



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 15-18 August 2017

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

15 August 2017, 14:00- 19:00, room 3A

16 August 2017, 08:30- 19:00, room 3A

17 August 2017, 08:30- 19:00, room 3A

18 August 2017, 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 15-18 August 2017. See August 2017 PDCO minutes (to be published post September 2017 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 15-17 August 2017.

1.3. Adoption of the minutes

PDCO minutes for 18-21 July 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. (R) - azasetron (as besylate) - Orphan - EMEA-002165-PIP01-17

Sensorion SA; Prevention of cisplatin-Induced ototoxicity

Day 60 opinion

Action: For adoption

Oto-rhino-laryngology

2.1.2. Ramucirumab - EMEA-002074-PIP01-16

Treatment of intestinal malignant neoplasm, Treatment of gastric cancer and gastro-oesophageal junction adenocarcinoma, Treatment of liver cancer, Treatment of urinary tract malignant neoplasm, Treatment of lung malignant neoplasm

Day 90 opinion

Action: For adoption

Oncology

2.1.3. Recombinant human monoclonal antibody to GM-CSF - EMEA-001882-PIP02-16

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis) / Treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 1 year of age and older, Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.4. tazobactam / ceftolozane - EMEA-001142-PIP02-16

Treatment of abdominal and gastrointestinal infections, Treatment of urinary tract infections, Treatment of pneumonia / Treatment of nosocomial pneumonia, Treatment of complicated intra-abdominal infections (cIAI)

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.5. EMEA-002057-PIP01-16

Treatment of ischemic stroke to improve recovery / Treatment of ischemic stroke to improve recovery

Day 120 opinion

Action: For adoption

Neurology

2.1.6. Pyridopyrimidione SMN2 Splicing Modifier - EMEA-002070-PIP01-16

Treatment of spinal muscular atrophy

Day 120 opinion

Action: For adoption

Neurology

2.1.7. EMEA-002072-PIP01-16

Treatment of select unresectable or metastatic solid tumours with epacadostat in combination with pembrolizumab in paediatric patients between the ages of 6 months and 18 years of age. / Select unresectable or metastatic solid tumours in paediatric patients >6 months and < 18 years

Day 120 opinion

Action: For adoption

Oncology

2.1.8. [Autologous CD4+ and CD8+ T cells Expressing a CD19-Specific Chimeric Antigen Receptor - EMEA-001995-PIP01-16](#)

Treatment of B-lymphoblastic leukemia/lymphoma, Treatment of mature B-cell neoplasms / Treatment of pediatric patients with relapsed or refractory CD19+ B-cell acute lymphoblastic leukemia, Treatment of pediatric patients with relapsed or refractory CD19+ B-NHL, including diffuse large B-cell lymphoma, Burkitt lymphoma, and primary mediastinal large B-cell lymphoma

Day 120 opinion

Action: For adoption

Oncology

2.1.9. [Enasidenib - Orphan - EMEA-001798-PIP02-16](#)

Celgene Europe Ltd; Treatment of Acute Myeloid Leukaemia / Treatment of patients aged 2 to 21 years old with relapsed or refractory IDH2- mutated AML after at least 2 prior induction attempts.

Day 120 opinion

Action: For adoption

Oncology

2.1.10. [Entospletinib - EMEA-002058-PIP01-16](#)

Treatment of Acute myeloid leukemia

Day 120 opinion

Action: For adoption

Oncology

2.1.11. [Angiotensin II - EMEA-001912-PIP02-16](#)

Catecholamine-resistant hypotension associated with distributive shock

Day 120 opinion

Action: For adoption

Other

2.1.12. [EMEA-002082-PIP01-16](#)

Treatment of cystic fibrosis / indicated to improve lung function and reduce pulmonary

exacerbations for patients in all age groups with cystic fibrosis in conjunction with standard therapies.

Day 120 opinion

Action: For adoption

Pneumology - Allergology

2.1.13. [Amlodipine / Perindopril arginine / Bisoprolol fumarate - EMEA-002173-PIP01-17](#)

Treatment of vascular hypertensive disorders, Treatment of ischaemic coronary artery disorders

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.14. [amlodipine besylate / hydrochlorothiazide / candesartan cilexetil - EMEA-002174-PIP01-17](#)

Treatment of essential hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.15. [Lenalidomide - Orphan - EMEA-000371-PIP04-16](#)

Celgene Europe Limited; treatment of mature b-cell neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.1.16. [Latanoprost / Netarsudil - EMEA-002175-PIP01-17](#)

Treatment of Glaucoma

Day 60 opinion

Action: For adoption

Ophthalmology

2.1.17. [benralizumab - EMEA-001214-PIP02-17](#)

chronic rhinosinusitis with nasal polyposis

Day 60 opinion

Action: For adoption

Oto-rhino-laryngology

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. Entolimod - EMEA-C1-002020-PIP01-16

Cleveland BioLabs Inc; Treatment of acute Radiation Syndrome / Entolimod is indicated for reducing the risk of death following exposure to potentially lethal irradiation occurring as the results of a radiation disaster

Day 0 letter

Action: For adoption

Other

2.2.2. Mexiletine hydrochloride - EMEA-C1-002012-PIP01-16

Lupin (Europe) Ltd; Treatment of myotonic disorders

Day 30 letter

Action: For adoption

Neurology

2.2.3. Damoctocog alfa pegol - EMEA-C-001229-PIP01-11-M03

Bayer AG; Treatment of hereditary Factor VIII deficiency

Day 30 opinion

Action: For adoption

Haematology-Hemostaseology

2.2.4. doravirine - EMEA-C1-001676-PIP01-14-M01

Merck Sharp & Dohme (Europe), Inc.; Treatment of human immunodeficiency virus type 1 (HIV-1) infection

Day 60 letter

Action: For adoption

Infectious Diseases

2.2.5. lamivudine / tenofovir disoproxil fumarate / doravirine - EMEA-C1-001695-PIP01-14-M01

Merck Sharp & Dohme (Europe), Inc.; Treatment of human immunodeficiency virus type 1 (HIV-1) infection

Day 60 letter

Action: For adoption

Infectious Diseases

2.2.6. depatuxizumab mafodotin - EMEA-C1-001732-PIP02-15

AbbVie Ltd; Treatment of high-grade glioma

Day 60 letter

Action: For adoption

Oncology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Alirocumab - EMEA-001169-PIP01-11-M03

Sanofi-aventis Recherche & Developpement; Treatment of elevated cholesterol / Treatment of heterozygous and homozygous familial hypercholesterolemia

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.2. Vestronidase alfa - Orphan - EMEA-001540-PIP01-13-M02

Ultragenyx Germany GmbH; Treatment of Mucopolysaccharidosis type VII (MPS VII)

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.3. Naloxegol (as naloxegol oxalate) - EMEA-001146-PIP01-11-M03

Kyowa Kirin Pharmaceutical Development Limited; Treatment of opioid-induced constipation

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.4. Eltrombopag (eltrombopag olamine) - EMEA-000170-PIP03-13-M03

Novartis Europharm Limited; Bone Marrow Depression and Hypoplastic Anaemia / Treatment of cytopenias in paediatric patients with severe aplastic anaemia who are not receiving hematopoietic stem cell transplant

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.5. Human thrombin / Human fibrinogen - EMEA-001340-PIP01-12-M03

Mallinckrodt Pharmaceuticals Ireland Ltd; Treatment of haemorrhage resulting from a surgical procedure / Supportive treatment where standard surgical techniques are insufficient for improvement of haemostasis

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.6. roxadustat - EMEA-001557-PIP01-13-M01

Astellas Pharma Europe B.V.; treatment of anaemia due to chronic disorders

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.7. Tenofovir alafenamide (as fumarate) - EMEA-001584-PIP01-13-M02

Gilead Sciences International Ltd.; Treatment of chronic hepatitis B / indicated for the treatment of chronic hepatitis B infection in paediatric patients aged 2 years and above.

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.8. Tasimelteon - Orphan - EMEA-001531-PIP01-13-M03

Vanda Pharmaceuticals; ICD-10 G47.24 Circadian rhythm sleep disorder, free-running type (Non-24) / Non24-Hour Sleep-Wake Disorder (Non-24) in the totally blind

Day 60 opinion

Action: For adoption

Neurology

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. Crisaborole - EMEA-002065-PIP01-16

Mild to moderate atopic dermatitis

Day 90 discussion

Action: For discussion

Dermatology

3.1.2. Ligelizumab - EMEA-001811-PIP02-15

Treatment of chronic spontaneous urticaria

Day 90 discussion

Action: For discussion

Dermatology

3.1.3. (2S)-2-{{(2R)-2-[[[3,3-dibutyl-7-(methylthio)-1,1-dioxido-5-phenyl-2,3,4,5-tetrahydro-1,2,5-benzothiadiazepin-8-yl]oxy}acetyl]amino]-2-(4-hydroxyphenyl)acetyl]amino}butanoic acid - Orphan - EMEA-002054-PIP01-16

Albireo AB; Treatment of Progressive Familial Intrahepatic Cholestasis

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.4. Iclaprim mesylate - EMEA-000345-PIP02-16

Infection with resistant Gram-positive bacteria / Treatment of acute bacterial skin and skin structure infections caused by susceptible strains of Gram-positive bacteria

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.5. [maribavir - Orphan - EMEA-000353-PIP02-16](#)

Shire Pharmaceuticals Ireland Limited; Treatment of CMV infection / Treatment of CMV infection in transplant patients from birth to <18 years of age

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.6. [allopregnanolone - EMEA-002051-PIP01-16](#)

Treatment of Status Epilepticus

Day 90 discussion

Action: For discussion

Neurology

3.1.7. [acalabrutinib - Orphan - EMEA-001796-PIP03-16](#)

ACERTA PHARMA, BV; Treatment of mature B cell neoplasms / Treatment of children from 1 to <18 years of age with previously untreated mature B-cell neoplasms (eg, diffuse large B-cell lymphoma [DLBCL], Burkitt lymphoma [BL] and primary mediastinal B-cell lymphoma [PMBCL]), Treatment of children from 1 to <18 years of age with relapsed/refractory mature B-cell neoplasms (eg, diffuse large B-cell lymphoma [DLBCL], Burkitt lymphoma [BL] and primary mediastinal B-cell lymphoma [PMBCL])

Day 90 discussion

Action: For discussion

Oncology

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

Infant Bacterial Therapeutics AB; Prevention of necrotising enterocolitis

Day 90 discussion

Action: For discussion

Other / Neonatology - Paediatric Intensive Care / Gastroenterology-Hepatology

3.1.9. ivacaftor / tezacaftor - EMEA-002086-PIP01-16

Treatment of Cystic Fibrosis

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.10. Fluoromisonidazole (18F) - EMEA-001977-PIP04-17

Visualisation of tissue hypoxia in solid tumours for diagnostic purposes / Gliomas, Renal Cell Carcinoma, Sarcomas

Day 60 discussion

Action: For discussion

Diagnostic / Oncology

3.1.11. EMEA-002109-PIP01-16

K75.8 Other specified inflammatory liver diseases (non-alcoholic steatohepatitis [NASH]) / Treatment of Non-Alcoholic Steatohepatitis (NASH) with mild to severe fibrosis (F1-F4) in paediatric subjects, 8 to < 18 years of age

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.12. Crizanlizumab - Orphan - EMEA-002141-PIP01-17

Novartis Europharm Limited; Treatment of sickle cell disease

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.13. Filgotinib - EMEA-001619-PIP04-17

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis, and juvenile idiopathic arthritis)

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.14. Influenza virus surface antigens (haemagglutinin) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin) of strain A (H1N1) / Influenza virus surface antigens (haemagglutinin) of strain B (Victoria lineage) - EMEA-002027-PIP02-17

Prevention of Influenza infection

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.15. EMEA-002184-PIP01-17

Treatment of excessive daytime sleepiness / Treatment of excessive daytime sleepiness in narcolepsy patients

Day 60 discussion

Action: For discussion

Neurology

3.1.16. D-Sorbitol / Naltrexone HCl / (RS)-Bacofen - Orphan - EMEA-002164-PIP01-17

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

Day 60 discussion

Action: For discussion

Neurology

3.1.17. Survival Motor Neuron Gene by Self-Complementary Adeno Associated Virus Serotype 9 (AAV9) - Orphan - EMEA-002168-PIP01-17

AveXis EU Limited; Spinal Muscular Atrophy

Day 60 discussion

Action: For discussion

Neurology

3.1.18. 16-base single-stranded PNA oligonucleotide linked to a 7 aminoacid peptide C214H290N114O57 - Orphan - EMEA-002119-PIP01-17

BIOGENERA SPA; Treatment of Neuroblastoma (NB) with MYCN expression/amplification

Day 60 discussion

Action: For discussion

Oncology

3.1.19. durvalumab - EMEA-002028-PIP01-16

Treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lymphoid tissue), Treatment of malignant neoplasms of haematopoietic and lymphoid tissue / Treatment of paediatric patients from birth to less than 18 years old with solid tumours, Treatment of paediatric patients from birth to less than 18 years old with haematological malignancies

Day 60 discussion

Action: For discussion

Oncology

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

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 discussion

Action: For discussion

Oncology

3.1.21. palbociclib - EMEA-002146-PIP01-17

Treatment of rhabdomyosarcoma, Treatment of Ewing sarcoma / treatment of refractory or recurrent rhabdomyosarcoma, treatment of refractory or recurrent Ewing sarcoma

Day 60 discussion

Action: For discussion

Oncology

3.1.22. tremelimumab - EMEA-002029-PIP01-16

Treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lymphoid tissue), Treatment of malignant neoplasms of haematopoietic and lymphoid tissue / Treatment of paediatric patients from birth to less than 18 years old with solid tumours, Treatment of paediatric patients from birth to less than 18 years old with haematological malignancies

Day 60 discussion

Action: For discussion

Oncology

3.1.23. sodium thiosulfate - EMEA-002147-PIP02-17

Platinum-induced ototoxic hearing loss / Reducing ototoxicity in patients > 1 month and <18 years of age receiving cisplatin chemotherapy for standard risk hepatoblastoma

Day 60 discussion

Action: For discussion

Oncology / Oto-rhino-laryngology

3.1.24. Hydrochlorothiazide / Irbesartan / Amlodipine - EMEA-002167-PIP01-17

Essential hypertension / Treatment of essential hypertension as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of amlodipine, irbesartan and hydrochlorothiazide, taken either as three single -component formulations or as a dual-component and a single component formulation

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.25. Meldonium dihydrate - EMEA-002212-PIP01-17

An adjuvant treatment of stable effort angina pectoris

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.26. Bimekizumab - EMEA-002189-PIP01-17

Treatment of psoriasis / Treatment of moderate to severe chronic plaque psoriasis in children from the age of 6 years and older

Day 30 discussion

Action: For discussion

Dermatology

3.1.27. Epegmatropin - EMEA-001227-PIP02-17

Treatment of growth hormone deficiency

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.28. Ezetimibe / Rosuvastatin - EMEA-002202-PIP01-17

E78.0 Pure hypercholesterolaemia, I25 Chronic ischaemic heart disease, E78.2 Mixed hyperlipidaemia

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases

3.1.29. Alicaforsen - Orphan - EMEA-002060-PIP02-17

Atlantic Pharmaceuticals (Holdings) Ltd; Treatment of gastrointestinal procedural complications / Treatment of active episodes of antibiotic refractory pouchitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

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

NASH / NASH with Fibrosis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.31. human normal immunoglobulin (IVIg) - EMEA-002190-PIP01-17

Treatment of myasthenia gravis exacerbations

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

Treatment of infections due to Enterobacteriaceae / Treatment of neonatal sepsis due to Enterobacteriaceae in patients with limited treatment options, Treatment of complicated urinary tract infections, including acute pyelonephritis, due to Enterobacteriaceae, including cases with concurrent bacteraemia.

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.33. Pritelivir - EMEA-002180-PIP01-17

Treatment of recurrent herpes labialis / Topical treatment of recurrent herpes labialis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.34. Mecasermin rinfabate - Orphan - EMEA-000534-PIP03-17

Premature AB, Chronic lung disease of prematurity

Day 30 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.1.35. Lasmiditan - EMEA-002166-PIP01-17

Migraine with and without aura

Day 30 discussion

Action: For discussion

Neurology

3.1.36. capmatinib - EMEA-002203-PIP01-17

Treatment of lung malignant neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.1.37. taselesib - EMEA-002210-PIP01-17

Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours, haematopoietic and lymphoid tissue neoplasms) / Treatment of children with relapsed or refractory solid tumors with known or anticipated PI3K activation.

Day 30 discussion

Action: For discussion

Oncology

3.1.38. veliparib - Orphan - EMEA-000499-PIP03-17

AbbVie Ltd; Treatment of breast cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.39. Oxymetazoline HCL / Pilocarpine HCL - EMEA-002181-PIP01-17

Presbyopia

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.40. ezetimibe / bempedoic acid - EMEA-002200-PIP01-17

Treatment of elevated cholesterol

Day 30 discussion

Action: For discussion

Other / Cardiovascular Diseases

3.1.41. Tanezumab - EMEA-001635-PIP03-17

Treatment of chronic pain

Day 30 discussion

Action: For discussion

Pain

3.1.42. Cow's milk protein extract - EMEA-002201-PIP01-17

Treatment of IgE-mediated cow's milk allergy

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. fidaxomicin - EMEA-C1-000636-PIP01-09-M05

Astellas Pharma Europe B.V.; Treatment of enterocolitis caused by clostridium difficile

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.2. Galcanezumab - EMEA-C1-001860-PIP04-16

Eli Lilly Nederland B.V.; Prevention of cluster headache

Day 30 discussion

Action: For discussion

Neurology

3.2.3. Galcanezumab - EMEA-C2-001860-PIP03-16

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

Day 30 discussion

Action: For discussion

Neurology

3.2.4. Autologous T cells transduced with lentiviral vector containing a chimeric antigen receptor directed against CD19 - EMEA-C1-001654-PIP01-14-M01

Novartis Europharm Limited; Treatment of B cell acute lymphoblastic leukaemia/lymphoblastic lymphoma

Day 30 discussion

Action: For discussion

Oncology

3.2.5. asenapine (maleate) - EMEA-C-000228-PIP01-08-M04

N.V. Organon; Treatment of bipolar I disorder

Day 30 discussion

Action: For discussion

Psychiatry

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. L-asparaginase encapsulated in erythrocytes - Orphan - EMEA-000341-PIP02-09-M04

ERYTECH pharma S.A.; Treatment of acute lymphoblastic leukaemia

Day discussion

Action: For discussion

Oncology

3.3.2. dabigatran etexilate mesilate - EMEA-000081-PIP01-07-M10

Boehringer Ingelheim International GmbH; Treatment of thromboembolic events, Prevention of thromboembolic events / Treatment of venous thromboembolic events in paediatric patients (secondary venous thrombotic event prevention)

Day 30 discussion

Action: For discussion

Cardiovascular Diseases / Haematology-Hemostaseology

3.3.3. edoxaban (tosylate) - EMEA-000788-PIP02-11-M06

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

Day 30 discussion

Action: For discussion

Cardiovascular Diseases / Haematology-Hemostaseology

3.3.4. Dapagliflozin - EMEA-000694-PIP02-14-M02

AstraZeneca AB; Type 1 Diabetes Mellitus / As an adjunct to insulin treatment to improve glycaemic control in adults with type 1 diabetes mellitus when insulin alone does not provide adequate control

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. [recombinant parathyroid hormone \[rhPTH\(1-84\)\] - Orphan - EMEA-001526-PIP01-13-M02](#)

Shire Pharmaceuticals Ireland Limited; Treatment of hypoparathyroidism

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. [Methoxy polyethylene glycol- epoetin beta - EMEA-000172-PIP01-07-M03](#)

Roche Registration Limited; Anaemia associated with chronic kidney disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.7. [Recombinant Human A Disintegrin and Metalloprotease with Thrombospondin Type-1 Motifs 13 - Orphan - EMEA-001160-PIP01-11-M01](#)

Baxalta Innovations GmbH; Treatment of thrombotic thrombocytopenic purpura (TTP)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.8. [Autologous CD34+ haematopoietic stem cells transduced ex vivo with EFS lentiviral vector encoding for the human ADA gene - Orphan - EMEA-001974-PIP01-16-M01](#)

Pr Bobby Gaspar; Treatment of severe combined immunodeficiency due to adenosine deaminase deficiency (ADA-SCID)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.9. [avacopan - Orphan - EMEA-002023-PIP01-16-M01](#)

ChemoCentryx, Ltd.; Treatment of ANCA-associated vasculitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.10. Eculizumab - Orphan - EMEA-000876-PIP05-15-M02

Alexion Europe SAS; Myasthenia Gravis / Treatment of Refractory Generalized Myasthenia Gravis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.11. guselkumab - EMEA-001523-PIP02-14-M01

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

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.12. Tofacitinib - EMEA-000576-PIP01-09-M07

Pfizer Limited; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.13. avibactam / ceftazidime - EMEA-001313-PIP01-12-M06

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.14. Cabotegravir - EMEA-001418-PIP01-13-M01

ViiV Healthcare UK Limited; Treatment of human immunodeficiency virus (HIV-1) Infection / Treatment of human immunodeficiency virus (HIV-1) Infection, in combination with other antiretroviral agents

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.15. Fostemsavir (tromethamine) - EMEA-001687-PIP01-14-M02

ViiV Healthcare UK Ltd; Treatment of human immunodeficiency virus (HIV-1) infection / Treatment of HIV-1 infection as part of a combination therapy in paediatric patients who have no more than 2 remaining available fully active antiretroviral therapies.

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.16. Domagrozumab - Orphan - EMEA-001763-PIP01-15-M01

Pfizer Limited; Duchenne Muscular Dystrophy

Day 30 discussion

Action: For discussion

Neurology

3.3.17. Erenumab - EMEA-001664-PIP02-15-M01

Novartis Europharm Limited; Prevention of migraine headaches

Day 30 discussion

Action: For discussion

Neurology

3.3.18. Fremanezumab - EMEA-001877-PIP01-15-M01

Teva GmbH; Prevention of migraine headaches

Day 30 discussion

Action: For discussion

Neurology

3.3.19. Gemtuzumab Ozogamicin - Orphan - EMEA-001733-PIP02-15-M01

Pfizer Limited; Treatment of Acute Myloid Leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.3.20. andexanet alfa - EMEA-001902-PIP01-15-M01

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

Day 30 discussion

Action: For discussion

Other

3.3.21. Febuxostat - EMEA-001417-PIP01-12-M03

Menarini International Operations Luxembourg S.A.; Prevention/treatment of hyperuricemia / Prevention or treatment of hyperuricemia in patients at intermediate or high risk of Tumor Lysis Syndrome (TLS) affected by hematologic malignancies

Day 30 discussion

Action: For discussion

Other / Oncology

3.3.22. Tapentadol - EMEA-000325-PIP01-08-M08

Grünenthal GmbH; Treatment of chronic pain

Day 30 discussion

Action: For discussion

Pain

3.3.23. Formoterol fumarate dihydrate / Beclometasone dipropionate - EMEA-000548-PIP01-09-M07

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

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.24. Ivacaftor - Orphan - EMEA-001640-PIP01-14-M03

Vertex Pharmaceuticals (Europe) Ltd.; Treatment of Cystic Fibrosis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.25. [tralokinumab - EMEA-000782-PIP01-09-M04](#)

MedImmune Ltd; Asthma / Reduce exacerbations and to improve asthma control and lung function in patients 12 years and older with severe asthma inadequately controlled with medium or high dose inhaled corticosteroids and another controller

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.26. [Brexpiprazole - EMEA-001185-PIP01-11-M04](#)

Otsuka Europe Development and Commercialisation Ltd; Schizophrenia / Treatment of schizophrenia in adolescents 13 to 17 years of age

Day 30 discussion

Action: For discussion

Psychiatry

3.3.27. [Everolimus - Orphan - EMEA-000019-PIP08-12-M03](#)

Novartis Europharm Limited; Tuberous Sclerosis Complex (TSC) / Treatment of refractory partial-onset seizures associated with tuberous sclerosis complex (TSC)

Day 30 discussion

Action: For discussion

Uro-nephrology / Neurology

3.3.28. [Influenza virus surface antigens \(haemagglutinin and neuraminidase\) of the following strains: A/<Official Strain>\(H1N1\), A/<Official Strain>\(H3N2\), B/<Official Strain>Yamagata lineage, B/<Official Strain>Victoria lineage - EMEA-001782-PIP01-15-M01](#)

Abbott Biologicals B.V.; Prevention of Influenza infection / Prophylaxis of influenza; especially in those who run an increased risk of associated complications

Day 30 discussion

Action: For discussion

Vaccines

3.3.29. Japanese encephalitis vaccine (inactivated, adsorbed) - EMEA-000559-PIP01-09-M04

Valneva Austria GmbH; Prevention of Japanese encephalitis / Active immunization against Japanese encephalitis in children aged 2 months to <18 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 17 October 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. Intepirdine - EMEA-13-2017

Treatment of Alzheimer's disease/Treatment of mild to moderate Alzheimer's disease

Action: For adoption

6.1.2. Humanized recombinant IgG4 anti-human tau antibody - EMEA-14-2017

Treatment of Alzheimer's disease/ Treatment of early Alzheimer's disease to delay disease progression

Action: For adoption

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

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

None

8. Annual reports on deferrals

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

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

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: Karen van Malderen

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.3.3. CMDh letter to PDCO after Art. 29 referral – Ozanex (ozenoxacin)

PDCO member: Marianne Orholm, Maria Fernandez Cortizo

Action: For information

9.3.4. Report from a workshop on personalised medicines held by EMA on 14 March 2017

Action: Document tabled for information

9.3.5. Lactose of bovine origin-containing medicinal products

Pfizer Croatia d.o.o. (Solu-Medrol), various

PDCO member: Adriana Andric
Scope: Review of the benefit-risk balance following notification by Croatia of a referral under Article 31 of Directive 2001/83/EC, based on pharmacovigilance data

Action: For information

9.3.6. Guideline on clinical investigation of medicinal products in the treatment of epileptic disorders

Action: For information

9.4. Cooperation within the EU regulatory network

9.4.1. European Network of Paediatric Research (Enpr) – at European Medicines Agency (Enpr-EMA): Presentation of the the European Child & Adolescent Psychopharmacology Network (ECAPN) by Alessandro Zuddas

Action: For discussion

9.5. Cooperation with International Regulators

None

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

None

9.7. PDCO work plan

None

9.8. Planning and reporting

10. Any other business

11. Breakout sessions

None

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/