20 March 2018
EMA/PDCO/140668/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 20-23 March 2018

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

20 March 2018, 17:30- 19:00, room 3A

21 March 2018, 08:30- 19:00, room 3A

22 March 2018, 08:30- 19:00, room 3A

23 March 2018, 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 20-23 March 2018. See March 2018 PDCO minutes (to be published post April 2018 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 20-23 March 2018.

1.3. Adoption of the minutes

PDCO minutes for 20-23 February 2018.

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. Palonosetron / fosnetupitant - EMEA-001198-PIP03-17

Prevention of Chemotherapy-Induced Nausea and Vomiting

Day 120 opinion

Action: For adoption

Other

2.1.2. Irbesartan / Amlodipine - EMEA-002192-PIP02-17

Treatment of essential hypertension as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of amlodipine and irbesartan taken as two single-component formulations.

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.3. Dusquetide - EMEA-002306-PIP01-17

Treatment of Oral Mucositis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.4. Xentuzumab - EMEA-002228-PIP01-17

Breast malignant neoplasms

Day 60 opinion

Action: For adoption, Oral Explanation Meeting to be held on 21 March 2018 at 14:00-15:00

Oncology

2.1.5. - EMEA-002291-PIP01-17

Treatment of dry eye disease

Day 60 opinion

Action: For adoption

Ophthalmology

2.1.6. Ranibizumab - EMEA-000527-PIP05-17

Diabetic retinopathy (DR)

Day 60 opinion

Action: For adoption

Ophthalmology

2.1.7. Clostridium botulinum neurotoxin type A - EMEA-001039-PIP03-17

Treatment of hemifacial spasm

Day 60 opinion

Action: For adoption

Ophthalmology / Neurology

2.1.8. Ibuprofen / paracetamol - EMEA-002002-PIP02-17

R52, R50.9 / Fever, unspecified, Pain, unspecified

Day 60 opinion

Action: For adoption

Other / Pain

2.1.9. Eszopiclone - EMEA-002309-PIP01-17

F51.0

Day 60 opinion

Action: For adoption

Psychiatry

2.1.10. Tenofovir Alafenamide / Emtricitabine - EMEA-001577-PIP03-17

Prevention of human immunodeficiency virus (HIV-1) infection / In combination with safer sex practices for prevention of HIV-1 infection in adolescents aged 12 years and above

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. Dabigatran etexilate mesilate - EMEA-C3-000081-PIP01-07-M10

Boehringer Ingelheim International GmbH; Treatment of thromboembolic events

Day 60 letter

Action: For adoption

Cardiovascular Diseases / Haematology-Hemostaseology

2.2.2. Ibrutinib - EMEA-C2-001397-PIP03-14-M03

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

Day 60 letter

Action: For adoption

Oncology

2.2.3. Lanadelumab - EMEA-C2-001864-PIP01-15-M02

Shire Pharmaceuticals Ireland Limited; Prevention of hereditary angioedema attacks

Day 1 letter

Action: For adoption

Others

2.2.4. Abatacept - EMEA-C-000118-PIP02-10-M03

Bristol-Myers Squibb Pharma EEIG; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis)

Day 1 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.2.1. Omadacycline - EMEA-C1-000560-PIP02-15

Paratek UK Limited; Treatment of acute bacterial skin and skin structure infections (ABSSSI)

Day 30 letter

Action: For adoption

Infectious Diseases

2.2.2. Omadacycline - EMEA-C1-000560-PIP03-15

Paratek UK Limited; Treatment of bacterial pneumonia

Day 30 letter

Action: For adoption

Infectious Diseases

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Angiotensin II - EMEA-001912-PIP02-16-M01

La Jolla Pharmaceutical II B.V.; Hypotension associated with distributive or vasodilatory shock

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. Treprostinil - EMEA-000207-PIP01-08-M06

Ferrer Internacional, S.A.; Primary pulmonary hypertension, Other secondary hypertension / Treatment of pulmonary arterial hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.3. Edoxaban (tosylate) - EMEA-000788-PIP02-11-M07

Daiichi Sankyo Europe GmbH; Prevention of arterial thromboembolism, Prevention of venous thromboembolism, Treatment of venous thromboembolism / Prevention of arterial thromboembolism in paediatric cardiac patients at risk of thrombotic events, Acute treatment & secondary prevention of symptomatic recurrent venous thrombotic events (VTE) in paediatric patients at risk

Day 60 opinion

Action: For adoption

Cardiovascular Diseases / Haematology-Hemostaseology

2.3.4. Liquid ethanolic extract 30 per cent (w/w) of Allium cepa L. (fresh bulb) and Citrus limon (L.) Burm. f. (fresh fruit), Paullinia cupana Kunth, Theobroma cacao L. - EMEA-001835-PIP01-15-M03

LEGACY HEALTHCARE; Treatment of alopecia

Day 60 opinion

Action: For adoption

Dermatology

2.3.5. Testosterone - EMEA-001529-PIP02-14-M01

Acerus Biopharma Inc.; Male hypogonadism

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.6. Guselkumab - EMEA-001523-PIP02-14-M02

Janssen Cilag International NV; Treatment of psoriasis / Treatment of severe plaque psoriasis in children ≥6 to <18 years of age who cannot be adequately controlled with

topical agents and/or phototherapy

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.7. Peginterferon alfa-2a - EMEA-000298-PIP01-08-M06

Roche Registration Ltd; Treatment of Chronic Hepatitis C in combination with other agent(s), Treatment of chronic hepatitis B

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.8. Galcanezumab - EMEA-001860-PIP03-16-M01

Eli Lilly and Company Limited; Prevention of migraine headaches

Day 60 opinion

Action: For adoption

Neurology

2.3.9. Inebilizumab - Orphan - EMEA-001911-PIP01-15-M01

MedImmune, LLC; neuromyelitis optica (NMO) or NMO spectrum disorders (NMOSD)

Day 60 opinion

Action: For adoption

Neurology

2.3.10. Sunitinib malate - EMEA-000342-PIP01-08-M07

Pfizer Limited; CD10 code C49.4 malignant neoplasms of connective and soft tissue of abdomen - gastro-intestinal stromal tumours (GIST) / Treatment of gastro-intestinal stromal tumour in paediatric patients aged 6 to less than 18

Day 60 opinion

Action: For adoption

Oncology

2.3.11. Naloxone hydrochloride - EMEA-001567-PIP01-13-M03

Develco Pharma GmbH; Treatment of opioid-induced constipation

Day 60 opinion

Action: For adoption

Other / Pain / 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. - EMEA-001527-PIP02-17

Treatment of obesity

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.2. Lasmiditan - EMEA-002166-PIP01-17

Migraine with and without aura

Day 90 discussion

Action: For discussion

Neurology

3.1.3. 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 90 discussion

Action: For discussion

Nutrition

3.1.4. Anetumab ravtansine - Orphan - EMEA-002123-PIP01-17

Bayer AG; Treatment of acute myeloid leukaemia, Treatment of mesothelioma / , Treatment of patients from 6 months to less than 18 years of age with relapsed and/or refractory mesothelin-positive acute myeloid leukaemia

Day 90 discussion

Action: For discussion

Oncology

3.1.5. Daratumumab - Orphan - EMEA-002152-PIP01-17

Janssen-Cilag international N.V.; Lymphoid malignancies except mature B-cell neoplasms / Daratumumab in combination with standard chemotherapy is indicated for the treatment of paediatric patients from birth to 18 years with T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma

Day 90 discussion

Action: For discussion

Oncology

3.1.6. 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 90 discussion

Action: For discussion

Oncology

3.1.7. Etripamil - EMEA-002303-PIP01-17

Treatment of acute paroxysmal supraventricular tachycardia (PSVT)

Day 60 discussion

Action: For discussion

Cardiovascular Diseases

3.1.8. - EMEA-002312-PIP01-17

Treatment of moderate to severe atopic dermatitis inadequately responsive to topical

therapies or where topical treatments are not appropriate.

Day 60 discussion

Action: For discussion

Dermatology

3.1.9. - EMEA-001710-PIP04-17

Treatment of Crohn's disease

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.10. Cenicriviroc - EMEA-001999-PIP02-17

NASH with Stage 2-3 fibrosis

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.11. Fluticasone propionate - Orphan - EMEA-002289-PIP01-17

Adare Pharmaceuticals; eosinophilic esophagitis

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.12. Hepcidin-25 acetate - Orphan - EMEA-002083-PIP01-16

La Jolla Pharmaceutical II B.V.; Treatment of iron overload

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.13. Human monoclonal IgG1 antibody against Tissue Factor Pathway Inhibitor - Orphan - EMEA-002285-PIP01-17

Pfizer Limited; Treatment of coagulation disorders congenital

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.14. Voclosporin - EMEA-002264-PIP01-17

Treatment of Systemic Lupus Erythematosus / Treatment of Active Lupus Nephritis

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.15. Upadacitinib Hemihydrate - EMEA-001741-PIP04-17

Treatment of Atopic Dermatitis

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Dermatology

3.1.16. Brincidofovir - Orphan - EMEA-001904-PIP02-17

Chimerix UK Limited; Treatment of AdV in immunocompromised patients

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.17. Evobrutinib - EMEA-002284-PIP01-17

Treatment of multiple sclerosis

Day 60 discussion

Action: For discussion

Neurology

3.1.18. Sarizotan Hydrochloride - Orphan - EMEA-001808-PIP03-17

Newron Pharmaceuticals SpA; Treatment of Rett Syndrome

Day 60 discussion

Action: For discussion

Neurology

3.1.19. Immunoglobulin G4 - EMEA-002290-PIP01-17

Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours, haematopoietic and lymphoid tissue neoplasms) / in combination with nivolumab for the treatment of malignant solid tumours in paediatric patients from 6 months to less than 18 years old.

Day 60 discussion

Action: For discussion

Oncology

3.1.20. Diphtheria Toxin Interleukin-3 Fusion Protein - Orphan - EMEA-002244-PIP01-17

Stemline Therapeutics, Inc.; Treatment of all conditions included in the category of myeloid and lymphoid neoplasms expressing CD123.

Day 60 discussion

Action: For discussion

Oncology

3.1.21. Molgramostim - Orphan - EMEA-002282-PIP01-17

Savara ApS; Treatment of Pulmonary Alveolar Proteinosis / Treatment of children from 2 to less than 18 years with secondary pulmonary alveolar proteinosis, Treatment of children from 2 to less than 18 years with autoimmune pulmonary alveolar proteinosis

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.22. Mavacamten - EMEA-002231-PIP01-17

Treatment of Hypertrophic Cardiomyopathy / Treatment of obstructive Hypertrophic Cardiomyopathy

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.23. Trandolapril / verapamil - EMEA-002276-PIP01-17

Hypertension in adults

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.24. Somapacitan - EMEA-001469-PIP02-17

Growth hormone deficiency, Short stature (ICD10 code: R6252)/ Treatment of paediatric patients with short stature born small for gestational age (SGA) with insufficient catch-up growth by age 2 to 4 years.

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.25. Relamorelin - EMEA-002323-PIP01-17

Diabetic Gastroparesis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.26. Brincidofovir - Orphan - EMEA-001904-PIP03-18

Chimerix UK Limited; Treatment of smallpox

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.27. Ibalizumab - EMEA-002311-PIP01-17

Treatment of human immunodeficiency virus (HIV-1) infection / Ibalizumab, a CD4 domain 2-directed HIV-1 inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of children and adolescents (aged 6 to less than 18 years) infected with HIV-1 resistant to at least 1 agent in 3 different classes.

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.28. Pretomanid - Orphan - EMEA-002115-PIP01-17

Global Alliance for TB Drug Development; Treatment of multi-drug-resistant tuberculosis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.29. Rezafungin acetate - EMEA-002319-PIP01-17

Treatment of invasive candidiasis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.30. Tedizolid phosphate - EMEA-001379-PIP03-17

Treatment of Gram-positive bacterial pneumonia

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.31. Andecaliximab - EMEA-002304-PIP01-17

Treatment of gastric adenocarcinoma

Day 30 discussion

Action: For discussion

Oncology

3.1.32. Brigatinib - EMEA-002296-PIP01-17

Inflammatory Myofibroblastic Tumors (IMT), Non-small cell lung cancer (NSCLC), Anaplastic large cell lymphoma (ALCL) / Treatment of anaplastic lymphoma kinase (ALK) positive advanced non-small cell lung cancer (NSCLC), Treatment of paediatric patients ≥2 years of age with ALK+ unresectable or recurrent IMT, Treatment in combination with standard chemotherapy in paediatric patients ≥2 years of age with newly diagnosed ALK+ ALCL at high risk for recurrence.

Day 30 discussion

Action: For discussion

Oncology

3.1.33. Botulinum Toxin Type A - EMEA-002149-PIP02-17

Cervical dystonia

Day 30 discussion

Action: For discussion

Other

3.1.34. Palovarotene - EMEA-001662-PIP03-17

Treatment of Multiple Osteochondromas (MO)

Day 30 discussion

Action: For discussion

Other

3.1.35. Meloxicam / Bupivacaine - EMEA-002246-PIP01-17

Acute Post Operative Pain

Day 30 discussion

Action: For discussion

Pain / Anaesthesiology

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. Drospirenone - EMEA-C-001495-PIP01-13-M01

LABORATIORIOS LEÓN FARMA, S.A.; Prevention of pregnancy

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.2. Cobicistat / Darunavir - EMEA-C2-001280-PIP01-12-M01

Janssen-Cilag International NV; Treatment of HIV-1 infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.3. Glecaprevir/ Pibrentasvir - EMEA-C1-001832-PIP01-15

AbbVie Ltd; Treatment of chronic hepatitis C

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.4. Ozanimod - EMEA-C3-001710-PIP02-14-M02

Celgene Europe Limited; Treatment of Multiple Sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.2.5. Conestat Alfa - EMEA-C-000367-PIP01-08-M07

Pharming Group N.V.; Treatment of hereditary angioedema (HAE)

Day 30 discussion

Action: For discussion

Other

3.2.6. Ivacaftor - EMEA-C8-000335-PIP01-08-M12

Vertex Pharmaceuticals (Europe) Limited; Treatment of cystic fibrosis

Day 30 discussion

Action: For discussion

Other

3.2.7. Esketamine hydrochloride - EMEA-C1-001428-PIP03-15

Janssen-Cilag International NV; Treatment of Major Depressive Disorder

Day 30 discussion

Action: For discussion

Psychiatry

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Apixaban - EMEA-000183-PIP01-08-M06

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 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. Apixaban - EMEA-000183-PIP02-12-M02

Bristol-Myers Squibb / Pfizer EEIG; Treatment of venous thromboembolism

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.3. Betrixaban - EMEA-001834-PIP02-16-M01

Portola Pharma UK Limited; Prevention of venous thromboembolism

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.4. Apremilast - EMEA-000715-PIP03-11-M05

Celgene Europe Limited; Psoriasis in children

Day 30 discussion

Action: For discussion

Dermatology

3.3.5. Dupilumab - EMEA-001501-PIP01-13-M05

Regeneron Pharmaceuticals, Inc; Atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.3.6. Empagliflozin - EMEA-000828-PIP04-16-M01

Boehringer Ingelheim International GmbH; Treatment of type 1 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.7. Vestronidase alfa - Orphan - EMEA-001540-PIP01-13-M03

Ultragenyx Germany GmbH; ICD-10: E76.2/ Treatment of Mucopolysaccharidosis type VII (MPS VII)

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.8. Human Fibrinogen - EMEA-001208-PIP01-11-M04

Octapharma Pharmazeutika Produktionsges.m.b.H; Treatment of congenital fibrinogen deficiency, Treatment of acquired fibrinogen deficiency

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.9. Baricitinib - EMEA-001220-PIP01-11-M03

Eli Lilly and Company Limited; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis) / Treatment of juvenile idiopathic arthritis, Treatment of JIA-associated uveitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.10. Emapalumab - Orphan - EMEA-002031-PIP01-16-M01

Novimmune B.V; Treatment of Haemophagocytic Lymphohistiocytosis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.11. Ceftaroline fosamil - EMEA-000769-PIP01-09-M08

Pfizer Limited; Treatment of cSSTI (complicated skin and soft tissue infections) / Treatment of CAP (community-aquired pneumonia)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.12. Ceftazidime / avibactam - EMEA-001313-PIP01-12-M07

Pfizer Limited; Treatment of bacterial infections / For the treatment of complicated urinary tract infections, For the treatment hospital acquired pneumonia, For the treatment of complicated intra-abdominal infections, For the treatment of Gram-negative bacterial infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.13. Dasabuvir sodium monohydrate - EMEA-001439-PIP01-13-M02

Abbvie Ltd; Treatment of chronic hepatitis C / Treatment of children and adolescents from >= 3 years to less than 18 years of age with chronic HCV infection with compensated cirrhosis or without compensated cirrhosis in combination with ombitasvir, paritaprevir and ritonavir

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.14. - EMEA-001975-PIP01-16-M01

Janssen-Cilag International NV; Treatment of influenza

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.15. Lamivudine / Dolutegravir - EMEA-001940-PIP01-16-M01

ViiV Healthcare UK Limited; Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.16. Ritonavir / paritaprevir / ombitasvir - EMEA-001440-PIP01-13-M02

Abbvie Ltd; Chronic Hepatitis C (HCV) infection / Treatment of children and adolescents from >= 3 years to < 18 years of age with chronic HCV infection with compensated cirrhosis or without compensated cirrhosis in combination with other medicinal products

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.17. Sofosbuvir - EMEA-001276-PIP01-12-M02

Gilead Sciences International Ltd.; Treatment of chronic Hepatitis C in adolescents and children 3 years of age and older

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.18. Tenofovir Alafenamide / Emtricitabine - EMEA-001577-PIP02-14-M03

Gilead Sciences International Ltd.; Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.19. Velpatasvir / Sofosbuvir - EMEA-001646-PIP01-14-M02

Gilead Sciences International Ltd.; Treatment of chronic Hepatitis C in adolescents and children 3 years of age and older

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.20. Fenfluramine hydrochloride - Orphan - EMEA-001990-PIP01-16-M01

Zogenix International Ltd; Dravet syndrome / The adjunctive treatment of seizures in paediatric patients at least 1 year of age with Dravet syndrome

Day 30 discussion

Action: For discussion

Neurology

3.3.21. Perampanel - EMEA-000467-PIP01-08-M09

Eisai Europe Limited; Treatment of treatment-resistant epilepsies / Adjunctive therapy in patients with other paediatric epilepsies, Adjunctive therapy in patients with refractory partial onset seizures including secondarily generalised seizures

Day 30 discussion

Action: For discussion

Neurology

3.3.22. Spheroids of human autologous matrix-associated chondrocytes - EMEA-001264-PIP01-12-M02

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

3.3.23. Formoterol fumarate dihydrate / Beclometasone dipropionate - EMEA-000548-PIP01-09-M08

Chiesi Farmaceutici S.p.A.; COPD, Asthma / Maintenance therapy of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate: - patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting beta2-agonist or - patients already adequately controlled on both inhaled corticosteroids and long-acting beta2-agonists

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.24. Peanut flour - EMEA-001734-PIP01-14-M02

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

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.25. Lurasidone hydrochloride - EMEA-001230-PIP01-11-M04

AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.p.A.; Schizophrenia / Schizophrenia

Day 30 discussion

Action: For discussion

Psychiatry

3.3.26. Etelcalcetide - EMEA-001554-PIP01-13-M02

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

Day 30 discussion

Action: For discussion

Uro-nephrology

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 29 May 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. Recombinant human monoclonal antibody to GM-CSF - EMEA-02-2018

GlaxoSmithKline Trading Services Limited; Primary and secondary osteoarthrosis/ Treatment of osteoarthritis in adult patients who are not adequately controlled by

NSAIDs

Action: For adoption

6.1.2. Inhibitor of ADAMTS-5 - EMEA-03-2018

LES LABORATOIRES SERVIER; Treatment of primary and secondary osteoarthrosis/ Treatment of mild to moderate osteoarthritis of the knee and hip to reduce the degradation of cartilage

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. Change to timing of Scientific Committee Chair and Vice-Chair elections

Action: For information

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. Committee for Medicinal Products for Human Use (CHMP)

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. Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP)

Draft Agenda of the PCWP/HCPWP joint meeting – 17-18 April 2018

Action: For information

Draft PCWP/HCPWP Work Plan for 2018-2019

Action: For adoption

9.3.4. Modelling and Simulation Working Group (MSWG)

Draft Paediatric Questions & Answers

MSWG member: Flora Musuamba Tshinanu and Kirstin Karlsson

Action: For discussion

9.4. Cooperation within the EU regulatory network

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

Action: For information

9.4.2. Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)

Request for PDCO advice (EMEA-000018-PIP01-07-M13)

PDCO member: Sabine Scherer

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

None

9.8. Planning and reporting

9.8.1. Strategic Review and Learning Meeting (SRLM) to be held in Vienna on 26-28 September 2018

PDCO member: Karl-Heinz Huemer

Action: For information

10. Any other business

10.1. AOB topic

10.1.1. Reflections and action plans following the Multi-stakeholder workshop to further improve the implementation of the paediatric regulation (held on Tuesday 20 March 2018)

Action: For discussion

10.1.2. Involvement of young people at PDCO

Report on the conclusions of the discussion, which took place on 15 March 2018, on how to trigger involvement of young people in the PDCO.

PDCO members: Helena Fonseca, Francesca Rocchi, Dimitrios Athanasiou, Viviana Giannuzzi

Action: For information

11. Breakout sessions

11.1.1. Paediatric oncology

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

11.1.2. Neonatology

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

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/