16 October 2018
EMA/PDCO/667076/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 16-19 October 2018

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

16 October 2018, 14:00- 19:00, room 3A

17 October 2018, 08:30- 19:00, room 3A

18 October 2018, 08:30- 19:00, room 3A

19 October 2018, 08:30- 13:00, room 3A

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the PDCO Committee meeting reports (after the PDCO Opinion is adopted), and on the Opinions and decisions on paediatric investigation plans webpage (after the EMA Decision is issued).

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

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1. Introductions

1.1. Welcome and declarations of interest of members, alternates and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PDCO plenary session to be held 16-19 October 2018. Please refer to the October 2018 PDCO minutes (to be published post November 2018 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 16-19 October 2018 meeting

1.3. Adoption of the minutes

PDCO minutes of 18-21 September 2018 meeting

2. Opinions

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

2.1. Opinions on Products

2.1.1. Small molecule Janus Kinase -1 inhibitor - EMEA-002312-PIP01-17

Moderate to severe atopic dermatitis

Day 120 opinion

Action: For adoption

Dermatology

2.1.2. Cenicriviroc - EMEA-001999-PIP02-17

NASH with Stage 2-3 fibrosis

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

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

Treatment of Atopic Dermatitis

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Dermatology

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

Chimerix UK Limited; Treatment of AdV in immunocompromised patients

Day 120 opinion

Action: For adoption

Infectious Diseases

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

Chimerix UK Limited; Treatment of smallpox

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.6. Eubacterial Spores, Purified Suspension, Encapsulated - EMEA-001970-PIP02-17

Treatment of Clostridium difficile infection / To reduce recurrence of Clostridium difficile infection (CDI) in paediatric patients who have received antibacterial drug treatment for recurrent CDI.

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.7. Evobrutinib - EMEA-002284-PIP01-17

Treatment of multiple sclerosis

Day 120 opinion

Action: For adoption

Neurology

2.1.8. Brigatinib - EMEA-002296-PIP01-17

Inflammatory Myofibroblastic Tumors (IMT), Non-small cell lung cancer (NSCLC), Anaplastic large cell lymphoma (ALCL) / Treatment of anaplastic lymphoma kinase (ALK) positive advanced non-small cell lung cancer (NSCLC), Treatment of paediatric patients ≥1 years of age with ALK+ unresectable or recurrent IMT, Treatment in combination with standard chemotherapy in paediatric patients ≥1 years of age with newly diagnosed ALK+ ALCL at high risk for recurrence.

Day 120 opinion

Action: For adoption

Oncology

2.1.9. Calcifediol - EMEA-002093-PIP02-17

Treatment of secondary hyperparathyroidism (SHPT) in non-dialysis chronic kidney disease (ND-CKD) patients with low serum 25-hydroxyvitamin D levels

Day 120 opinion

Action: For adoption

Uro-nephrology

2.1.10. Ezetimibe / atorvastatin - EMEA-002410-PIP01-18

Treatment of hypercholesterolaemia

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.11. Flurpiridaz F18 - EMEA-002413-PIP01-18

Coronary artery disease

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.12. Sarilumab - EMEA-001045-PIP04-18

Muscular auto-immune disorder

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.13. Entacapone / carbidopa monohydrate / levodopa - EMEA-002421-PIP01-18

Treatment of Parkinson's disease and parkinsonism

Day 60 opinion

Action: For adoption

Neurology

2.1.14. Alectinib hydrochloride - EMEA-002431-PIP01-18

Treatment of non-small cell lung cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.15. Avadomide - Orphan - EMEA-002405-PIP01-18

Celgene Europe Limited; Treatment of mature B-cell neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.1.16. Crizotinib - EMEA-001493-PIP02-18

Treatment of lung malignant neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.1.17. Ipatasertib - EMEA-002396-PIP01-18

Treatment of prostate cancer, Treatment of breast cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.18. Molibresib - EMEA-002406-PIP01-18

Malignant neoplasm of breast / Oestrogen receptor-positive breast cancer (ER+BC)

Day 60 opinion

Action: For adoption

Oncology

2.1.19. Pemigatinib - EMEA-002370-PIP01-18

Treatment of urothelial carcinoma, Treatment of cholangiocarcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.20. Selinexor - Orphan - EMEA-002387-PIP01-18

Karyopharm Europe GmbH; Relapse/ Refractory Multiple myeloma

Day 60 opinion

Action: For adoption

Oncology

2.1.21. Ibuprofen - EMEA-002400-PIP01-18

Short-term symptomatic treatment of pain

Day 60 opinion

Action: For adoption

Pain

2.1.22. Dapagliflozin - EMEA-000694-PIP04-18

N18 Chronic Kidney Disease

Day 60 opinion

Action: For adoption

Uro-nephrology

2.2. Opinions on Compliance Check

No items

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Enalapril maleate - EMEA-001706-PIP01-14-M02

Ethicare GmbH; Treatment of Heart Failure

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. Tadalafil - EMEA-000452-PIP02-10-M05

Eli Lilly and Company Ltd; Benign prostatic hyperplasia (already approved in adults), Pulmonary arterial hypertension (already approved in adults) / Treatment of Persistent Pulmonary Hypertension of the Newborn, Treatment of Pulmonary Arterial Hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.3. Dabigatran etexilate mesilate - EMEA-000081-PIP01-07-M11

Boehringer Ingelheim International GmbH; Treatment of thromboembolic events, Prevention

of thomboembolic events / Treatment of venous thromboembolic events in paediatric patients (secondary venous thrombotic event prevention)

Day 60 opinion

Action: For adoption

Cardiovascular Diseases / Haematology-Hemostaseology

2.3.4. Edoxaban (tosylate) - EMEA-000788-PIP02-11-M08

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

Day 60 opinion

Action: For adoption

Cardiovascular Diseases / Haematology-Hemostaseology

2.3.5. Certolizumab pegol - EMEA-001071-PIP03-14-M01

UCB Pharma SA; Treatment of psoriasis / Moderate to severe chronic plaque psoriasis

Day 60 opinion

Action: For adoption

Dermatology

2.3.6. Lixisenatide - EMEA-000916-PIP01-10-M06

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

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.7. Tolvaptan - EMEA-001231-PIP02-13-M06

Otsuka Pharmaceutical Europe Ltd.; Polycystic Kidney Disease (PKD) / Treatment of progression of ADPKD, Treatment of progression of ARPKD

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology

2.3.8. Apremilast - EMEA-000715-PIP05-13-M03

Celgene Europe Limited; Treatment of Behçet's Disease / Treatment of oral ulcers associated

with Behçet's Disease in children and adolescents from the age of 6 to less than 18 years

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.9. Autologous CD34+ haematopoietic stem cells transduced ex vivo with EFS lentiviral vector encoding for the human ADA gene - Orphan - EMEA-001974-PIP01-16-M02

Orchard Therapeutics Limited; Treatment of severe combined immunodeficiency due to adenosine deaminase deficiency (ADA-SCID)

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.10. Filgotinib - EMEA-001619-PIP04-17-M01

Gilead Sciences International Ltd.; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis, and juvenile idiopathic arthritis) / Treatment of juvenile idiopathic arthritis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.11. Ixekizumab - EMEA-001050-PIP01-10-M04

Eli Lilly & Company Limited; Plaque psoriasis / Treatment of severe chronic plaque psoriasis in paediatric patients from the age of 6 years who are not adequately controlled by topical therapies

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.12. Secukinumab - EMEA-000380-PIP02-09-M04

Novartis Europharm Limited; Chronic Idiopathic Arthritis / Treatment of juvenile psoriatic arthritis, Treatment of enthesitis-related arthritis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.13. Avibactam / ceftazidime - EMEA-001313-PIP01-12-M08

Pfizer Limited; Treatment of bacterial infections / Treatment of complicated urinary tract infections / Treatment of complicated intra-abdominal infections / Treatment of pneumonia / Treatment of infections due to aerobic Gram-negative organisms

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.14. Letermovir - Orphan - EMEA-001631-PIP01-14-M03

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.15. Amikacin sulfate - Orphan - EMEA-000525-PIP01-08-M06

Insmed Limited; Treatment of Pseudomonas aeruginosa lung infection/colonisation in cystic fibrosis patients, Treatment of nontuberculous mycobacterial (NTM) lung infection

Day 60 opinion

Action: For adoption

Infectious Diseases / Pneumology - Allergology

2.3.16. Nanobody directed towards the fusion protein of human respiratory syncytial virus - EMEA-001553-PIP01-13-M02

Ablynx NV; Lower respiratory tract disease caused by RSV / Treatment of RSV lower respiratory tract infection

Day 60 opinion

Action: For adoption

Neonatology - Paediatric Intensive Care

2.3.17. D-Sorbitol / Naltrexone HCl / (RS)-Bacoflen - Orphan - EMEA-002164-PIP01-17-M01

Pharnext SA; Charcot-Marie-Tooth disease Type 1A / Treatment of Charcot-Marie-Tooth Type 1A in symptomatic paediatric patients

Day 60 opinion

Action: For adoption

Neurology

2.3.18. Eculizumab - Orphan - EMEA-000876-PIP03-14-M02

Alexion Europe SAS; Treatment of paediatric patients with relapsing neuromyelitis optica spectrum disorders

Day 60 opinion

Action: For adoption

Neurology

2.3.19. Lasmiditan - EMEA-002166-PIP01-17-M01

Eli Lilly and Company Limited; Treatment of migraine with and without aura

Day 60 opinion

Action: For adoption

Neurology

2.3.20. Risdiplam - EMEA-002070-PIP01-16-M02

Roche Registration GmbH; Treatment of spinal muscular atrophy

Day 60 opinion

Action: For adoption

Neurology

2.3.21. Daunorubicin (liposomal formulation) / cytarabine (liposomal formulation) - Orphan - EMEA-001858-PIP02-16-M02

JAZZ PHARMACEUTICALS IRELAND LIMITED; acute myeloid leukaemia

Day 60 opinion

Action: For adoption

Oncology

2.3.22. Idasanutlin - Orphan - EMEA-001489-PIP01-13-M01

Roche Registration GmbH; Treatment of acute myeloid leukaemia, Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoietic and lymphoid tissue), Treatment of acute lymphoblastic leukaemia / Treatment of children with first relapse of, or with frontline-refractory acute myeloid leukaemia, Treatment of children with first relapse of, or with frontline-refractory acute lymphoblastic leukaemia, Treatment of children with a solid malignant tumour which is newly-diagnosed and metastatic, or refractory to first-line treatment

Day 60 opinion

Action: For adoption

Oncology

2.3.23. Idelalisib - EMEA-001350-PIP02-13-M04

Gilead Sciences International Ltd; Treatment of mature B-cell neoplasm / Treatment of children from 1 year to less than 18 years of age with a relapsed or refractory diffuse large B-cell lymphoma (DLBCL), mediastinal B-cell lymphoma (MBCL) or Burkitt lymphoma

Day 60 opinion

Action: For adoption

Oncology

2.3.24. Ixazomib - Orphan - EMEA-001410-PIP02-17-M01

Takeda Pharm A/S; Treatment of Acute Lymphoblastic Leukaemia (ALL), Treatment of Multiple Myeloma (MM) / Treatment of adult patients with Newly Diagnosed Multiple Myeloma (NDMM), Treatment of paediatric patients diagnosed with relapsed precursor B-ALL or T-ALL

Day 60 opinion

Action: For adoption

Oncology

2.3.25. Lenvatinib - Orphan - EMEA-001119-PIP02-12-M04

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

Day 60 opinion

Action: For adoption

Oncology

2.3.26. Dexamethasone / Povidone-Iodine - EMEA-001936-PIP01-16-M01

Shire Pharmaceuticals Ireland Ltd; Treatment of Infectious conjunctivitis (adenoviral and bacterial)

Day 60 opinion

Action: For adoption

Ophthalmology

2.3.27. Ex vivo expanded autologous human corneal epithelium cells containing stem cells - Orphan - EMEA-001082-PIP02-11-M02

Chiesi Farmaceutici S.p.A.; Limbal stem cell deficiency due to ocular burns

Day 60 opinion

Action: For adoption

Ophthalmology

2.3.28. Ketorolac trometamol / phenylephrine hydrochloride - EMEA-001256-PIP02-12-M02

Omeros Corporation; Lens therapeutic procedure

Day 60 opinion

Action: For adoption

Ophthalmology

2.3.29. Conestat alfa - EMEA-000367-PIP01-08-M08

Pharming Group N.V.; D84.1 Defects in the complement system esterase inhibitor (C1-INH) deficiency / Treatment of acute attacks of angioedema associated with hereditary C1 esterase inhibitor deficiency

Day 60 opinion

Action: For adoption

Other

2.3.30. Ivacaftor - Orphan - EMEA-000335-PIP01-08-M13

Vertex Pharmaceuticals (Europe) Limited; Treatment of Cystic Fibrosis

Day 60 opinion

Action: For adoption

Other

2.3.31. Palonosetron / fosnetupitant - EMEA-001198-PIP03-17-M01

Helsinn Birex Pharmaceuticals Limited; Prevention of Chemotherapy-Induced Nausea and Vomiting

Day 60 opinion

Action: For adoption

Other

2.3.32. Aluminium hydroxide adsorbed, de-pigmented glutaraldehyde polymerised, allergen extract of Betula alba pollen (birch pollen) - EMEA-000630-PIP02-09-M04

LETI Pharma GmbH; 30.1 Allergic rhinitis due to pollen, J30.2 Other seasonal allergic rhinitis, J30.3 Other allergic rhinitis, J30.4 Allergic rhinitis, unspecified H10.1 Acute allergic conjunctivitis / Treatment of patients with allergic rhinoconjunctivitis with or without intermittent allergic asthma due to sensitisation against tree pollens (Betula alba family), Treatment of patients with allergic rhinitis with or without intermittent allergic asthma due to sensitisation against tree pollens (Betula alba family)

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.33. Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extracts of birch, alder and hazel pollen - EMEA-000662-PIP02-09-M04

LETI Pharma GmbH; J 30.1 Allergic rhinitis due to pollen J 30.2 Other seasonal allergic rhinitis J 30.03 Other allergic rhinitis J 30.4 Allergic rhinitis, unspecified H10.1 Acute allergic conjunctivitis / Treatment of patients with allergic rhinitis with or without intermittent allergic asthma due to sensitisation against tree pollens (Betula alba family), Treatment of patients with allergic rhino-conjunctivitis with or without intermittent allergic asthma due to sensitisation against tree pollens (Betula alba family)

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.34. Peanut flour - EMEA-001734-PIP01-14-M03

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

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.35. Tezepelumab - EMEA-001613-PIP01-14-M02

AstraZeneca AB; Treatment of asthma / Add-on maintenance treatment of patients with severe asthma aged 5 years and older

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.36. Potassium hydrogen carbonate / Potassium citrate monohydrated - Orphan - EMEA-001357-PIP01-12-M02

Advicenne Pharma; treatment of renal tubular acidosis

Day 60 opinion

Action: For adoption

Uro-nephrology

2.3.37. Cholera vaccine, live attenuated, oral (Strain CVD 103-HgR) - EMEA-001490-PIP01-13-M01

PaxVax Netherlands B.V.; Prevention of disease caused by V. cholerae serogroup O1

Day 60 opinion

Action: For adoption

Vaccines

2.3.38. 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-001715-PIP01-14-M01

Seqirus Netherlands B.V.; prevention of influenza

Day 60 opinion

Action: For adoption

Vaccines

2.3.39. 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-M02

Seqirus UK Limited; Prevention of influenza

Day 60 opinion

Action: For adoption

Vaccines

2.3.40. Pneumococcal Polysaccharide Serotype 33F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 22F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 18C – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 14 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 9V – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6B – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 5 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 4 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 1 – Diphtheria CRM197 Conjugate - EMEA-002215-PIP01-17-M01

Merck Sharp & Dohme (Europe), Inc.; Prevention of disease caused by Streptococcus pneumoniae / Active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae in infants, children and adolescents from 6 weeks to less than 18 years of age

Day 60 opinion

Action: For adoption

Vaccines

2.4. Opinions on Re-examinations

2.4.1. Peanut Allergen Extract - EMEA-001481-PIP01-13-M03

DBV Technologies S.A; peanut allergy

Action: For information

Pneumology - Allergology

2.5. Opinions on Review of Granted Waivers

No items

2.6. Finalisation and adoption of opinions

No items

2.7. Partial Compliance Checks completed by EMA

No items

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. Evinacumab - EMEA-002298-PIP01-17

Treatment of elevated cholesterol / Treatment of homozygous familial hypercholesterolemia (HoFH)

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.2. Semaglutide - EMEA-001441-PIP03-17

Treatment of obesity

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.3. Ibrutinib - Orphan - EMEA-001397-PIP04-17

Janssen-Cilag International N.V.; Treatment of cGVHD / Ttreatment of cGVHD in children 1 year of age and older.

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

Treatment of invasive candidiasis

Day 90 discussion

Action: For discussion

Infectious Diseases

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

Treatment of Gram-positive bacterial pneumonia

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.6. Bilastine - EMEA-000347-PIP02-16

Treatment of allergic conjunctivitis

Day 90 discussion

Action: For discussion

Ophthalmology

3.1.7. Bupivacaine - EMEA-000877-PIP03-17

Postsurgical analgesia

Day 90 discussion

Action: For discussion

Pain

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

Acute Post-Operative Pain

Day 90 discussion

Action: For discussion

Pain / Anaesthesiology

3.1.9. Remimazolam (as besylate) - EMEA-001880-PIP01-18

Anaesthetic and allied procedures / ICU sedation, General anaesthesia, Procedural sedation

Day 60 discussion

Action: For discussion

Anaesthesiology

3.1.10. Glycopyrronium bromide - EMEA-002383-PIP01-18

Treatment of primary axillary hyperhidrosis

Day 60 discussion

Action: For discussion

Dermatology

3.1.11. Oxalobacter formigenes Strain HC-1 - Orphan - EMEA-000370-PIP02-18

OxThera AB; Treatment of Primary Hyperoxaluria

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology

3.1.12. Dusquetide - EMEA-002306-PIP02-18

Treatment of Severe Oral Mucositis

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.13. Adeno-associated viral vector serotype 5 containing a B domain deleted variant of human coagulation factor VIII gene - Orphan - EMEA-002427-PIP01-18

BioMarin International Limited; Treatment of patients with haemophilia A

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.14. Allogeneic CD34+ umbilical cord blood cells cultured ex vivo with Notch ligand Delta1 - Orphan - EMEA-002271-PIP01-17

Nohla Therapeutics, Inc.; Haematopoietic Stem Cell Transplantation (HSCT) / Patients with high risk haematologic malignancies undergoing myeloablative cord blood transplant (CBT)

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.15. Ixekizumab - EMEA-001050-PIP02-18

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis) / Children with juvenile idiopathic arthritis subtypes of enthesitis-related arthritis (including JoAS) and juvenile psoriatic arthritis.

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.16. Inolimomab - Orphan - EMEA-002372-PIP01-18

ElsaLys Biotech SA; Acute Graft versus Host Disease following heamatopoietic stem cell transplantation

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Oncology / Haematology-Hemostaseology

3.1.17. Ganaxolone - EMEA-002341-PIP01-18

Cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder / Adjunctive treatment of seizures in paediatric patients aged 2 to < 18 years old with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder

Day 60 discussion

Action: For discussion

Neurology

3.1.18. Humanized IgG1 monoclonal antibody against GD2 (hu3F8) - EMEA-002346-PIP01-18

Treatment of neuroblastoma

Day 60 discussion

Action: For discussion

Oncology

3.1.19. Aflibercept - EMEA-000236-PIP05-18

Aflibercept is indicated for the treatment of retinopathy of prematurity (ROP)

Day 60 discussion

Action: For discussion

Ophthalmology

3.1.20. lentiviral vector containing the human ABCA4 gene for treatment of Stargardt's disease - Orphan - EMEA-002407-PIP01-18

Genzyme Europe B.V.; Treatment of inherited retinal disorders

Day 60 discussion

Action: For discussion

Ophthalmology

3.1.21. A fully human, IgG2 mAb - EMEA-002433-PIP01-18

Asthma / Treatment of severe asthma in patients 6 year-olds and above as an add-on therapy of standard of care

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.22. Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) / Recombinant Influenza Hemagglutinin-strain B (Victoria lineage) / Recombinant Influenza

Hemagglutinin-strain A (H3N2 subtype) / Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype) - EMEA-002418-PIP01-18

Prevention of influenza infection

Day 60 discussion

Action: For discussion

Vaccines

3.1.23. Synthetic double-stranded siRNA oligonucleotide targeted against transthyretin mRNA, with six phosphorothioate linkages in the backbone, and nine 2'-fluoro and thirty-five 2'-O-methyl nucleoside residues in the sequence, which is covalently linked via a phosphodiester group to a ligand containing three N- acetylgalactosamine residues - Orphan - EMEA-002425-PIP01-18

Alnylam Netherlands BV; Transthyretin-mediated amyloidosis

Day 30 discussion

Action: For discussion

Cardiovascular Diseases / Neurology

3.1.24. Budesonide - EMEA-002417-PIP01-18

Eosinophilic oesophagitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.25. Bimekizumab - EMEA-002189-PIP02-18

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondyloarthritis, psoriatic arthritis and juvenile idiopathic arthritis) / Treatment of JIA (enthesitis-related arthritis [ERA] and juvenile psoriatic arthritis [JPsA]) in patients from ≥2 years to <18 years of age.

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.26. Bruton's tyrosine kinase inhibitor - Orphan - EMEA-002438-PIP01-18

Principia Biopharma, Inc.; Treatment of Pemphigus

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.27. Synthetic 47-amino-acid N-myristoylated lipopeptide - Orphan - EMEA-002399-PIP01-18

MYR GmbH; Chronic hepatitis D infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.28. Anti-VEGF and anti-DLL4 dual variable domain immunoglobulin - EMEA-002420-PIP01-18

Treatment of colorectal malignant neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.1.29. Palbociclib - EMEA-002146-PIP02-18

Treatment of breast malignant neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.1.30. Dexamethasone - EMEA-002423-PIP01-18

ICD10 H59.9 Postprocedural disorder of eye and adnexa

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.31. Germanium (68Ge) chloride / Gallium (68Ga) chloride - EMEA-002436-PIP01-18

Radiolabelling agent

Day 30 discussion

Action: For discussion

Other

3.1.32. (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-PIP03-17

Corbus Pharmaceuticals, Inc.; Treatment of Cystic Fibrosis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.2. Discussions on Compliance Check

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

3.2.1. Dupilumab - EMEA-C2-001501-PIP01-13-M05

Regeneron Pharmaceuticals, Inc.; Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.2.2. Metreleptin - EMEA-C2-001701-PIP01-14-M01

Aegerion Pharmaceuticals B.V.; Treatment of lipodystrophy

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.2.3. Belimumab - EMEA-C-000520-PIP01-08-M05

Glaxo Group Limited; Treatment of systemic lupus erythematosus

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.4. Ceftaroline fosamil - EMEA-C-000769-PIP01-09-M08

Pfizer Limited; Treatment of community-acquired pneumonia

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.5. Fenfluramine hydrochloride - EMEA-C3-001990-PIP01-16-M01

Zogenix International Ltd; Treatment of Dravet syndrome

Day 30 discussion

Action: For discussion

Neurology

3.2.6. Perampanel - EMEA-C5-000467-PIP01-08-M10

Eisai Europe Ltd; Treatment of treatment-resistant epilepsies

Day 30 discussion

Action: For discussion

Neurology

3.2.7. Depatuxizumab mafodotin - EMEA-C2-001732-PIP02-15

AbbVie Ltd; Treatment of high-grade glioma

Day 30 discussion

Action: For discussion

Oncology

3.2.8. Gemtuzumab Ozogamicin - EMEA-C2-001733-PIP02-15-M01

Pfizer Limited; Treatment of acute myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.2.9. Quizartinib - EMEA-C2-001821-PIP01-15-M02

Daiichi Sankyo Europe GmbH; Treatment of acute myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.2.10. Ranibizumab - EMEA-C-000527-PIP04-13-M01

Novartis Europharm Limited; Treatment of retinopathy of prematurity

Day 30 discussion

Action: For discussion

Ophthalmology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Rabeprazole sodium - EMEA-000055-PIP01-07-M06

Eisai Limited; E16.4 Abnormal secretion of gastrin: Zollinger-Ellison Syndrome, K26 Duodenal Ulcer, K25 Gastric Ulcer, B96.8 Helicobacter pylori in patients with peptic ulcer disease, K21.0

Gastro-oesophageal reflux disease / Treatment of symptomatic erosive or ulcerative gastro-oesophageal reflux disease (GORD); symptomatic treatment of moderate to very severe gastro-oesophageal reflux disease (symptomatic GORD), Treatment in combination with appropriate antibacterial therapeutic regimens for the eradication of helicobacter pylori in patients with peptic ulcer disease

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.2. Bedaquiline (fumarate) - Orphan - EMEA-000912-PIP01-10-M04

Janssen-Cilag International NV; Treatment of multi-drug resistant tuberculosis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.3. Ceftobiprole medocaril sodium - EMEA-000205-PIP02-11-M03

Basilea Pharmaceutica International Ltd.; J15: Bacterial pneumoniae no elsewhere classified, J13: Pneumonia due to Streptococcus pneumoniae, J14: Pneumonia due to Hemophilus influenzae / Treatment of nosocomial pneumonia, Treatment of community acquired pneumonia

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.4. Cobicistat / darunavir - EMEA-001280-PIP01-12-M02

Janssen-Cilag International NV; Treatment of HIV-1 infection / Treatment of HIV-1 infection in pediatric patients from 3 to less than 18 years

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.5. Dolutegravir (DTG) - EMEA-000409-PIP01-08-M05

ViiV Healthcare UK Ltd.; Treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.6. EMEA-001975-PIP01-16-M02

Janssen-Cilag International NV; Treatment of influenza / To be used in combination with oseltamivir for the treatment of acute influenza A in adults and children < 18 years of age with complicated influenza or at high risk for complications

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.7. Lamivudine (3TC) / Abacavir (ABC) / Dolutegravir (DTG) - EMEA-001219-PIP01-11-M04

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.8. Fenfluramine hydrochloride - Orphan - EMEA-001990-PIP01-16-M02

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

Day 30 discussion

Action: For discussion

Neurology

3.3.9. Autologous T cells transduced with lentiviral vector containing a chimeric antigen receptor directed against CD19 - Orphan - EMEA-001654-PIP01-14-M03

Novartis Europharm Limited; Treatment of B cell acute lymphoblastic leukaemia/lymphoblastic lymphoma / Treatment of CD19+ B cell acute lymphoblastic leukaemia (ALL) in paediatric patients whose disease is refractory to a standard chemotherapy regimen, relapsed after stem cell transplantation (SCT) or are ineligible for allogenic SCT.

Day 30 discussion

Action: For discussion

Oncology

3.3.10. Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta chimeric antigen receptor - Orphan - EMEA-001862-PIP01-15-M01

Kite Pharma EU B.V.; Treatment of acute lymphoblastic leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.3.11. Axicabtagene ciloleucel - Orphan - EMEA-002010-PIP01-16-M01

Kite Pharma EU B.V.; Treatment of mature B-cell neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.3.12. Pazopanib EMEA-000601-PIP01-09-M05

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 30 discussion

Action: For discussion

Oncology

3.3.13. Ivacaftor / lumacaftor - EMEA-001582-PIP01-13-M08

Vertex Pharmaceuticals (Europe) Limited; Treatment of cystic fibrosis

Day 30 discussion

Action: For discussion

Other

3.3.14. Sildenafil - Orphan - EMEA-000671-PIP01-09-M10

Pfizer Limited; Treatment of Pulmonary Arterial Hypertension (PAH)

Day 30 discussion

Action: For discussion

Other

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 03 January 2019 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

No items

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. Daromun EMEA-16-2018

Philogen S.p.A.; The class of immunomodulatory cytokine medicinal products for treatment of skin malignant neoplasms/Neoadjuvant treatment of fully resectable, clinical stage IIIB and IIIC cutaneous melanoma with injectable cutaneous, subcutaneous or nodal metastases

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. Fedratinib - EMEA-001325-PIP01-12

Celgene; Treatment of essential thrombocythaemia / Treatment of polycythaemia vera / Treatment of primary myelofibrosis

Proposed indication: Treatment of disease-related splenomegaly or symptoms in adult patients with primary myelofibrosis, post-polycythaemia vera myelofibrosis or post-essential thrombocythaemia myelofibrosis, including patients who have been previously exposed with ruxolitinib

Rapporteur: to be appointed

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

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

CHMP/PDCO joint session

Action: For discussion

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

9.3.1. Non-clinical Working Group: D30 Products identified

PDCO member: Karen van Malderen

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

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

Agenda PCWP meeting 25 Sep 2018

Agenda Joint PCWP/HCPWP meeting 25 Sep 2018

Agenda HCPWP meeting 26 Sep 2018

Action: For information

9.3.4. EMA Reflection Paper on the use of extrapolation in the development of medicines for paediatrics

Action: For adoption

9.3.5. Quality Working Party

9.3.5.1. Small Volume Q&A

Rapporteur: Diana van Riet

Action: For adoption

9.3.5.2. Enteral feeding tubes Q&A

Rapporteur: Abigail Moran

Action: For adoption

9.4. Cooperation within the EU regulatory network

None

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. Report from the FDA cluster TC

Action: For information

10.1.2. Summary of the Recommendations of the HMA-EMA Joint Big Data Taskforce

Action: For discussion

10.1.3. Concepts of significant benefit (follow-up to PDCO Work Plan 2017)

Action: For discussion

10.1.4. ICH harmonised guideline on Nonclinical Safety Testing In Support Of Development Of Paediatric Medicines S11, draft version – Step 2

Rapporteur: Jan Willem van der Laan

Action: For information

10.1.5. Report from the PDCO Strategic Review and Learning Meeting, 26 September – 28 September 2018, Vienna, Austria

PDCO member: Karl-Heinz Huemer

Action: For information

10.1.6. Business Pipeline quarterly update report

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/