



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

16 May 2017
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Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Agenda for the meeting on 16-19 May 2017

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

16 May 2017, 14:00- 19:00, room 2F

17 May 2017, 08:30- 19:00, room 2F

18 May 2017, 08:30- 19:00, room 2F

19 May 2017, 08:30- 13:00, room 2F

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 16-19 May 2017. See May 2017 PDCO minutes (to be published post June 2017 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 16-19 May 2017.

1.3. Adoption of the minutes

PDCO minutes for 18-21 April 2017.

2. Opinions

Disclosure of some information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

2.1. Opinions on Products

2.1.1. Iacosamide - EMEA-000402-PIP03-17

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

Day 30 opinion

Action: For adoption

Neurology

2.1.2. Empagliflozin - EMEA-000828-PIP04-16

Treatment of type 1 diabetes mellitus

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.3. Seletalisib - EMEA-001938-PIP01-16

Primary Immunodeficiency syndrome

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.4. Omadacycline - EMEA-000560-PIP02-15

Treatment of acute bacterial skin and skin structure infections (ABSSSI)

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.5. Omadacycline - EMEA-000560-PIP03-15

Treatment of bacterial pneumonia

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.6. Larotrectinib - Orphan - EMEA-001971-PIP02-16

Loxo Oncology, Inc.; Treatment of solid tumours / The treatment of adults, adolescents, children and infants with advanced solid tumours harbouring an NTRK fusion, as established prior to initiation of larotrectinib therapy

Day 120 opinion

Action: For adoption

Oncology

2.1.7. Fluocinolone Acetonide - Orphan - EMEA-000801-PIP03-16

CAMPHARM Limited; Chronic non-infectious uveitis affecting the posterior segment of the eye

Day 120 opinion

Action: For adoption

Ophthalmology

2.1.8. Mexiletine hydrochloride - Orphan - EMEA-002012-PIP01-16

Lupin (Europe) Ltd.; Treatment of myotonic disorders / Symptomatic treatment of myotonic disorders

Day 120 opinion

Action: For adoption

Other

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

Prevention of dengue fever

Day 120 opinion

Action: For adoption

Vaccines

2.1.10. Amlodipine / Rosuvastatin - EMEA-002130-PIP01-17

Treatment of angina and dyslipidaemia, Treatment of concomitant hypertension and dyslipidemia, Treatment of essential hypertension in patients who are estimated to have a high risk for a first cardiovascular event

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.11. Amlodipine / Rosuvastatin - EMEA-002136-PIP01-17

Treatment of angina and dyslipidaemia, Treatment of concomitant hypertension and dyslipidemia, Treatment of essential hypertension in patients who are estimated to have a high risk for a first cardiovascular event

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.12. dezamizumab - Orphan - EMEA-002110-PIP02-17

GlaxoSmithKline Trading Services Limited; Treatment of transthyretin amyloidosis (ATTR)

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.13. Ezetimibe / Rosuvastatin (calcium) - EMEA-002131-PIP01-17

Treatment of hypercholesterolaemia

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.14. Ezetimibe / Rosuvastatin (calcium) - EMEA-002135-PIP01-17

Treatment of hypercholesterolaemia

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.15. Hydrochlorothiazide / Amlodipine besilate / Olmesartan medoxomil - EMEA-002104-PIP01-16

Essential Hypertension (MedDRA PT: 10015488)

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.16. miridesap - Orphan - EMEA-002111-PIP02-17

GlaxoSmithKline Trading Services Limited; Treatment of transthyretin amyloidosis (ATTR)

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.17. Benzydamine hydrochloride / Econazole nitrate - EMEA-002143-PIP01-17

Treatment of vulvovaginal candidosis (VVC)

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.18. dezamizumab - Orphan - EMEA-002110-PIP01-17

GlaxoSmithKline Trading Services Limited; Systemic AL amyloidosis

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.19. miridesap - Orphan - EMEA-002111-PIP01-17

GlaxoSmithKline Trading Services Limited; Systemic AL amyloidosis

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.20. (6aR,10aR)-1-Hydroxy-6,6-dimethyl-3-(2-methyl-2-octanyl)-6a,7,10,10a-tetrahydro-6H-benzo[c]chromene-9-carboxylic acid - Orphan - EMEA-002069-PIP01-16

Corbus Pharmaceuticals Inc.; Treatment of Systemic Sclerosis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.21. efavirenz / lamivudine / abacavir - EMEA-002114-PIP01-16

Treatment of human immunodeficiency virus (HIV-1) infection

Day 60 opinion

Action: For adoption

Infectious Diseases

2.1.22. pseudoephedrine HCl / ibuprofen - EMEA-002102-PIP01-16

J06.9/For the relief of symptoms of cold and flu with associated pain, fever, congestion and runny nose

Day 60 opinion

Action: For adoption

Infectious Diseases / Oto-rhino-laryngology

2.1.23. Radium Ra 223 dichloride - EMEA-001986-PIP01-16

C00 - C70, C73 - C80, C97: Treatment of all conditions contained in the category of malignant neoplasms (except central nervous system tumours, haematopoietic and lymphoid tissue neoplasms), C90: Treatment of Multiple Myeloma

Day 60 opinion

Action: For adoption

Oncology

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. Cinacalcet (as hydrochloride) - EMEA-C-000078-PIP01-07-M08

Amgen Europe B.V.; Hyperparathyroidism and other disorders of parathyroid gland (E21), Other disorders resulting from impaired renal tubular function. Secondary hyperparathyroidism of renal origin (N25.8), Treatment of secondary hyperparathyroidism (HPT) in patients with end-stage renal disease (ESRD) on maintenance dialysis therapy

Day 0 opinion

Action: For adoption

Uro-nephrology

2.2.2. emicizumab - EMEA-C1-001839-PIP01-15

Roche Registration Limited; Treatment of Hereditary FVIII Deficiency

Day 60 letter

Action: For adoption

Haematology-Hemostaseology

2.2.3. mepolizumab - EMEA-C1-000069-PIP04-13-M01

GSK Trading Services Limited; Treatment of vasculitides

Day 60 letter

Action: For adoption

Pneumology - Allergology

2.2.4. mirabegron - EMEA-C2-000597-PIP02-10-M05

Astellas Pharma Europe B.V.; Treatment of Idiopathic overactive bladder

Day 60 letter

Action: For adoption

Uro-nephrology

2.2.5. [mirabegron - EMEA-C2-000597-PIP03-15-M03](#)

Astellas Pharma Europe B.V.; Treatment of neurogenic detrusor overactivity

Day 60 letter

Action: For adoption

Uro-nephrology

2.3. **Opinions on Modification of an Agreed Paediatric Investigation Plan**

2.3.1. [lacosamide - EMEA-000402-PIPO2-11-M04](#)

UCB Pharma S.A.; Treatment of Epilepsy - Partial-onset seizures [G40.0 - G40.1 - G40.2] / Adjunctive therapy in the treatment of partial-onset seizures with or without secondary generalization in pediatric patients with epilepsy (birth to <16 years), Monotherapy in the treatment of partial-onset seizures with or without secondary generalization in pediatric patients (1 month to <18 years)

Day 30 opinion

Action: For adoption

Neurology

2.3.2. [ferric maltol - EMEA-001195-PIP01-11-M03](#)

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

Day 30 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.3. [Dobutamine - EMEA-001262-PIP01-12-M03](#)

Proveca Limited; Circulatory impairment / haemodynamic insufficiency

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.4. ticagrelor - EMEA-000480-PIP01-08-M10

AstraZeneca AB; thromboembolic events (children), acute coronary syndrome, history of myocardial infarction / reduction in occurrence of vaso-occlusive crises in paediatric patients with sickle cell disease, waiver

Day 60 opinion

Action: For adoption

Cardiovascular Diseases / Haematology-Hemostaseology

2.3.5. Lonoctocog alfa - EMEA-001215-PIP01-11-M05

CSL Behring GmbH; Haemophilia A

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.6. Apremilast - Orphan - EMEA-000715-PIP05-13-M01

Celgene Europe Limited; Treatment of Behcets Disease / Treatment of patients with active oral ulcers (with or without genital ulcers) associated with Behcets Disease, who are candidates for systemic therapy

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.7. Certolizumab pegol - EMEA-001071-PIP02-12-M02

UCB Pharma S.A.; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis) / Treatment of juvenile idiopathic arthritis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.8. Aciclovir - EMEA-001066-PIP02-11-M02

ONXEO; Treatment of herpes simplex labialis / Treatment of recurrent herpes simplex virus infections of the lips in immunocompetent children aged 10 to less than 18 years

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.9. cobicistat / atazanavir sulphate - EMEA-001465-PIP01-13-M01

Bristol-Myers Squibb Pharma EEIG; Treatment of HIV-1 infection / indicated in combination with other ARV medicinal products for the treatment of HIV-1 infected adults and adolescents from 12 years of age without known mutations associated with resistance to atazanavir

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.10. Colistimethate sodium - Orphan - EMEA-000176-PIP01-07-M05

TEVA B.V.; Cystic fibrosis with pulmonary manifestations ICD-10 (version 2007) E84.0 / Treatment of Pseudomonas aeruginosa pulmonary infection in patients with cystic fibrosis aged 6 years and over

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.11. Velpatasvir / Sofosbuvir - EMEA-001646-PIP01-14-M01

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.12. Dimethyl fumarate - EMEA-000832-PIP01-10-M04

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

Day 60 opinion

Action: For adoption

Neurology

2.3.13. ozanimod - EMEA-001710-PIP02-14-M01

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

Day 60 opinion

Action: For adoption

Neurology

2.3.14. Teriflunomide - EMEA-001094-PIP01-10-M04

Genzyme Europe B.V. / Sanofi-Aventis groupe; Multiple Sclerosis / Treatment of children and adolescents from 10 to less than 18 years of age with relapsing forms of Multiple Sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.3.15. pazopanib - EMEA-000601-PIP01-09-M04

Novartis Europharm Limited; Ewing sarcoma family of tumours, Rhabdomyosarcoma, Non-rhabdomyosarcoma soft tissue sarcoma / Treatment of pediatric patients with rhabdomyosarcoma, Treatment of pediatric patients with Ewing sarcoma family of tumours, Treatment of pediatric patients with non-rhabdomyosarcoma soft tissue sarcoma

Day 60 opinion

Action: For adoption

Oncology / Uro-nephrology

2.3.16. CYSTEAMINE HYDROCHLORIDE - Orphan - EMEA-000322-PIP01-08-M05

ORPHAN EUROPE SARL; CYSTINOSIS / Treatment of corneal cystine crystal deposits in cystinosis

Day 60 opinion

Action: For adoption

Ophthalmology

2.3.17. Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with lentiviral vector that encodes for the human ARSA cDNA sequence - Orphan - EMEA-001765-PIP02-15-M01

GlaxoSmithKline Trading Services Limited; For the treatment of metachromatic leukodystrophy (MLD)

Day 60 opinion

Action: For adoption

Other

2.3.18. methoxyflurane - EMEA-000334-PIP01-08-M06

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. Ivacaftor - EMEA-001640-PIP01-14-M02

Vertex Pharamceuticals (Europe) ITd; Treatment of Cystic Fibrosis

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.20. vilanterol / vilanterol - EMEA-000431-PIP01-08-M10

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

Day 60 opinion

Action: For adoption

Pneumology - Allergology

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

Alexion Europe SAS; Paroxysmal Nocturnal Haemoglobinuria / Treatment of Paroxysmal Nocturnal Haemoglobinuria

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.2. Daunorubicin (liposomal combination) / Cytarabine (liposomal combination) - Orphan - EMEA-001858-PIP02-16

Jazz Pharmaceuticals Ireland Limited; Acute myeloid

Day 90 discussion

Action: For discussion

Oncology

3.1.3. Venetoclax - Orphan - EMEA-002018-PIP02-16

AbbVie Ltd; Treatment of haematopoietic and lymphoid malignant neoplasms, Treatment of solid tumour malignant neoplasms / As monotherapy, or in combination with chemotherapy, for the treatment of relapsed or refractory NHL patients < 18 years of age, who have progressed following autologous stem cell transplantation or who are ineligible for transplantation, As monotherapy or in combination for the treatment of patients with relapsed or refractory neuroblastoma < 18 years of age, As monotherapy, or in combination with chemotherapy, for the treatment of relapsed or refractory ALL in the third line setting in patients < 18 years of age, As monotherapy, or in combination with chemotherapy, for the treatment of relapsed or refractory AML in patients < 18 years of age

Day 90 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.1.4. 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 90 discussion

Action: For discussion

Vaccines

3.1.5. EMEA-001749-PIP02-16

Treatment of Atopic Dermatitis

Day 60 discussion

Action: For discussion

Dermatology

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

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

Day 60 discussion

Action: For discussion

Neurology

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

Treatment of insomnia

Day 60 discussion

Action: For discussion

Neurology

3.1.8. Sulindac / Eflornithine - Orphan - EMEA-001518-PIP02-16

Cancer Prevention Pharma Ltd.; Treatment of Familial Adenomatous Polyposis

Day 60 discussion

Action: For discussion

Oncology

3.1.9. Lactobacillus reuteri - Orphan - EMEA-001895-PIP01-15

Infant Bacterial Therapeutics AB; Prevention of necrotising enterocolitis

Day 60 discussion

Action: For discussion

Other / Neonatology - Paediatric Intensive Care / Gastroenterology-Hepatology

3.1.10. EMEA-002148-PIP01-17

Treatment of venous and mixed (venous/arterial) leg ulcers

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.11. macitentan - Orphan - EMEA-001032-PIP02-17

Actelion Registration Ltd.; Chronic Thromboembolic Pulmonary Hypertension (CTEPH)

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.12. Methacholine Chloride - EMEA-002120-PIP01-17

Diagnosis of asthma

Day 30 discussion

Action: For discussion

Diagnostic

3.1.13. Empagliflozin - EMEA-000828-PIP05-17

Prevention of cardiovascular events in patients with chronic heart failure

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases

3.1.14. Recombinant protein derived from the saliva of Ornithodoros moubata tick - EMEA-002100-PIP01-16

Atypical haemolytic uraemic syndrome

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.15. Recombinant protein derived from the saliva of Ornithodoros moubata tick - Orphan - EMEA-002100-PIP02-16

Akari Therapeutics plc; Paroxysmal nocturnal haemoglobinuria

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.16. tocilizumab - EMEA-000309-PIP04-17

Treatment of SSc (ICD 10-M34)/scleroderma and associated disorders (MedDRA)/
Treatment of juvenile Systemic Sclerosis (jSSc) in children 5 years of age and older

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.17. Cefiderocol - EMEA-002133-PIP01-17

Treatment of Gram-negative bacterial infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.18. 5-[4-[2-(5-(1-hydroxyethyl)-2-pyridinyl)ethoxy]benzyl]-2,4-thiazolidinedione hydrochloride - Orphan - EMEA-002106-PIP01-16

Minoryx Therapeutics SL; Treatment of adrenoleukodystrophy / Treatment of X-linked adrenoleukodystrophy

Day 30 discussion

Action: For discussion

Neurology

3.1.19. Adeno-associated viral vector serotype rh.10 carrying the human N-sulfoglucosamine sulfohydrolase cDNA - Orphan - EMEA-002122-PIP02-17

LYSOGENE; Mucopolysaccharidosis type IIIA

Day 30 discussion

Action: For discussion

Neurology

3.1.20. H-Tyr-Gly-Arg-Lys-Lys-Arg-Arg-Gln-Arg-Arg-Arg-Lys-Leu-Ser-Ser-Ile-Glu-Ser-Asp-Val-OH (YGRKKRRQRRRLSSIESDV) - EMEA-002108-PIP01-16

Acute Ischemic Stroke (AIS) in adult subjects with a large intracranial arterial occlusion, a

small ischemic core, and good collaterals

Day 30 discussion

Action: For discussion

Neurology

3.1.21. Recombinant humanized anti-alpha-synuclein IgG1 monoclonal antibody - EMEA-002137-PIP01-17

treatment of Parkinson's disease (in adults)

Day 30 discussion

Action: For discussion

Neurology

3.1.22. Entrectinib - Orphan - EMEA-002096-PIP01-16

Ignity, Inc.; 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 primary brain tumours with NTRK1/2/3, ROS1 or ALK gene fusions, Treatment of extracranial solid tumours with NTRK1/2/3, ROS1 or ALK gene fusions

Day 30 discussion

Action: For discussion

Oncology

3.1.23. OSIMERTINIB MESYLATE - EMEA-002125-PIP01-17

Treatment of lung carcinoma (small cell and non-small cell carcinoma)

Day 30 discussion

Action: For discussion

Oncology

3.1.24. Pevonedistat - EMEA-002117-PIP01-17

Acute Myeloid Leukemia (AML), Myelodysplastic Syndromes (MDS) / The treatment of paediatric patients with relapsed or refractory (R/R) MDS (including juvenile myelomonocytic leukemia), The treatment of paediatric patients with relapsed or refractory (R/R) AML.

Day 30 discussion

Action: For discussion

Oncology

3.1.25. Pexastimogene devacirepvec - Orphan - EMEA-002124-PIP01-17

Transgene S.A.; Treatment of hepatocellular carcinoma. (MedDra PT: 10073071)

Day 30 discussion

Action: For discussion

Oncology

3.1.26. daxibotulinumtoxinA - EMEA-002149-PIP01-17

Treatment for temporary improvement in the appearance of moderate to severe glabellar lines with corrugator and/or procerus muscle activity in adults

Day 30 discussion

Action: For discussion

Other

3.1.27. Diclofenac sodium - EMEA-002132-PIP01-17

Symptomatic relief of pain associated with osteoarthritis, Symptomatic relief of mild to moderate pain and inflammation / Indicated for the symptomatic relief of pain associated with osteoarthritis in superficial joints, including the knee., For the local symptomatic relief of mild to moderate pain and inflammation following acute blunt trauma of small and medium-sized joints and periarticular structures, such as trauma of the tendons, ligaments, muscles and joints e.g. due to sprains and strains.

Day 30 discussion

Action: For discussion

Pain

3.1.28. EMEA-002121-PIP01-17

Treatment of insomnia / Treatment of attention deficit hyperactivity disorder (ADHD)-related insomnia

Day 30 discussion

Action: For discussion

Psychiatry

3.1.29. Recombinant Clostridium difficile Toxoid B / Recombinant Clostridium difficile Toxoid A - EMEA-002112-PIP01-16

Prevention of Clostridium difficile infection (CDI) / Active immunization for the prevention of primary Clostridium difficile infection in children and adolescents 2 to 18 years of age

Day 30 discussion

Action: For discussion

Vaccines

3.2. Discussions on Compliance Check

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

3.2.1. Brentuximab vedotin - EMEA-C2-000980-PIP01-10-M04

Takeda Pharma A/S; Treatment of anaplastic large cell lymphoma

Day 12 discussion

Action: For discussion

Oncology

3.2.2. Tofacitinib - EMEA-C1-000576-PIP03-12

Pfizer Limited; Treatment of Ulcerative Colitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.3. Human normal immunoglobulin - EMEA-C1-001797-PIP01-15

Octapharma Pharamzeutika Produktionsges.m.b.H; Treatment of primary immunodeficiency

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology

3.2.4. Dolutegravir (DTG) / Rilpivirine (RPV) - EMEA-C1-001750-PIP01-15-M01

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.5. Clostridium Botulinum neurotoxin type A (150 kD), free from complexing proteins - EMEA-C1-001039-PIP01-10-M02

Merz Pharmaceuticals GmbH; Treatment of muscle spasticity

Day 30 discussion

Action: For discussion

Neurology

3.2.6. Ibrutinib - EMEA-C1-001397-PIP03-14-M02

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. apixaban - EMEA-000183-PIP01-08-M05

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

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. Allantoin - Orphan - EMEA-001590-PIP01-13-M04

Scioderm, Inc.; Treatment of epidermolysis bullosa

Day 30 discussion

Action: For discussion

Dermatology

3.3.3. Asfotase alfa - Orphan - EMEA-000987-PIP01-10-M03

Alexion Europe SAS; Treatment of hypophosphatasia

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. [Canagliflozin - EMEA-001030-PIP01-10-M07](#)

Janssen-Cilag International NV; Treatment of Type 2 Diabetes Mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. [Liraglutide - EMEA-000128-PIP01-07-M08](#)

Novo Nordisk A/S; E11 Non-insulin-dependent diabetes mellitus / Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. [semaglutide - EMEA-001441-PIP02-15-M01](#)

Novo Nordisk; Type 2 Diabetes Mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.7. [Sodium zirconium cyclosilicate - EMEA-001539-PIP01-13-M02](#)

AstraZeneca AB; Treatment of Hyperkalaemia

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.8. [sotagliflozin - EMEA-001517-PIP01-13-M01](#)

sanofi-aventis R&D; Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.9. sotagliflozin - EMEA-001517-PIP02-14-M01

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

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.10. Obeticholic Acid (6 alpha-ethylchenodeoxycholic acid) - Orphan - EMEA-001304-PIP02-13-M03

Intercept Pharma Ltd.; Primary Biliary Cirrhosis (PBC) / Biliary Atresia

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.11. Coagulation Factor VIIa (Recombinant) - EMEA-001203-PIP02-14-M02

LFB SA; Treatment of congenital coagulation disorders, Treatment of acquired haemophilia / Treatment of bleeding and prevention of bleeding in those undergoing surgery or invasive procedures in patients with haemophilia A or B with inhibitors to Factors VIII or IX, Treatment of bleeding and prevention of bleeding in those undergoing surgery or invasive procedures in patients with acquired haemophilia

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.12. Damoctocog alfa pegol - Orphan - EMEA-001229-PIP01-11-M03

Bayer AG; Treatment of hereditary factor VIII deficiency / Treatment and prophylaxis of bleeding in patients with haemophilia A (hereditary factor VIII deficiency).

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.13. Luspatercept - Orphan - EMEA-001521-PIP01-13-M01

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

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.14. Recombinant fusion protein linking coagulation factor IX with albumin - Orphan - EMEA-001107-PIP01-10-M03

CSL Behring GmbH; Treatment of hereditary factor IX deficiency

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.15. Recombinant Fusion Protein Linking Coagulation Factor VIIa with Albumin (rVIIa-FP) - Orphan - EMEA-001886-PIP01-15-M01

CSL Behring GmbH; Treatment of Haemophilia B, Treatment of Haemophilia A / Treatment of Haemophilia B with Inhibitors, Treatment of Haemophilia A with Inhibitors

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.16. Recombinant Fusion Protein Linking Coagulation Factor VIIa with Albumin (rVIIa-FP) - Orphan - EMEA-001886-PIP02-15-M01

CSL Behring GmbH; Treatment of congenital Factor VII Deficiency / Treatment of congenital Factor VII Deficiency

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.17. Romiplostim - Orphan - EMEA-000653-PIP01-09-M05

Amgen Europe B.V.; Treatment of disease-related thrombocytopenia in myelodysplastic syndrome, Treatment of immune thrombocytopenia (idiopathic thrombocytopenic purpura) / Treatment of chronic immune thrombocytopenia (idiopathic thrombocytopenic purpura; ITP) in paediatric patients who are refractory or intolerant to other treatments (e.g., glucocorticosteroids, immunoglobulins, splenectomy)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.18. Treosulfan - Orphan - EMEA-000883-PIP01-10-M04

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

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Oncology

3.3.19. Lamivudine (3TC) / Abacavir (ABC) / Dolutegravir (DTG) - EMEA-001219-PIP01-11-M03

ViiV Healthcare UK Limited; Treatment Human Immunodeficiency Virus (HIV-1) infection in paediatric population

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.20. Tenofovir Alafenamide / Emtricitabine - EMEA-001577-PIP02-14-M02

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.21. Tenofovir Alafenamide / Emtricitabine / Cobicistat / Elvitegravir - EMEA-001460-PIP01-13-M02

Gilead Sciences International Ltd.; Treatment of human immunodeficiency virus (HIV-1) infection / treatment of HIV-1 infection in paediatric patients from 6 years to less than 18 years.

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.22. zanamivir - EMEA-001318-PIP01-12-M02

GlaxoSmithKline Trading Services Limited; Treatment of influenza, Prevention of influenza / Treatment of influenza A and B virus infection, Prevention of influenza A and B virus infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.23. Bivalent anti-human myostatin adnectin recombinant human IgG1-Fc fusion protein - EMEA-001793-PIP01-15-M02

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 30 discussion

Action: For discussion

Neurology

3.3.24. Brentuximab vedotin - Orphan - EMEA-000980-PIP01-10-M05

Takeda Pharma A/S; Treatment of Hodgkin Lymphoma / Treatment of paediatric patients with newly diagnosed, relapsed or refractory Hodgkin Lymphoma (from 5 years of age)

Day 30 discussion

Action: For discussion

Oncology

3.3.25. decitabine - Orphan - EMEA-000555-PIP01-09-M06

Janssen-Cilag International NV; Treatment of acute myeloid leukemia / Treatment of paediatric patients with acute myeloid leukaemia who have high-risk cytogenetics, or are refractory to, or have a relapse after first-line treatment

Day 30 discussion

Action: For discussion

Oncology

3.3.26. Isopropyl Alcohol / Chlorhexidine Gluconate - EMEA-000989-PIP01-10-M02

3M Health Care Limited; Prevention of infection

Day 30 discussion

Action: For discussion

Other

3.3.27. ivacaftor / lumacaftor - EMEA-001582-PIP01-13-M06

Vertex Pharmaceuticals (Europe) Limited; Treatment of cystic fibrosis

Day 30 discussion

Action: For discussion

Other

3.3.28. Recombinant Varicella Zoster Virus (VZV) glycoprotein E - EMEA-001426-PIP01-13-M01

GlaxoSmithKline Biologicals SA; Prevention of Varicella Zoster Virus reactivation /
Prevention of herpes zoster in immunocompromised subjects aged 1 to 17 years

Day 30 discussion

Action: For discussion

Vaccines

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 18 July 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 volunteers for the Paediatric addendum to CHMP guidelines on the clinical investigations of Venous thromboembolism (VTE)

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

None

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

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

7.1.1. rilpivirine (as hydrochloride) - EMEA-000317-PIP01-08-M09

Janssen Infectious Diseases BVBA/Janssen-Cilag International NV; Treatment of human immunodeficiency virus (HIV-1) infection

Proposed indication: Maintenance of virologic suppression in HIV-1-infected patients without evidence of prior virologic failure on ARV therapy, in combination with cabotegravir long acting

Action: For adoption

8. Annual reports on deferrals

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

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

None

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

Action: For information

Joint CHMP/PDCO session

Action: For information

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

9.3.1. Non-clinical Working Group: D30 Products identified and Election of the Non-clinical Working Group Chair

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.3.3. Paediatric Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections

PDCO member: Maria Fernandez Cortizo

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

9.5. Cooperation with International Regulators

9.5.1. Gaucher disease - A strategic collaborative approach from EMA and FDA

PDCO member: Sylvie Benchetrit

Action: For information

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

None

9.7. PDCO work plan

None

9.8. Planning and reporting

9.8.1. Report from the Strategic Review and Learning Meeting held in Malta on 11-12 April 2017

PDCO Chair: Dirk Mentzer; PDCO member: Herbert Lenicker

Action: For information

10. Any other business

10.1.1. Preparedness of the system and capacity increase

Action: For discussion

11. Breakout sessions

11.1.1. Paediatric oncology

Action: For discussion on Thursday, 14:00 – 15:00, room 3M

11.1.2. Neonatology

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

11.1.3. Inventory

Action: For discussion on Thursday, 14:00 – 15:00,

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/