



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

18 April 2017
EMA/PDCO/213348/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 18-21 April 2017

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

18 April 2017, 14:00- 17:00, room 2F

19 April 2017, 08:30- 19:00, room 2F

20 April 2017, 08:30- 19:00, room 2F

21 April 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 ongoing 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 18-21 April 2017. See April 2017 PDCO minutes (to be published post May 2017 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 18-21 April 2017.

1.3. Adoption of the minutes

PDCO minutes for 21-24 March 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. Expanded donor-derived allogeneic T cells transduced with the retroviral vector expressing the transgenes for inducible caspase9 and the truncated CD19 selectable marker - Orphan - EMEA-001869-PIP01-15

Bellicum Pharma Ltd.; Treatment in haematopoietic stem cell transplantation / Treatment of immunodeficiency after mismatched, related, allogeneic transplantation in paediatric patients with malignant and non-malignant disorders amenable to haematopoietic stem cell transplantation

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.2. Rimiducid - Orphan - EMEA-001870-PIP01-15

Bellicum Pharma Ltd.; Treatment of Graft Versus Host Disease (ICD 279.50) / Treatment of graft versus host disease (GvHD) in paediatric patients who have received a mismatched, related, allogeneic haematopoietic stem cell transplantation together with rivotigenlecleucel (expanded T lymphocytes transduced with a retroviral vector containing inducible caspase 9 and truncated CD19).

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.3. EMEA-001975-PIP01-16

Treatment of influenza

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.4. Cannabidiol - Orphan - EMEA-001964-PIP01-16

GW Research Ltd; Treatment of seizures associated with Tuberous Sclerosis Complex (TSC), Treatment of seizures associated with Dravet Syndrome (DS), Treatment of seizures associated with Infantile Spasms (IS), Treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) / Treatment of seizures associated with Tuberous Sclerosis Complex (TSC), Treatment of seizures associated with Dravet Syndrome (DS), Treatment of seizures associated with Infantile Spasms (IS), Treatment of seizures associated with Lennox-Gastaut Syndrome (LGS)

Day 120 opinion

Action: For adoption

Neurology

2.1.5. Polihexanide (PHMB) - Orphan - EMEA-002053-PIP01-16

Società Industria Farmaceutica Italiana (S.I.F.I.) SpA; ICD10: B.60.1 Keratitis and keratoconjunctivitis (interstitial) in acanthamoebiasis

Day 120 opinion

Action: For adoption

Ophthalmology

2.1.6. Ezetimibe / Rosuvastatin (calcium) - EMEA-002118-PIP01-17

Treatment of hypercholesterolaemia

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.7. Nimodipine - Orphan - EMEA-002097-PIP01-16

Edge Therapeutics, Inc.; Treatment of aneurysmal subarchnoidal haemorrhage

Day 60 opinion

Action: For adoption

Neurology

2.1.8. Malic acid / Zinc sulphate / Sodium acetate / Potassium chloride / Magnesium sulphate / Sodium glycerophosphate / Calcium chloride / Glucose / Valine / Tyrosine / Tryptophan / Threonine / Serine / Proline / Phenylalanine / Methionine / Lysine acetate / Leucine / Isoleucin / Histidine / Glycine / Arginine / Alanine / Acetyl-cysteine / Fish oil / Olive oil / Medium-chain triglycerides / Soybean oil - EMEA-002067-PIP02-17

Need for parenteral nutrition

Day 60 opinion

Action: For adoption

Nutrition

2.1.9. Buprenorphine hydrochloride - EMEA-002099-PIP01-16

Treatment of opioid dependence

Day 60 opinion

Action: For adoption

Psychiatry

2.2. Opinions on Compliance Check

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

2.2.1. Tetracaine hydrochloride / oxymetazoline hydrochloride - EMEA-C-001764-PIP03-15

St. Renatus, LLC; Local anesthesia

Day 60 opinion

Action: For adoption

Anaesthesiology

2.2.2. voretigene neparvovec - EMEA-C-001684-PIP01-14

Spark Therapeutics Inc.; Treatment of genetic congenital retinal disorders

Day 60 opinion

Action: For adoption

Ophthalmology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Cinacalcet (as hydrochloride) - EMEA-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 30 opinion

Action: For adoption

Uro-nephrology

2.3.2. Rubidium Rb-82 Chloride - EMEA-000882-PIP03-11-M03

Jubilant DraxImage Inc.; Visualization of myocardial perfusion for diagnostic purposes

Day 60 opinion

Action: For adoption

2.3.3. Enalapril maleate - EMEA-001706-PIP01-14-M01

Ethicare GmbH; Treatment of Heart Failure

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.4. rivaroxaban - EMEA-000430-PIP01-08-M10

Bayer Pharma AG; Treatment of thromboembolic events, Prevention of thromboembolic events, Treatment (secondary prevention) of venous thromboembolism

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.5. Apremilast - EMEA-000715-PIP03-11-M04

Celgene Europe Limited; Psoriasis in children

Day 60 opinion

Action: For adoption

Dermatology

2.3.6. Telbivudine - EMEA-000065-PIP01-07-M05

Novartis Europharm Limited; Treatment of chronic hepatitis B / Treatment of children and adolescents from 2 to below 18 years of age with compensated HBeAg-positive or HBeAg-negative chronic hepatitis B

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.7. vedolizumab - EMEA-000645-PIP01-09-M05

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

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.8. turoctocog alfa pegol - Orphan - EMEA-001174-PIP02-12-M02

Novo Nordisk A/S; ICD10 - D66 - Hereditary factor VIII deficiency

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.9. Sirukumab - EMEA-001043-PIP01-10-M03

Janssen-Cilag International NV; Children: Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondyloarthritis, psoriatic arthritis and juvenile idiopathic arthritis) (ICD: M08), Adults: Rheumatoid Arthritis (ICD: M05), Treatment of juvenile idiopathic arthritis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.10. Isavuconazonium (sulfate) - Orphan - EMEA-001301-PIP02-12-M01

Basilea Pharmaceutica International Ltd.; Treatment of mucormycosis, Treatment of

invasive aspergillosis

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.11. Laquinimod - EMEA-000972-PIP01-10-M05

Teva GmbH; Multiple Sclerosis (MS) / Treatment of relapsing remitting multiple sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.3.12. olatumab - Orphan - EMEA-001760-PIP01-15-M02

Eli Lilly and Company Limited; Treatment of Soft Tissue Sarcoma, Treatment of Osteosarcoma / Treatment of recurrent rhabdomyosarcoma in children aged from birth to less than 18 years in combination with a standard-of-care chemotherapy regimen, First-line treatment of osteosarcoma in children aged from 5 to 18 years in combination with a standard-of-care chemotherapy regimen.

Day 60 opinion

Action: For adoption

Oncology

2.3.13. Human recombinant IgG1 monoclonal antibody targeting fibroblast growth factor 23 (FGF23) - Orphan - EMEA-001659-PIP01-15-M02

Ultragenyx Pharmaceutical Inc.; X-linked Hypophosphatemia

Day 60 opinion

Action: For adoption

Other

2.3.14. ivacaftor - Orphan - EMEA-000335-PIP01-08-M11

Vertex Pharmaceuticals (Europe) Limited; Treatment of Cystic Fibrosis

Day 60 opinion

Action: For adoption

Other

2.3.15. Tapentadol - EMEA-000325-PIP01-08-M07

Grünenthal GmbH; Treatment of chronic pain

Day 60 opinion

Action: For adoption

Pain

2.3.16. Mometasone furoate / Indacaterol acetate (dose expressed as free base) - EMEA-001217-PIP01-11-M03

NOVARTIS EUROPHARM LTD.; Treatment of asthma

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. Empagliflozin - EMEA-000828-PIP04-16

Treatment of type 1 diabetes mellitus

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.2. Cenicriviroc mesylate - EMEA-001999-PIP01-16

Treatment of liver fibrosis in patients with nonalcoholic steatohepatitis

Day 90 discussion

Action: For discussion

3.1.3. Seletalisib - EMEA-001938-PIP01-16

Primary Immunodeficiency syndrome

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.4. Omadacycline - EMEA-000560-PIP02-15

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

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.5. Omadacycline - EMEA-000560-PIP03-15

Treatment of bacterial pneumonia

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.6. 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 90 discussion

Action: For discussion

Oncology

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

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

Day 90 discussion

Action: For discussion

Ophthalmology

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

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

Day 90 discussion

Action: For discussion

Other

3.1.9. 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 90 discussion

Action: For discussion

Vaccines

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

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

Day 60 discussion

Action: For discussion

Cardiovascular Diseases

3.1.11. Iucerastat - Orphan - EMEA-002095-PIP01-16

Actelion Registration Ltd.; Treatment of Fabry disease

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

Iron deficiency anemia, Iron deficiency

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.13. Human anti-interferon gamma monoclonal antibody - Orphan - EMEA-002031-PIPO1-16

Novimmune B.V; Treatment of histiocytosis haematophagic conditions

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.14. Pexidartinib - Orphan - EMEA-001939-PIP03-16

Daiichi Sankyo Inc; Benign soft tissue neoplasms except tenosynovial giant cell tumour, Tenosynovial giant cell tumour, Treatment of debilitating tenosynovial giant cell tumour (TGCT), also known as pigmented villonodular synovitis (PVNS) and giant cell tumour of the tendon sheath (GCT-TS), in paediatric patients from 6 to 18 years where there is no other acceptable treatment

Day 60 discussion

Action: For discussion

Oncology

3.1.15. 17 α ,21-dihydroxy-16 α -methyl-pregna-1,4,9(11)-triene-3,20-dione - Orphan - EMEA-001794-PIP02-16

ReveraGen BioPharma Ltd; Treatment of duchenne muscular dystrophy

Day 60 discussion

Action: For discussion

Other

3.1.16. (S)-6-hydroxy-2,5,7,8-tetramethyl-N-((R)-piperidin-3-yl)chroman-2-carboxamide hydrochloride - Orphan - EMEA-002113-PIP01-16

Khondrion BV; Treatment of mitochondrial respiratory chain/oxidative phosphorylation defects

Day 60 discussion

Action: For discussion

Other

3.1.17. Bupivacaine - EMEA-000877-PIP02-16

postsurgical analgesia

Day 60 discussion

Action: For discussion

Pain

3.1.18. allopregnanolone - EMEA-002051-PIP02-16

Treatment of postpartum depression

Day 60 discussion

Action: For discussion

Psychiatry

3.1.19. calcifediol - EMEA-002093-PIP01-16

secondary Hyperparathyroidism (SHPT)

Day 60 discussion

Action: For discussion

Uro-nephrology

3.1.20. 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 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.21. 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 30 discussion

Action: For discussion

Cardiovascular Diseases

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

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

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

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

Treatment of hypercholesterolaemia

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

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

Treatment of hypercholesterolaemia

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

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

Essential Hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

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

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

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.27. EMEA-001749-PIP02-16

Treatment of Atopic Dermatitis

Day 30 discussion

Action: For discussion

Dermatology

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

Treatment of vulvovaginal candidosis (VVC)

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

GlaxoSmithKline Trading Services Limited; Systemic AL amyloidosis

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

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

GlaxoSmithKline Trading Services Limited; Systemic AL amyloidosis

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.31. (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 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

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

J06.9

Day 30 discussion

Action: For discussion

Infectious Diseases / Oto-rhino-laryngology

3.1.34. [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 30 discussion

Action: For discussion

Neurology

3.1.35. [trazodone hydrochloride - EMEA-002142-PIP01-17](#)

Treatment of insomnia

Day 30 discussion

Action: For discussion

Neurology

3.1.36. [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 30 discussion

Action: For discussion

Oncology

3.1.37. [Sulindac / Eflornithine - Orphan - EMEA-001518-PIP02-16](#)

Cancer Prevention Pharma Ltd.; Treatment of Familial Adenomatous Polyposis

Day 30 discussion

Action: For discussion

Oncology

3.1.38. [Lactobacillus reuteri - Orphan - EMEA-001895-PIP01-15](#)

Infant Bacterial Therapeutics AB; Prevention of necrotising enterocolitis

Day 30 discussion

Action: For discussion

Other / Neonatology - Paediatric Intensive Care / Gastroenterology-Hepatology

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. Melatonin - EMEA-C-000440-PIP02-11-M05

RAD Neurim Pharmaceuticals EEC Ltd; Treatment of insomnia

Day 0 discussion

Action: For discussion

Neurology

3.2.2. glucagon - EMEA-C1-001657-PIP01-14

Eli Lilly and Company Limited; Treatment of hypoglycemia

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

Roche Registration Limited; Treatment of Hereditary FVIII Deficiency

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.2.4. Galcanezumab - EMEA-C1-001860-PIP03-16

Eli Lilly Nederland B.V.; Prevention of migraine headaches

Day 30 discussion

Action: For discussion

Neurology

3.2.5. dasatinib (as monohydrate) - EMEA-C4-000567-PIP01-09-M04

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

Day 30 discussion

Action: For discussion

Oncology

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

GSK Trading Services Limited; Treatment of vasculitides

Day 30 discussion

Action: For discussion

Pneumology - Allergology

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

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

Day 30 discussion

Action: For discussion

Uro-nephrology

3.2.8. mirabegron - EMEA-C2-000597-PIP03-15-M03

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

Day 30 discussion

Action: For discussion

Uro-nephrology

3.2.9. Purified antigen fractions of inactivated split virion Influenza virus type A, H1N1 / Influenza virus type A, H3N2 / Influenza virus type B, Victoria lineage / Influenza virus type B, Yamagata lineage - EMEA-C-000817-PIP02-11-M01

GlaxoSmithKline Biologicals S.A.; Prevention of influenza infection

Day 30 discussion

Action: For discussion

Vaccines

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Dobutamine - EMEA-001262-PIP01-12-M03

Proveca Limited; Circulatory impairment / haemodynamic insufficiency

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. 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 30 discussion

Action: For discussion

Cardiovascular Diseases / Haematology-Hemostaseology

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

CSL Behring GmbH; Haemophilia A

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.4. 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 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.5. 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)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.6. 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 30 discussion

Action: For discussion

Infectious Diseases

3.3.7. [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 30 discussion

Action: For discussion

Infectious Diseases

3.3.8. [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 30 discussion

Action: For discussion

Infectious Diseases

3.3.9. [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 30 discussion

Action: For discussion

Infectious Diseases

3.3.10. [Dimethyl fumarate - EMEA-000832-PIP01-10-M04](#)

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

Day 30 discussion

Action: For discussion

Neurology

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

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

Day 30 discussion

Action: For discussion

Neurology

3.3.12. 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 30 discussion

Action: For discussion

Neurology

3.3.13. pazopanib (5-[[4-[(2,3-dimethyl-2H-indazol-6-yl)methylamino]-2-pyrimidinyl]amino]-2-methylbenzenesulfonamide monohydrochloride - EMEA-000601-PIP01-09-M04

Novartis Europharm Limited; 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 30 discussion

Action: For discussion

Oncology / Uro-nephrology

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

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

Day 30 discussion

Action: For discussion

Ophthalmology

3.3.15. 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 30 discussion

Action: For discussion

Other

3.3.16. [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 30 discussion

Action: For discussion

Pain

3.3.17. [Ivacaftor - EMEA-001640-PIP01-14-M02](#)

Vertex Pharamceuticals (Europe) ITd; Treatment of Cystic Fibrosis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.18. [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 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.19. [Split influenza virus, inactivated containing antigens equivalent to the B-like strain Victoria lineage\) / Split influenza virus, inactivated containing antigens equivalent to the B-like strain \(B/Yamagata lineage\) / Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain / Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain - EMEA-001254-PIP01-11-M02](#)

Sanofi Pasteur; Prevention of influenza infection

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 20 June 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

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. Melphalan flufenamide (melflufen) - EMEA-03-2017

The class of primarily alkylating medicinal products for treatment of myeloproliferative neoplasms and mature B, T and NK cell neoplasms/ Treatment of multiple myeloma

Action: For adoption

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

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

7.1.1. Synthetic double-stranded siRNA oligonucleotide directed against transthyretin mRNA - EMEA-001520-PIP01-13

Anylam UK Limited.; Familial Amyloidotic Polyneuropathy (FAP)/Treatment of polyneuropathy in patients with hATTR amyloidosis

Action: For adoption

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

Janssen Infectious Diseases BVBA/Janssen-Cilag International NV; Treatment of human immunodeficiency virus (HIV-1) infection/Treatment of HIV-1 infection, in combination with dolutegravir, in virologically-suppressed (HIV-1 RNA < 50 c/mL) adult subjects without known or suspected resistance to rilpivirine or dolutegravir

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

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

9.3.1. Non-clinical Working Group: D30 Products identified

PDCO member: Jacqueline Carleer

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.3.3. Extrapolation principles for PIP evaluation

PDCO member: Dirk Mentzer

Action: For discussion

9.3.4. Respiratory Drafting Group request for advice from CHMP and PDCO on how to address issues related to therapeutic equivalence for orally inhaled products for children

PDCO member: Eva Agurell

Action: For adoption

9.3.5. Guideline on the clinical development of medicinal products for the treatment of Autism Spectrum Disorder (ASD)

PDCO member: Martina Riegl

Action: For adoption

9.3.6. Minutes of the PCWP meeting with all eligible organisations - 30 Nov (EMA/801985/2016)

Action: Document tabled for information

9.3.7. Agenda of the Workshop on personalised medicines: role of patients, consumers and healthcare professionals - 14 March 2017 (EMA/762357/2016): Document tabled for information

Action: Document tabled for information

9.3.8. Agenda of the PCWP/HCPWP joint meeting – 15 March 2017 (EMA/69326/2017): Document tabled for information

Action: Document tabled for information

9.4. Cooperation within the EU regulatory network

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

Action: For information

9.5. Cooperation with International Regulators

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

PDCO member: Sylvie Benchetrit

Action: For adoption

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

9.6.1. EMA framework of collaboration with academia

Action: For information

9.7. PDCO work plan

None

9.8. Planning and reporting

None

10. Any other business

None

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 3L

11.1.3. Inventory

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

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/