19 February 2018
EMA/PDCO/66082/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 20-23 February 2018

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

20 February 2018, 14:00- 17:00, room 3A

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

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

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

1.2. Adoption of agenda

PDCO agenda for 20-23 February 2018.

1.3. Adoption of the minutes

PDCO minutes for 23-26 January 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. - EMEA-002162-PIP01-17

type 2 diabetes mellitus

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.2. Obeticholic Acid - EMEA-001304-PIP03-17

NASH / NASH with Fibrosis

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.3. Plazomicin Sulfate - EMEA-001639-PIP02-17

Infections due to enterobacteriaceae in patients with limited treatment options, complicated urinary tract infections including pyelonephritis / Treatment of infections due to enterobacteriaceae in patients with limited treatment options, Treatment of complicated urinary tract infections

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.4. Ixazomib - Orphan - EMEA-001410-PIP02-17

Takeda Pharm A/S; Treatment of Acute Lymphoblastic Leukaemia (ALL), Treatment of Multiple Myeloma / Treatment of adult patients with Newly Diagnosed Multiple Myeloma (NDMM), Treatment of paediatric patients diagnosed with relapsed precursor B-ALL or T-ALL, Maintenance treatment of paediatric patients with newly diagnosed intermediate-risk or very high risk T-ALL/LLy

Day 120 opinion

Action: For adoption

Oncology

2.1.5. Fevipiprant - EMEA-001315-PIP02-16

Asthma / Treatment of uncontrolled persistent asthma

Day 120 opinion

Action: For adoption

Pneumology - Allergology

2.1.6. B from Yamagata VLP Influenza Drug Substance (4 of 4) / B from Victoria lineage VLP Influenza Drug Substance (3 of 4) / H3 VLP Influenza Drug Substance (2 of 4) / Plant-derived Quadrivalent VLP Influenza vaccine composed of 4 active substances: H1 VLP Influenza Drug Substance (1 of 4) - EMEA-002220-PIP01-17

Prevention of influenza / For active immunization of persons six months of age and older for the prevention of influenza caused by influenza virus subtypes A and type B covered by the vaccine.

Day 120 opinion

Action: For adoption

Vaccines

2.1.7. Rosuvastatin / ezetimibe - EMEA-001344-PIP02-17

Prevention of Cardiovascular Events

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.8. Humanized recombinant IgG4 anti-human tau antibody - Orphan - EMEA-002226-PIP02-17

AbbVie Ltd; Progressive Supranuclear Palsy

Day 60 opinion

Action: For adoption

Neurology

2.1.9. Enfortumab vedotin - EMEA-002299-PIP01-17

Treatment of locally advanced or metastatic urothelial cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.10. Polatuzumab vedotin - EMEA-002255-PIP01-17

Treatment of Diffuse Large B-Cell lymphoma (DLBCL), Treatment of Burkitt lymphoma, Burkitt leukemia (BL/B-ALL), Treatment of Follicular lymphoma (FL)

Day 60 opinion

Action: For adoption

Oncology

2.1.11. Rovalpituzumab tesirine - Orphan - EMEA-002292-PIP01-17

AbbVie Ltd; Treatment of lung carcinoma (small cell and non-small cell carcinoma)

Day 60 opinion

Action: For adoption

Oncology

2.1.12. - EMEA-002293-PIP01-17

Oxaliplatin induced peripheral neuropathy (CIPN)

Day 60 opinion

Action: For adoption

Other / Oncology

2.1.13. Recombinant human acid ceramidase - Orphan - EMEA-002266-PIP01-17

Enzyvant Farber Ireland Ltd; Farber disease

Day 60 opinion

Action: For adoption

Other

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. Crisaborole - EMEA-C2-002065-PIP01-16

Pfizer Limited; Treatment of atopic dermatitis

Day 60 letter

Action: For adoption

Dermatology

2.2.2. Lubiprostone - EMEA-C3-000245-PIP01-08-M04

Sucampo AG; Treatment of Constipation

Day 60 letter

Action: For adoption

Gastroenterology-Hepatology

2.2.3. Fc- and CDR-modified humanised monoclonal antibody against C5 - EMEA-C1-002077-PIP01-16-M01

Alexion Europe SAS; Treatment of Paroxysmal Nocturnal Haemoglobinuria

Day 60 letter

Action: For adoption

Haematology-Hemostaseology

2.2.4. Glutamine - EMEA-C1-001996-PIP02-16

Emmaus Medical Europe Ltd; Treatment of sickle cell disease

Day 60 letter

Action: For adoption

Haematology-Hemostaseology

2.2.5. Belatacept - EMEA-C3-000157-PIP01-07-M03

Bristol-Myers Squibb Pharma EEIG; Prevention of rejection of transplanted kidney

Day 60 letter

Action: For adoption

Immunology-Rheumatology-Transplantation

2.2.6. Tocilizumab - EMEA-C-000309-PIP01-08-M07

Roche Registration Limited; Chronic Idiopathic Arthritis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.2.7. Dasatinib (as monohydrate) - EMEA-C-000567-PIP01-09-M05

Bristol-Myers Squibb Pharma EEIG; Treatment of Philadelphia chromosome (BCR-ABL translocation)-positive acute lymphoblastic leukaemia

Day 60 opinion

Action: For adoption

Oncology

2.2.8. Influenza virus surface antigens (haemagglutinin and neuraminidase) of the following strains: A/<Official Strain>(H1N1), A/<Official Strain>(H3N2), B/<Official Strain>Yamagata lineage, B/<Official Strain>Victoria lineage based on annual recommendations by WHO, CHMP (EU) and other regional or local authorities / Influenza virus surface antigens (haemagglutinin and neuraminidase) of the following strains: A/<Official Strain>(H1N1), A/<Official Strain>(H3N2), B/<Official Strain>Yamagata lineage, B/<Official Strain>Victoria lineage based on annual recommendations by WHO, CHMP (EU) and other regional or local authorities - EMEA-C2-001782-PIP01-15-M02

Abbott Biologicals B.V.; Prevention of influenza infection

Day 60 letter

Action: For adoption

Vaccines

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Dopamine hydrochloride - EMEA-001105-PIP01-10-M04

BrePco Biopharma Limited; Other hypotension (I95.8) / Treatment of hypotension in neonates including the extremely low gestational age newborn. Treatment of hypotension in infants and children.

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. Evolocumab - EMEA-001268-PIP01-12-M05

Amgen Europe B.V.; Treatment of mixed dyslipidaemia, Treatment of elevated cholesterol / Heterozygous Familial Hypercholesterolaemia (HeFH) and Homozygous Familial Hypercholesterolaemia (HoFH) after Prior Lipid-Lowering Therapy in paediatric subjects aged 10 years and above

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.3. Crisaborole - EMEA-002065-PIP01-16-M01

Pfizer Ltd; Mild to moderate atopic dermatitis

Day 60 opinion

Action: For adoption

Dermatology

2.3.4. Tilmanocept - EMEA-001255-PIP01-11-M03

Norgine BV; Visualisation of lymphatic drainage of solid tumours for diagnostic purposes / Visualisation of lymphatic drainage of rhabdomyosarcoma and melanoma for diagnostic purposes

Day 60 opinion

Action: For adoption

Diagnostic / Oncology

2.3.5. Vedolizumab - EMEA-000645-PIP01-09-M06

Takeda Pharma A/S; Crohn's Disease, Ulcerative colitis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.6. Luspatercept - Orphan - EMEA-001521-PIP01-13-M02

Celgene Europe Ltd; Anemias due to chronic disorders / Treatment of anemia in patients with b-thalassemia

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.7. Abatacept - EMEA-000118-PIP02-10-M03

Bristol-Myers Squibb Pharma EEIG; Chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthitis)

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.8. Dalbavancin - EMEA-000016-PIP01-07-M06

Allergan Pharmaceuticals International Limited; Treatment of acute bacterial skin and skin structure infections

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.9. Nusinersen - Orphan - EMEA-001448-PIP01-13-M03

Biogen Idec Ltd; Spinal muscular atrophy

Day 60 opinion

Action: For adoption

Neurology

2.3.10. Peginterferon beta-1a - EMEA-001129-PIP01-11-M02

Biogen Idec Ltd; Multiple Sclerosis / Treatment of relapsing remitting forms of Multiple Sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.3.11. Ponesimod - EMEA-000798-PIP01-09-M01

Actelion Registration Ltd; Multiple Sclerosis / Relapsing Remitting forms of Multiple Sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.3.12. Autologous CD4+ and CD8+ T cells Expressing a CD19-Specific Chimeric Antigen Receptor - Orphan - EMEA-001995-PIP01-16-M01

Celgene Europe Limited; Treatment of B-lymphoblastic leukemia/lymphoma, Treatment of mature B-cell neoplasms / Treatment of paediatric patients with CD19+ relapsed or refractory B-cell acute lymphoblastic leukaemia, Treatment of paediatric patients with CD19+ relapsed or refractory diffuse-large B-cell lymphoma, Burkitt lymphoma or primary mediastinal large B-cell lymphoma

Day 60 opinion

Action: For adoption

Oncology

2.3.13. Quizartinib - Orphan - EMEA-001821-PIP01-15-M01

Daiichi Sankyo Europe GmbH; Treatment of acute myeloid leukaemia / For the treatment of paediatric patients aged from 1 month to less than 18 years of age with newly diagnosed AML with FLT3-ITD mutations., For the treatment of paediatric patients aged from 1 month to less than 18 years of age with refractory or relapsed AML with FLT3-ITD mutations after failure of front line intensive chemotherapy regimen, in combination with standard chemotherapy.

Day 60 opinion

Action: For adoption

Oncology

2.3.14. Andexanet alfa - EMEA-001902-PIP01-15-M02

Portola Pharma UK Limited; prevention of factor Xa inhibitor associated haemorrhage, treatment of factor Xa inhibitor associated haemorrhage / For the reversal of anticoagulation due to direct and indirect factor Xa inhibitors in patients requiring urgent surgery, For the reversal of anticoagulation due to direct and indirect factor Xa inhibitors in patients experiencing an acute major bleeding episode

Day 60 opinion

Action: For adoption

Other

2.3.15. Concentrate of proteolytic enzyme enriched in bromelain - Orphan - EMEA-000142-PIP02-09-M06

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

Day 60 opinion

Action: For adoption

Other

2.3.16. Lanadelumab - Orphan - EMEA-001864-PIP01-15-M02

Shire Pharmaceuticals Ireland Limited; Hereditary angioedema / Treatment of hereditary angioedema

Day 60 opinion

Action: For adoption

Other

2.3.17. Palovarotene - Orphan - EMEA-001662-PIP01-14-M02

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

Day 60 opinion

Action: For adoption

Other

2.3.18. Methoxyflurane - EMEA-000334-PIP01-08-M07

Medical Developments UK Ltd; treatment of acute pain / 1. Self administration to conscious patients with minor trauma and associated pain, under supervision of personnel trained in its use, 2. For the management of acute pain associated with short surgical procedures, such as the change of dressings, dislocations and injections.

Day 60 opinion

Action: For adoption

Pain

2.3.19. Tapentadol - EMEA-000325-PIP01-08-M09

Grünenthal GmbH; Treatment of chronic pain

Day 60 opinion

Action: For adoption

Pain

2.3.20. Benralizumab - EMEA-001214-PIP01-11-M07

AstraZeneca AB; Asthma

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.4. Opinions on Re-examinations

2.4.1. Midostaurin - Orphan - EMEA-000780-PIP01-09-M04

Novartis Europharm Ltd; C92.0 Acute myeloid leukaemia, C94.3 Mast cell leukaemia, C96.2 Malignant mastocytosis / Treatment of paediatric patients with FLT3 mutated AML, newly diagnosed

Day 30 opinion

Action: For adoption, Oral Explanation Meeting to be held on 22 February 2018 at 10:30-11:30

Oncology

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

Prevention of Chemotherapy-Induced Nausea and Vomiting

Day 90 discussion

Action: For discussion

Other

3.1.2. Neladenoson bialanate - EMEA-002262-PIP01-17

Treatment of Heart Failure

Day 60 discussion

Action: For discussion

Cardiovascular Diseases

3.1.3. - EMEA-002287-PIP01-17

Treatment of Type 2 Diabetes Mellitus

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.4. - EMEA-002310-PIP01-17

Treatment of paroxysmal nocturnal haemoglobinuria

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.5. Baricitinib - EMEA-001220-PIP04-17

Treatment of systemic lupus erythematosus

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.6. Recombinant IgG degrading enzyme of Streptococcus pyogenes - Orphan - EMEA-002183-PIP01-17

Hansa Medical AB; Patients with chronic kidney disease in need of kidney transplantation / Prevention of graft rejection following solid organ transplantation

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.7. Aztreonam / Avibactam sodium - EMEA-002283-PIP01-17

Infections caused by Gram-negative bacteria, including those that produce metallo-β-lactamases, for which there are limited or no treatment options. / For the treatment of complicated urinary tract infections, For the treatment of Ventilator associated pneumonia, For the treatment of complicated intra-abdominal infections, For the treatment of hospital-acquired pneumonia

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.8. Ridinilazole - EMEA-002250-PIP02-17

Treatment of Clostridium difficile Infection (CDI) and reducing the recurrence of CDI

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.9. Tafenoquine - EMEA-002301-PIP01-17

Prevention of malaria

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.10. Allogeneic Epstein-Barr virus specific cytotoxic T lymphocytes - Orphan - EMEA-002025-PIP03-17

Atara Biotherapeutics, Inc.; Treatment of Epstein-Barr virus associated lymphoproliferative diseases in patients with primary immune disorders

Day 60 discussion

Action: For discussion

Oncology

3.1.11. Ipilimumab / nivolumab - EMEA-002049-PIP01-16

Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours, haematopoietic and lymphoid tissue neoplasms). / Treatment of patients with unresectable or metastatic melanoma in the age group from 12 to less than 18 years old, Treatment of a paediatric malignant solid tumour in paediatric patients from 6 months to less than 18 years old.

Day 60 discussion

Action: For discussion

Oncology

3.1.12. Ivosidenib - EMEA-002247-PIP02-17

Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours, haematopoietic and lymphoid tissue neoplasms), Treatment of malignant neoplasms of the central nervous system / Treatment of paediatric patients (2 to less than 18 years of age) with recurrent or progressive (R/P) malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms), including central nervous system tumours, with an isocitrate dehydrogenase-1 (IDH1) mutation.

Day 60 discussion

Action: For discussion

Oncology

3.1.13. Ivosidenib - Orphan - EMEA-002247-PIP03-17

Agios Pharmaceuticals, Inc.; Treatment of Acute Myeloid Leukaemia / Treatment of paediatric patients from 2 to less than 18 years of age with newly diagnosed and relapsed or refractory (R/R) AML with an isocitrate dehydrogenase-1 (IDH1) mutation.

Day 60 discussion

Action: For discussion

Oncology

3.1.14. Olaparib - Orphan - EMEA-002269-PIP01-17

AstraZeneca AB; Treatment of all conditions included in the category of malignant neoplasms (except central nervous system [CNS], haematopoietic, and lymphoid tissue). / Treatment of paediatric patients from 6 months to ≤18 years old with homologous recombination repair (HRR) mutated solid tumours

Day 60 discussion

Action: For discussion

Oncology

3.1.15. Olodanrigan - EMEA-002286-PIP01-17

Peripheral neuropathic pain / Treatment of moderate to severe peripheral neuropathic pain

Day 60 discussion

Action: For discussion

Pain

3.1.16. - EMEA-002310-PIP02-17

Treatment of C3 glomerulopathy

Day 60 discussion

Action: For discussion

Uro-nephrology

3.1.17. Ferric Pyrophosphate Citrate - EMEA-002261-PIP01-17

Iron deficient anaemia / Treatment of iron deficient anaemia in haemodialysis patients

Day 60 discussion

Action: For discussion

Uro-nephrology / Haematology-Hemostaseology

3.1.18. Etripamil - EMEA-002303-PIP01-17

Treatment of acute paroxysmal supraventricular tachycardia (PSVT)

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

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

Treatment of Essential Hypertension / 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 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.20. - EMEA-002312-PIP01-17

Treatment of moderate to severe atopic dermatitis inadequately responsive to topical therapies or where topical treatments are not appropriate.

Day 30 discussion

Action: For discussion

Dermatology

3.1.21. - EMEA-001710-PIP04-17

Treatment of Crohn's disease

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.22. Cenicriviroc - EMEA-001999-PIP02-17

NASH with Stage 2-3 fibrosis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.23. Dusquetide - EMEA-002306-PIP01-17

Treatment of Oral Mucositis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

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

Adare Pharmaceuticals; eosinophilic esophagitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

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

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

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

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

Pfizer Limited; Treatment of coagulation disorders congenital

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.27. Voclosporin - EMEA-002264-PIP01-17

Treatment of Systemic Lupus Erythematosus / Treatment of Active Lupus Nephritis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

Treatment of Atopic Dermatitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Dermatology

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

Chimerix UK Limited; Treatment of adenovirus (AdV) infections in immunocompromised patients

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.30. 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 30 discussion

Action: For discussion

Infectious Diseases

3.1.31. Evobrutinib - EMEA-002284-PIP01-17

Treatment of Multiple Sclerosis

Day 30 discussion

Action: For discussion

Neurology

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

Newron Pharmaceuticals SpA; Treatment of Rett Syndrome

Day 30 discussion

Action: For discussion

Neurology

3.1.33. 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 30 discussion

Action: For discussion

Oncology

3.1.34. 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. / Treatment of all conditions included in the category of myeloid and lymphoid neoplasms expressing CD123.

Day 30 discussion

Action: For discussion

Oncology

3.1.35. Xentuzumab - EMEA-002228-PIP01-17

Breast malignant neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.1.36. - EMEA-002291-PIP01-17

Treatment of dry eye disease

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.37. Ranibizumab - EMEA-000527-PIP05-17

Diabetic retinopathy (DR)

Day 30 discussion

Action: For discussion

Ophthalmology

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

Treatment of hemifacial spasm

Day 30 discussion

Action: For discussion

Ophthalmology / Neurology

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

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

Day 30 discussion

Action: For discussion

Other / Pain

3.1.40. 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 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.41. Eszopiclone - EMEA-002309-PIP01-17

F51.0

Day 30 discussion

Action: For discussion

Psychiatry

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

Boehringer Ingelheim International GmbH; Treatment of thromboembolic events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases / Haematology-Hemostaseology

3.2.2. Brentuximab vedotin - EMEA-C3-000980-PIP01-10-M05

Takeda Pharma A/S; Treatment of Hodgkin lymphoma

Day 30 discussion

Action: For discussion

Oncology

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

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

Day 30 discussion

Action: For discussion

Oncology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

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

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

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

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

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

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.3. 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 30 discussion

Action: For discussion

Cardiovascular Diseases / Haematology-Hemostaseology

3.3.4. - EMEA-001835-PIP01-15-M03

Legacy Healthcare; Treatment of alopecia

Day 30 discussion

Action: For discussion

Dermatology

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

Acerus Biopharma Inc.; Male hypogonadism

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. 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 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.8. Delta-9-tetrahydrocannabinol / Cannabidiol - EMEA-000181-PIP01-08-M05

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

Day 30 discussion

Action: For discussion

Neurology

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

Eli Lilly and Company Limited; Prevention of migraine headaches

Day 30 discussion

Action: For discussion

Neurology

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

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

Day 30 discussion

Action: For discussion

Neurology

3.3.11. 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 30 discussion

Action: For discussion

Oncology

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

Develco Pharma GmbH; Treatment of opioid-induced constipation

Day 30 discussion

Action: For discussion

Other / Pain / Gastroenterology-Hepatology

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 02 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. fixed combination with apalutamide and abiraterone acetate- EMEA-20-2017

Janssen-Cilag International N.V; The classes of androgen receptor modulator, of oestrogen receptor modulator, of growth and sex hormone as well as their releasing or inhibiting factors, and of sex hormone-metabolism modulator medicinal products for treatment of breast malignant neoplasms, prostate malignant neoplasms and neuroendocrine malignant neoplasms/ Apalutamide in combination with abiraterone acetate (ZYTIGA), prednisone and ADT (GnRHa or orchiectomy) is indicated for the treatment of metastatic castration

resistant prostate cancer that has progressed after treatment with GnRHa or orchiectomy

Action: For adoption

6.1.2. Budesonide, glycopyrronium bromide, formoterol fumarate dihydrate - EMEA-01-2018

AstraZeneca AB; All classes of medicinal products for treatment of chronic obstructive pulmonary disease (COPD) (excluding chronic lung diseases associated with long-term airflow limitation, such as asthma, bronchopulmonary dysplasia, primary cilia dyskinesia, obstructive lung disease related to graft-versus-host disease after [bone-marrow] transplantation)/ Maintenance treatment of patients with moderate to severe COPD

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

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

Action: For information

9.2.1.1. Joint CHMP/PDCO session

Action: For discussion

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

Estimands

CHMP member: Robert Hemmings

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: Karen van Malderen

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.3.3. Guideline on the clinical investigation of recombinant and 4 human plasma-derived factor VIII products

Action: For information

9.3.4. Q&A on paediatric aspects on the use of modeling and simulation in paediatric development – POSTPONED TO MARCH PDCO

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

9.4.2. European Directorate for the Quality of Medicines and HealthCare (EDQM)

Update on EDQM PaedForm project

PDCO member: Siri Wang

Action: For information

9.5. Cooperation with International Regulators

None

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

None

9.7. PDCO work plan

None

9.8. Planning and reporting

None

10. Any other business

10.1. AOB topic

10.1.1. Multi-stakeholder workshop to further improve the implementation of the paediatric regulation

Scope: Update on the organisation of the workshop

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/