Recombinant human monoclonal antibody to GM-CSF - EMEA-001882-PIP02-16

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis) / Treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 1 year of age and older, Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.6. Iclaprim mesylate - EMEA-000345-PIP02-16

Treatment of acute bacterial skin and skin structure infections caused by susceptible strains of Gram-positive bacteria

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.7. Lefamulin - EMEA-002075-PIP01-16

Treatment of community-acquired pneumonia

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.8. EMEA-002070-PIP01-16

Treatment of spinal muscular atrophy

Day 60 discussion

Action: For discussion

Neurology

3.1.9. fenfluramine hydrochloride - Orphan - EMEA-001990-PIP01-16

Zogenix International Ltd; The adjunctive treatment of seizures in paediatric patients at least 2 years of age with Dravet Syndrome

Day 60 discussion

Action: For discussion

Neurology

3.1.10. Autologous CD3+ T Cells Expressing CD19 Chimeric Antigen Receptor - EMEA-001994-PIP01-16

Treatment of B-cell non-Hodgkin's lymphoma, Treatment of B-cell acute lymphoblastic leukemia / Treatment of pediatric patients with relapsed or refractory B-cell acute lymphoblastic leukemia, Treatment of pediatric patients with relapsed or refractory diffuse large B-cell lymphoma, Burkitt lymphoma, and primary mediastinal large B-cell lymphoma

Day 60 discussion

Action: For discussion

Oncology

3.1.11. Autologous CD4+ and CD8+ T cells Expressing a CD19-Specific Chimeric Antigen Receptor - EMEA-001995-PIP01-16

Treatment of B-cell non-Hodgkin's lymphoma, Treatment of B-cell acute lymphoblastic leukemia / Treatment of pediatric patients with relapsed or refractory B-cell acute lymphoblastic leukemia, Treatment of pediatric patients with relapsed or refractory diffuse large B-cell lymphoma, Burkitt lymphoma, and primary mediastinal large B-cell lymphoma

Day 60 discussion

Action: For discussion

Oncology

3.1.12. Enasidenib - Orphan - EMEA-001798-PIP02-16

Celgene Europe Ltd; Treatment of Acute Myeloid Leukaemia / Treatment of patients aged 2 to 21 years old with relapsed or refractory IDH2- mutated AML after at least 2 prior induction attempts.

Day 60 discussion

Action: For discussion

Oncology

3.1.13. Entospletinib - EMEA-002058-PIP01-16

Treatment of Acute myeloid leukemia / Treatment of Acute myeloid leukemia

Day 60 discussion

Action: For discussion

Oncology

3.1.14. epacadostat - EMEA-002072-PIP01-16

Treatment of melanoma / Melanoma >12years - <18 years

Day 60 discussion

Action: For discussion

Oncology

3.1.15. Ramucirumab - EMEA-002074-PIP01-16

Treatment of soft tissue sarcoma, Treatment of intestinal malignant neoplasm, Treatment of gastric cancer and gastro-oesophageal junction adenocarcinoma, Treatment of liver cancer, Treatment of urinary tract malignant neoplasm, Treatment of lung malignant neoplasm / , Treatment of synovial sarcoma and / or desmoplastic small round cell tumour

Day 60 discussion

Action: For discussion

Oncology

3.1.16. ruxolitinib phosphate - EMEA-002056-PIP01-16

Treatment of acute graft versus host disease / Steroid refractory (SR) acute (a) Graft vs Host Disease (GvHD) after allogeneic hematopoietic stem cell transplantation (alloSCT)

Day 60 discussion

Action: For discussion

Oncology

3.1.17. Vadastuximab Talirine - Orphan - EMEA-002013-PIP01-16

Seattle Genetics UK, Limited; Treatment of Acute Myeloid Leukaemia / Treatment of relapsed or refractory AML

Day 60 discussion

Action: For discussion

Oncology

3.1.18. Angiotensin II - EMEA-001912-PIP02-16

Treatment of catecholamine-resistant hypotension associated with distributive shock

Day 60 discussion

Action: For discussion

Other

3.1.19. Ketamine hydrochloride / Sufentanil citrate - EMEA-001739-PIP02-16

Treatment of pain, unspecified

Day 60 discussion

Action: For discussion

Pain

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

Prevention of influenza

Day 60 discussion

Action: For discussion

Vaccines

3.1.21. Chloroprocaine Hydrochloride - EMEA-000639-PIP03-16

Treatment of peripheral nerve block (local anesthesia by perineural injection)

Day 30 discussion

Action: For discussion

Anaesthesiology

3.1.22. Indapamide / Ramipril - EMEA-002081-PIP01-16

Treatment of hypertension ICD10 I10-I15 / Treatment of hypertension as substitution therapy in adults whose blood pressure is adequately controlled by the use of ramipril and indapamide with the individual products given concurrently at the same dose level as in the combination, but as separate medicinal products., Treatment of hypertension in adults whose blood pressure is not adequately controlled by the use of ramipril monotherapy and for whom the use of the second medicinal product is an optimal therapeutic procedure.

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.23. Recombinant modified human growth hormone - Orphan - EMEA-001152-PIP02-16

Richardson Associates Regulatory Affairs Ltd; Treatment of growth hormone deficiency / Treatment of children with growth failure due to inadequate secretion of endogenous growth hormone

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.24. Selonsertib - EMEA-001868-PIP03-16

Treatment of Non-Alcoholic Steatohepatitis (NASH) with moderate to severe fibrosis (F2-F4) in paediatric subjects, 8 to < 18 years of age

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.25. Human normal immunoglobulin - EMEA-002084-PIP01-16

Treatment of Primary Immunodeficiency Diseases

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.26. Human Normal Immunoglobulin for Intravenous Administration (IVIg) - EMEA-002092-PIP01-16

Treatment of primary immunodeficiency (PID), Treatment of idiopathic thrombocytopenic purpura (ITP) / Primary immunodeficiency syndromes with impaired antibody production, Primary immune thrombocytopenia (ITP), in patients at high risk of bleeding or prior to surgery to correct the platelet count

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.27. Influenza virus surface antigens (haemagglutinin) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin) of strain A (H1N1) / Influenza virus surface antigens (haemagglutinin) of strain B (Victoria lineage) - EMEA-002027-PIP01-16

Prevention of Influenza infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.28. maribavir - Orphan - EMEA-000353-PIP02-16

Shire Pharmaceuticals Ireland Limited; Treatment of CMV infection / Treatment of CMV infection in transplant patients who are ≥2 to <18 years of age

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.29. allopregnanolone - EMEA-002051-PIP01-16

Treatment of Super Refractory Status Epilepticus

Day 30 discussion

Action: For discussion

Neurology

3.1.30. GIVINOSTAT - Orphan - EMEA-000551-PIP03-16

Italfarmaco S.p.A.; Treatment of Duchenne Muscular Dystrophy (DMD) / Treatment of Duchenne Muscular Dystrophy (DMD)

Day 30 discussion

Action: For discussion

Neurology

3.1.31. Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta chimeric antigen receptor - Orphan - EMEA-001862-PIP01-15

Kite Pharma EU B.V.; Treatment of B-precursor Acute Lymphoblastic Leukaemia (ALL)

Day 30 discussion

Action: For discussion

Oncology

3.1.32. Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta chimeric antigen receptor - Orphan - EMEA-002010-PIP01-16

Kite Pharma EU B.V.; Treatment of primary mediastinal B cell lymphoma (PMBCL), Treatment of follicular lymphoma (FL), Treatment of diffuse large B cell lymphoma (DLBCL)

Day 30 discussion

Action: For discussion

Oncology

3.1.33. erdafitinib - EMEA-002042-PIP01-16

Treatment of Ureter and Bladder Carcinoma

Day 30 discussion

Action: For discussion

Oncology

3.1.34. Small interfering RNA targeting human TRPV1 - EMEA-002061-PIP01-16

Treatment of dry eye disease

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.35. Brimapitide - Orphan - EMEA-001926-PIP02-16

Auris Medical Ltd.; Treatment of Idiopathic Sudden Sensorineural Hearing Loss (ISSNHL)

Day 30 discussion

Action: For discussion

Oto-rhino-laryngology

3.1.36. EMEA-001815-PIP02-16

Treatment of grass pollen induced seasonal allergic rhinoconjunctivitis (SAR)

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.37. ivacaftor / tezacaftor - EMEA-002086-PIP01-16

Treatment of Cystic Fibrosis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.38. mepolizumab - Orphan - EMEA-000069-PIP05-16

GSK Trading Services Limited; Treatment of nasal polyposis / is indicated for the add-on maintenance treatment of adult patients with severe bilateral nasal polyposis who have had prior nasal polyp surgery

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. Eravacycline - EMEA-C1-001555-PIP01-13-M02

Tetraphase Pharmaceuticals, Inc.; Treatment of complicated intra-abdominal infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.2. darbepoetin alfa - EMEA-C-000329-PIP02-09-M05

Amgen Ltd.; Treatment of anaemia due to chronic disorders

Day 30 discussion

Action: For discussion

Oncology / Uro-nephrology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Dopamine hydrochloride - EMEA-001105-PIP01-10-M03

BrePco Biopharma Limited; Treatment of vascular hypotensive disorders / Treatment of hypotension in neonates including the extremely low gestational age newborn. Treatment of hypotension in infants and children

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. 3-[[5-chloro-1-[3-(methylsulfonyl)propyl]-1H-indol-2-yl]methyl]-1-(2,2,2-trifluoroethyl)-1,3-dihydro-2H-imidazo[4,5-c]pyridine-2-one - EMEA-001838-PIP01-15-M01

Janssen-Cilag International NV; Treatment of respiratory tract disease caused by human respiratory syncytial virus (RSV) / Treatment of respiratory tract disease caused by human RSV

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.3. doravirine - EMEA-001676-PIP01-14-M01

Merck Sharp & Dohme (Europe), Inc.; Treatment of human immunodeficiency virus-1 (HIV-1) infection / Antiretroviral therapy, in combination with other antiretroviral agents, for the treatment of HIV-1 infection in children aged from birth to 18 years

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.4. tenofovir disoproxil fumarate / lamivudine / doravirine - EMEA-001695-PIP01-14-M01

Merck Sharp & Dohme (Europe), Inc.; Treatment of human immunodeficiency virus-1 (HIV-1) infection / Antiretroviral combination therapy, for the treatment of HIV-1 infection in adults and children aged 2 to 18 years

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.5. ponatinib (as hydrochloride) - Orphan - EMEA-001186-PIP01-11-M01

Incyte Biosciences UK Ltd.; Treatment of chronic myeloid leukaemia, Philadelphia chromosome positive acute lymphoblastic leukaemia / Paediatric population with Chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant or intolerant to at least one prior BCR-ABL TKI therapy; or who have the T315I mutation., Paediatric population with Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) who are resistant or intolerant to at least one prior BCR-ABL TKI therapy; or who have the T315I mutation.

Day 30 discussion

Action: For discussion

Oncology

3.3.6. Febuxostat - EMEA-001417-PIP01-12-M02

Menarini International Operations Luxembourg S.A.; Prevention/treatment of hyperuricemia / Prevention or treatment of hyperuricemia in patients at intermediate or high risk of Tumor Lysis Sindrome (TLS) affected by hematologic malignancies

Day 30 discussion

Action: For discussion

Other / Oncology

3.3.7. Tapentadol - EMEA-000018-PIP01-07-M13

Grünenthal GmbH; Treatment of acute pain

Day 30 discussion

Action: For discussion

Pain

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 25 April 2017 for Nomination of Rapporteur and Peer reviewer

Action: For adoption

4.2. Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver.

Action: For adoption

4.3. Nominations for other activities

4.3.1. Call for a PDCO representative to be Co-Chair of a new Work Group on 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. Atezolizumab - EMEA-42-2016

Treatment of multiple myeloma/ Atezolizumab in combination with daratumumab for the treatment of patients with relapsed/refractory multiple myeloma (MM) who have received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory drug (IMiD), or who are double refractory to a PI and an IMiD; Atezolizumab in combination with daratumumab, and an IMiD in previously untreated MM patients

Action: For adoption

6.1.2. Axalimogene filolisbac - EMEA-01-2017

Treatment of cervix and corpus uteri carcinoma/ Treatment of persistent or recurrent squamous or non-squamous cell carcinoma of the cervix in women ⩾18 years of age who

progress beyond first-line chemotherapy

Action: For adoption

6.1.3. (anti-vascular endothelial growth factor)- EMEA-02-2017

Age-related macular degeneration/ Treatment of neovascular age-related macular degeneration

Action: For adoption

7. Discussion on the inclusion of an indication within a condition in an agreed PIP/waiver

7.1. Discussion on the possibility to include an indication within a condition in an agreed PIP/waiver

None

8. Annual reports on deferrals

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

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. Committee meeting dates 2019-2021

Action: For adoption

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

Action: For information

9.2.2. Joint CHMP-PDCO session

Action: For information

9.2.3. Sodium-glucose co-transporter 2 (SGLT2) inhibitors: Canaglifozin – INVOKANA (CAP); canagliflozin, metformin – VOKANAMET (CAP);

dapaglifozin – EDISTRIDE (CAP), FORXIGA (CAP); dapaglifozin, metformin – XIGDUO (CAP), EBYMECT (CAP); empaglifozin – JARDIANCE (CAP); empaglifozin, metformin – SYNJARDY (CAP) - EMEA/H/A-20/1442

Applicant: Janssen-Cilag International N.V. (Invokana, Vokanamet); AstraZeneca AB (Edistride, Forxiga, Xigduo, Ebymect); Boehringer Ingelheim International GmbH (Jardiance; Synjardy)

Scope: Review of the benefit-risk balance of sodium-glucose co-transporter-2 (SGLT2) inhibitors following notification by the European Commission of a referral under Article 20 of Regulation (EC) No 726/2004, based on pharmacovigilance data

Action: For discussion

9.2.4. Human coagulation (plasma-derived) factor VIII: human coagulation factor VIII (antihemophilic factor A) (NAP); human coagulation factor VIII (inhibitor bypassing fraction) (NAP); human coagulation factor VIII, human von Willebrand factor - VONCENTO (CAP) Recombinant factor VIII: antihemophilic factor (recombinant) (NAP); moroctocog alfa – REFACTO AF (CAP) octocog alfa – ADVATE (CAP), HELIXATE NEXGEN (CAP), IBLIAS (CAP), KOGENATE (CAP), KOVALTRY (CAP) - EMEA/H/A-31/1448

Applicant: Baxter AG (Advate), Bayer Pharma AG (Helixate Nexgen, Iblias, Kogenate, Kovaltry), CSL Behring GmbH (Voncento), Pfizer Limited (Refacto AF), various

Scope: Review of the benefit-risk balance of factor VIII following notification by Germany of a referral under Article 31 of Directive 2001/83/EC, based on pharmacovigilance data

Action: For information

9.2.5. Fluoroquinolones for systemic and inhalation use: ciprofloxacin (NAP); enoxacin (NAP); flumequin (NAP); levofloxacin – QUINSAIR (CAP), NAP; lomefloxacin (NAP); moxifloxacin (NAP); norfloxacin (NAP); ofloxacin (NAP); pefloxacin (NAP); prulifloxacin (NAP); rufloxacin (NAP)
Quinolones for systemic and inhalation use: cinoxacin (NAP); nalidixic acid (NAP); pipemidic acid (NAP)

Applicant: Raptor Pharmaceuticals Europe BV (Quinsair), various

Scope: Review of the benefit-risk balance following notification by Germany of a referral under Article 31 of Directive 2001/83/EC, based on pharmacovigilance data

Action: For information

9.2.6. Selexipag - UPTRAVI (CAP)

Applicant: Actelion Registration Ltd.

Action: For information

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

9.3.1. Non-clinical Working Group: D30 Products identified

PDCO member: Jacqueline Carleer

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.4. Cooperation within the EU regulatory network

9.4.1. The 2017 Commission Report on the Paediatric Regulation

Action: For discussion

9.5. Cooperation with International Regulators

None

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

None

9.7. PDCO work plan

9.7.1. Preliminary discussion of PDCO on the scope of inventories

PDCO member: Karl-Heinz Huemer

Action: For discussion

9.8. Planning and reporting

None

10. Any other business

10.1.1. Survey to committee members on the service provided by the Scientific Committees Service

Action: For information

10.1.2. Results on the first 18 months of the 'Early Paediatric Interaction Meeting'

Action: For adoption

10.1.3. Results of juvenile animal studies (JAS) and impact on anti-cancer medicine development and use in children

PDCO member: Jacqueline Carleer

Action: For adoption

11. Breakout sessions

11.1.1. Paediatric oncology

Action: For discussion on Thursday, 14:00-15:00, room 9B

11.1.2. Neonatology

Action: For discussion on Thursday, 14:00-15:00, room 9A

11.1.3. Inventory

Action: For discussion on Thursday, 14:00-15:00, 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/