23 January 2018
EMA/PDCO/8432/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 23-26 January 2018

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

23 January 2018, 14:00- 19:00, room 2A

24 January 2018, 08:30- 19:00, room 2A

25 January 2018, 08:30- 19:00, room 2A

26 January 2018, 08:30- 13:00, room 2A

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 23-26 January 2018. See January 2018 PDCO minutes (to be published post February 2018 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 23-26 January 2018.

1.3. Adoption of the minutes

PDCO minutes for 12-15 December 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. Tralokinumab - EMEA-001900-PIP02-17

Treatment of Atopic Dermatitis

Day 120 opinion

Action: For adoption

Dermatology

2.1.2. Non-Pathogenic Bacterial Lysate of Escherichia coli (DSM 17252) and Enterococcus faecalis (DSM 16440) - EMEA-002155-PIP01-17

Irritable bowel syndrome (IBS)

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

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

Novartis Europharm Limited; Treatment of sickle cell disease / Prevention of vaso-occlusive crises in patients with sickle cell disease

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.4. - EMEA-001741-PIP03-16

Treatment of Crohn's Disease

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.5. Anifrolumab - EMEA-001435-PIP02-16

Lupus nephritis, Systemic lupus erythematosis / Treatment of

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.6. Insulin human - EMEA-002116-PIP01-17

Treatment of intestinal malabsorption in preterm infants

Day 120 opinion

Action: For adoption

Neonatology - Paediatric Intensive Care / Gastroenterology-Hepatology

2.1.7. Adeno-Associated Viral vector serotype rh.10 carrying the human N-sulfoglucosamine sulfohydrolase cDNA - Orphan - EMEA-002122-PIP02-17

LYSOGENE; Mucopolysaccharidosis type IIIA

Day 120 opinion

Action: For adoption

Neurology

2.1.8. D-Sorbitol / Naltrexone HCl / (RS)-Bacoflen - 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 120 opinion

Action: For adoption

Neurology

2.1.9. 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 120 opinion

Action: For adoption

Oncology

2.1.10. Pevonedistat - EMEA-002117-PIP01-17

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

Day 120 opinion

Action: For adoption

Oncology

2.1.11. 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 120 opinion

Action: For adoption

Oncology

2.1.12. 17α,21-dihydroxy-16α-methyl-pregna-1,4,9(11)-triene-3,20-dione - Orphan - EMEA-001794-PIP02-16

ReveraGen BioPharma Ltd; Treatment of duchenne muscular dystrophy

Day 120 opinion

Action: For adoption

Other

2.1.13. Tanezumab - EMEA-001635-PIP03-17

Treatment of chronic pain

Day 120 opinion

Action: For adoption

Pain

2.1.14. Vilanterol trifenatate / Umeclidinium bromide / Fluticasone furoate - EMEA-002153-PIP01-17

ICD-10 J45.5x severe persistent asthma

Day 120 opinion

Action: For adoption

Pneumology - Allergology

2.1.15. Candesartan cilexetil / Amlodipine besylate - EMEA-002248-PIP01-17

Treatment of essential hypertension (ICD9: 401, ICD10: I10)

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.16. Ezetimibe / Rosuvastatin - EMEA-002257-PIP01-17

Treatment of hypercholesterolemia / The combination of Rosuvastatin and Ezetimibe is indicated for the treatment of hypercholesterolemia as substitution therapy in adult patients adequately controlled with the individual substances given concurrently at the same dose level as in the fixed dose combination, but as separate products.

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.17. Treprostinil sodium - Orphan - EMEA-002254-PIP01-17

SciPharm Sàrl; Treatment of (inoperable) chronic thromboembolic pulmonary hypertension (CTEPH)

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.18. Levothyroxine sodium - EMEA-002259-PIP01-17

Benign thyroid nodules, Goitre, Hypothyroidism

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.19. Metformin hydrochloride / dapagliflozin - EMEA-001151-PIP02-17

Type 2 diabetes

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.20. Metformin hydrochloride / saxagliptin / dapagliflozin - EMEA-002249-PIP01-17

Type 2 diabetes

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.21. Pemafibrate - EMEA-001573-PIP02-17

Treatment of hypertriglyceridaemia, Prevention of cardiovascular events in patients with elevated triglycerides levels

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases

2.1.22. Venglustat - EMEA-001716-PIP02-17 (previously EMEA-002260-PIP01-17)

ICD-10: G20; Disease of the nervous system; Extrapyramidal and movement disorders (G20-G26); Parkinson disease.

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism / Neurology

2.1.23. Entinostat Polymorph B - EMEA-002272-PIP01-17

Treatment of breast cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.24. Niraparib - Orphan - EMEA-002268-PIP01-17

Janssen Research & Development; Treatment of prostate malignant neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.1.25. T-cell bispecific antibody targeting carcinoembryonic antigen expressed on tumor cells and CD3 epsilon chain present on T-cells - EMEA-002252-PIP01-17

Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours, haematopoietic and lymphoid tissue neoplasms)

Day 60 opinion

Action: For adoption

Oncology

2.1.26. Veliparib - Orphan - EMEA-000499-PIP04-17

AbbVie Ltd; Treatment of lung carcinoma (SCLC and NSCLC)

Day 60 opinion

Action: For adoption

Oncology

2.1.27. Gabapentin / Trazodone hydrochloride - EMEA-002263-PIP01-17

Painful diabetic neuropathy

Day 60 opinion

Action: For adoption

Pain

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. Tolvaptan - EMEA-C1-001231-PIP02-13-M05

Otsuka Pharmaceutical Europe Ltd.; Treatment of polycystic kidney disease

Day 60 letter

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.2.2. Ozanimod - EMEA-C2-001710-PIP02-14-M02

Celgene Europe Limited; Treatment of Multiple Sclerosis

Day 60 letter

Action: For adoption

Neurology

2.2.3. Artenimol / piperaquine tetraphosphate - EMEA-C-000153-PIP01-07-M05

Alfasigma S.p.A.; Treatment of uncomplicated malaria caused by Plasmodium falciparum

Day 0 opinion

Action: For adoption

Infectious Diseases

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Alirocumab - EMEA-001169-PIP01-11-M04

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. Osilodrostat - Orphan - EMEA-000315-PIP02-15-M01

Novartis Europharm Limited; Treatment of adrenal cortical hyperfunctions / Treatment of Cushing's disease in adolescents and children aged 6 years and older

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.3. Sodium zirconium cyclosilicate - EMEA-001539-PIP01-13-M03

AstraZeneca AB; Treatment of hyperkalemia

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.4. Autologous CD34+ haematopoietic stem cells transduced with lentiviral vector encoding the human betaA-T87Q-globin gene - Orphan - EMEA-001665-PIP01-14-M02

bluebird bio France; β-thalassaemia

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.5. Lonoctocog alfa - EMEA-001215-PIP01-11-M06

CSL Behring GmbH; Haemophilia A

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.6. Octocog alfa - EMEA-001064-PIP01-10-M03

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

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.7. Rolapitant - EMEA-001768-PIP02-15-M01

Tesaro UK Ltd; Chemotherapy-Induced Nausea and Vomiting (CINV) in Subjects Receiving Highly Emetogenic Chemotherapy (HEC) / Prevention of delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy in adults. given as part of combination therapy

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.8. Golimumab - EMEA-000265-PIP02-11-M02

Janssen Biologics B.V.; Treatment of ulcerative colitis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.9. Denosumab - EMEA-000145-PIP01-07-M09

Amgen Europe B.V.; Prevention of skeletal related events in patients with bone metastases, Treatment of hypercalcemia of malignancy, Treatment of chronic idiopathic artritis, Treatment of bone loss associated with sex hormone ablative therapy, Treatment of giant cell tumour of bone / Treatment of giant cell tumour of bone in children (12-17 years old)

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Endocrinology-Gynaecology-Fertility-Metabolism / Oncology

2.3.10. Fidaxomicin - EMEA-000636-PIP01-09-M07

Astellas Pharma Europe B.V.; Treatment of enterocolitis caused by clostridium difficile / Treatment of Clostridium difficile infections (CDI) also known as C. difficile-associated diarrhoea (CDAD)

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.11. Erenumab - EMEA-001664-PIP02-15-M02

Novartis Europharm Limited; Prevention of migraine headaches

Day 60 opinion

Action: For adoption

Neurology

2.3.12. Lacosamide - EMEA-000402-PIP03-17-M02

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

Day 60 opinion

Action: For adoption

Neurology

2.3.13. Pyridopyrimidione SMN2 Splicing Modifier - EMEA-002070-PIP01-16-M01

Roche Registration Limited; Treatment of spinal muscular atrophy

Day 60 opinion

Action: For adoption

Neurology

2.3.14. Allogeneic T cells genetically modified with a retroviral vector encoding for a truncated low affinity nerve growth factor receptor (ΔLNGFR) and herpes simplex I virus thymidine kinase (HSV-Tk Mut2) - Orphan - EMEA-001370-PIP02-13-M01

MolMed S.p.A; Adjunctive treatment in haematopoietic cell transplantation

Day 60 opinion

Action: For adoption

Oncology

2.3.15. Binimetinib - EMEA-001454-PIP03-15-M01

PIERRE FABRE MEDICAMENT; Treatment of melanoma / Binimetinib in combination with encorafenib is indicated for the treatment of patients aged 12 years and older with unresectable or metastatic melanoma harbouring BRAF V600 mutations.

Day 60 opinion

Action: For adoption

Oncology

2.3.16. Encorafenib - EMEA-001588-PIP01-13-M01

PIERRE FABRE MEDICAMENT; Treatment of melanoma / Encorafenib in combination with binimetinib is indicated for the treatment of patients aged 12 years and older with unresectable or metastatic melanoma harbouring BRAF V600 mutations.

Day 60 opinion

Action: For adoption

Oncology

2.3.17. Nivolumab - EMEA-001407-PIP01-12-M01

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

Day 60 opinion

Action: For adoption

Oncology

2.3.18. Nivolumab - EMEA-001407-PIP02-15-M02

Bristol-Myers Squibb Pharma EEIG; Treatment of malignant neoplasms of lymphoid tissue, Treatment of malignant neoplasms of the central nervous system / Treatment of paediatric patients with relapsed or refractory Hodgkin lymphoma in the age group from 5 years to < 18 years., Treatment of paediatric patients with a relapsed or refractory non-Hodgkin

lymphoma in the age group from 6 months to less than 18 years old., Treatment of paediatric patients from 6 months to less than 18 years of age with a recurrent or progressive high-grade glioma.

Day 60 opinion

Action: For adoption

Oncology

2.3.19. Pembrolizumab - EMEA-001474-PIP01-13-M01

Merck Sharp & Dohme (Europe), Inc.; Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoietic and lymphoid tissue). / Treatment of advanced, untreated or previously treated, malignant melanoma in children from 12 year old to less than 18 years of age. Treatment as monotherapy of a PD-L1 positive paediatric malignant solid tumor in children from 6 months to less than 18 years of age.

Day 60 opinion

Action: For adoption

Oncology

2.3.20. Selumetinib - EMEA-001585-PIP01-13-M02

AstraZeneca AB; Treatment of Thyroid Cancer, Treatment of Neurofibromatosis-Type 1 / Selumetinib in combination with adjuvant radioactive iodine therapy is medicated for the treatment of adolescents newly diagnosed with differentiated thyroid cancer who are at h1gh risk of primary treatment failure., Selumetinib is indicated for the treatment of inoperable NFl related plexiform neurofibroma in children and adolescents

Day 60 opinion

Action: For adoption

Oncology

2.3.21. Ivacaftor - Orphan - EMEA-000335-PIP01-08-M12

Vertex Pharmaceuticals (Europe) Limited; Treatment of Cystic Fibrosis

Day 60 opinion

Action: For adoption

Other

2.3.22. Dermatophagoides farinae / Dermatophagoides pteronyssinus - EMEA-001258-PIP01-11-M03

ALK-Abelló A/S; Treatment of allergic rhinitis, Treatment of asthma / indicated in house dust mite allergic asthma

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.23. Ivacaftor - Orphan - EMEA-001640-PIP01-14-M04

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

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.24. Mometasone furoate / Indacaterol acetate - EMEA-001217-PIP01-11-M04

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. - EMEA-002162-PIP01-17

Type 2 diabetes mellitus

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

NASH / NASH with Fibrosis

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

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

Infections due to enterobacteriaceae in patients with limited treatment options, Complicated urinary tract infections including pyelonephritis

Day 90 discussion

Action: For discussion

Infectious Diseases

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

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

Day 90 discussion

Action: For discussion

Oncology

3.1.5. Taselisib - EMEA-002210-PIP01-17

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

Day 90 discussion

Action: For discussion

Oncology

3.1.6. (R) - azasetron (as besylate) - Orphan - EMEA-002165-PIP01-17

Sensorion SA; Prevention of cisplatin-Induced otoxicity

Day 90 discussion

Action: For discussion

Oto-rhino-laryngology

3.1.7. Fevipiprant - EMEA-001315-PIP02-16

Asthma / Treatment of uncontrolled persistent asthma

Day 90 discussion

Action: For discussion

Pneumology - Allergology

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

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

Day 90 discussion

Action: For discussion

Vaccines

3.1.9. Birch bark extract - Orphan - EMEA-001299-PIP03-17

Amryt Research Limited; Treatment of epidermolysis bullosa

Day 60 discussion

Action: For discussion

Dermatology

3.1.10. a genetically modified Lactococcus lactis - EMEA-002237-PIP01-17

Treatment of Type 1 diabetes mellitus

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.11. - EMEA-001710-PIP03-17

Treatment of ulcerative colitis

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.12. Risankizumab - EMEA-001776-PIP03-17

Crohn's Disease

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.13. Risankizumab - EMEA-001776-PIP04-17

Ulcerative Colitis

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.14. Autologous CD34+ haematopoietic stem cells transduced with lentiviral vector encoding the human βA-T87Q-globin gene - Orphan - EMEA-001665-PIP02-17

bluebird bio France; Sickle Cell Disease

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.15. Eptinezumab - EMEA-002243-PIP01-17

Prevention of migraine headaches

Day 60 discussion

Action: For discussion

Neurology

3.1.16. Ruxolitinib phosphate - EMEA-000901-PIP04-17

Chronic graft versus host disease / Treatment of chronic Graft vs Host Disease (GvHD) after allogeneic hematopoietic stem cell transplantation (alloSCT) in paediatric patients aged 28 days and above.

Day 60 discussion

Action: For discussion

Oncology

3.1.17. Bilastine - EMEA-000347-PIP02-16

Treatment of allergic conjunctivitis

Day 60 discussion

Action: For discussion

Ophthalmology

3.1.18. Human Plasminogen - Orphan - EMEA-002253-PIP01-17

Kedrion S.p.A.; Treatment of Ligneous Conjunctivitis and prevention of pseudomembranes recurrence in patients affected by Ligneous Conjunctivitis

Day 60 discussion

Action: For discussion

Ophthalmology

3.1.19. Recombinant humanised monoclonal IgG2 lambda antibody against human sclerostin - Orphan - EMEA-002169-PIP01-17

Mereo Biopharma 3 Ltd; Treatment of osteogenesis imperfecta / Treatment of osteogenesis imperfecta, types 1, 3 and 4

Day 60 discussion

Action: For discussion

Other

3.1.20. Interferon beta-1a - Orphan - EMEA-002238-PIP01-17

Faron Pharmaceuticals Ltd; Treatment of Acute Respiratory Distress Syndrome

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.21. - EMEA-002172-PIP02-17

Prevention of lower respiratory tract disease caused by respiratory syncytial virus / Prevention of lower respiratory tract disease caused by respiratory syncytial virus (RSV)

Day 60 discussion

Action: For discussion

Vaccines / Infectious Diseases

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

Treatment of Heart Failure

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

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

Prevention of Cardiovascular Events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.24. - EMEA-002287-PIP01-17

Treatment of Type 2 Diabetes Mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.25. - EMEA-002310-PIP01-17

Treatment of paroxysmal nocturnal haemoglobinuria

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.26. Baricitinib - EMEA-001220-PIP04-17

Treatment of systemic lupus erythematosus

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

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

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.29. Ridinilazole - EMEA-002250-PIP02-17

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.30. Tafenoquine - EMEA-002301-PIP01-17

Prevention of malaria

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.31. Brivaracetam - Orphan - EMEA-000332-PIP02-17

UCB Pharma S.A.; treatment of paediatric epilepsy syndromes / treatment of refractory paediatric epilepsy syndromes with adjunctive administration of brivaracetam

Day 30 discussion

Action: For discussion

Neurology

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

AbbVie Ltd; Progressive Supranuclear Palsy

Day 30 discussion

Action: For discussion

Neurology

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

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

Day 30 discussion

Action: For discussion

Oncology

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

Treatment of locally advanced or metastatic urothelial cancer

Day 30 discussion

Action: For discussion

Oncology

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

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

Day 30 discussion

Action: For discussion

Oncology

3.1.36. Ivosidenib - EMEA-002247-PIP02-17

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

Day 30 discussion

Action: For discussion

Oncology

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

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

Day 30 discussion

Action: For discussion

Oncology

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

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

Day 30 discussion

Action: For discussion

Oncology

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

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

Day 30 discussion

Action: For discussion

Oncology

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

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

Day 30 discussion

Action: For discussion

Oncology

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

Enzyvant Farber Ireland Ltd; Farber disease

Day 30 discussion

Action: For discussion

Other

3.1.42. - EMEA-002293-PIP01-17

Oxaliplatin induced periperal neuropathy (CIPN)

Day 30 discussion

Action: For discussion

Other / Oncology

3.1.43. Ibuprofen - EMEA-002302-PIP01-17

Fever, unspecified, Pain, unspecified

Day 30 discussion

Action: For discussion

Other / Pain

3.1.44. Olodanrigan - EMEA-002286-PIP01-17

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

Day 30 discussion

Action: For discussion

Pain

3.1.45. 3-pentylbenzeneacetic acid sodium salt - Orphan - EMEA-002265-PIP01-17

Prometic Pharma SMT Limited; Idiopathic pulmonary fibrosis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.46. - EMEA-002310-PIP02-17

Treatment of C3 glomerulopathy

Day 30 discussion

Action: For discussion

Uro-nephrology

3.1.47. Ferric Pyrophosphate Citrate (USAN) - EMEA-002261-PIP01-17

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

Day 30 discussion

Action: For discussion

Uro-nephrology / Haematology-Hemostaseology

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

Pfizer Limited; Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

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

Sucampo AG; Treatment of Constipation

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

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

Alexion Europe SAS; Treatment of Paroxysmal Nocturnal Haemoglobinuria

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.2.4. Human coagulation factor X - EMEA-C-000971-PIP01-10-M03

Bio Products Laboratory Ltd; Treatment of hereditary factor X deficiency

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

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

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

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.6. Guselkumab - EMEA-C1-001523-PIP02-14-M01

Janssen Cilag International NV; Treatment of Psoriasis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

Roche Registration Limited; Chronic Idiopathic Arthritis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.8. Plerixafor - EMEA-C-000174-PIP01-07-M03

Genzyme Europe B.V.; Myelosuppression caused by chemotherapy to treat malignant

disorders, which requires an autologous haematopoietic stem cell transplant

Day 30 discussion

Action: For discussion

Oncology

3.2.9. Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with lentiviral vector that encodes for the human Arylsulfatase A (ARSA) cDNA sequence - EMEA-C2-001765-PIP02-15-M01

GlaxoSmithKline Trading Services Limited; Treatment of metachromatic leukodystrophy (MLD)

Day 30 discussion

Action: For discussion

Other

3.2.10. Ivacaftor/ Lumacaftor - EMEA-C5-001582-PIP01-13-M06

Vertex Pharmaceuticals (Europe) Limited; Treatment of cystic fibrosis

Day 30 discussion

Action: For discussion

Other

3.2.11. Lanadelumab - EMEA-C1-001864-PIP01-15-M01

Shire Pharmaceuticals Ireland Limited; Prevention against Acute Attacks of Hereditary Angioedema

Day 30 discussion

Action: For discussion

Other

3.2.12. Dupilumab - EMEA-C1-001501-PIP02-13-M02

sanofi-aventis recherche & développement; Treatment of asthma

Day 30 discussion

Action: For discussion

Pneumology – Allergology

3.2.13. L-asparaginase encapsulated in erythrocytes - EMEA-C3-000341-PIP02-09-M05

ERYTECH Pharma S.A.; Treatment of Acute Lymphoblastic Leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

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

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

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

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

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

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

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

Pfizer Ltd; Mild to moderate atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

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

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

Day 30 discussion

Action: For discussion

Diagnostic / Oncology

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

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

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

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

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

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

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

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

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.9. Brivaracetam - Orphan - EMEA-000332-PIP01-08-M13

UCB Pharma S.A.; Treatment of epilepsy with partial onset seizures, Treatment of neonatal seizures / Treatment of neonatal seizures with adjunctive administration of brivaracetam, Treatment of paediatric patients with partial onset seizures

Day 30 discussion

Action: For discussion

Neurology

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

Biogen Idec Ltd; Spinal muscular atrophy

Day 30 discussion

Action: For discussion

Neurology

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

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

Day 30 discussion

Action: For discussion

Neurology

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

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

Day 30 discussion

Action: For discussion

Neurology

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

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

Day 30 discussion

Action: For discussion

Oncology

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

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

Day 30 discussion

Action: For discussion

Oncology

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

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

Day 30 discussion

Action: For discussion

Other

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

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

Day 30 discussion

Action: For discussion

Other

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

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

Day 30 discussion

Action: For discussion

Other

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

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

Day 30 discussion

Action: For discussion

Pain

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

Grünenthal GmbH; Treatment of chronic pain

Day 30 discussion

Action: For discussion

Pain

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

AstraZeneca AB; Asthma

Day 30 discussion

Action: For discussion

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

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

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

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

Day 30 discussion

Action: For discussion

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 3 April 2018 for Nomination of Rapporteur and Peer reviewer

Action: For adoption

4.2. Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver.

Action: For adoption

4.3. Nominations for other activities

Action: For adoption

5. Scientific Advice Working Party (SAWP) and Paediatric Committee (PDCO) Interaction

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

6. Discussion on the applicability of class waivers

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

6.1. Discussions on the applicability of class waiver for products

6.1.1. 5-fluorouracil - EMEA-18-2017

PIERRE FABRE DERMATOLOGIE; Topical treatment of actinic keratosis lesions of the face, ears and/or scalp / Treatment of actinic keratosis

Action: For adoption

6.1.2. Trastuzumab emtansine - EMEA-19-2017

Roche Registration Limited; Single agent for the adjuvant treatment of adult patients with HER2-positive early breast cancer / Class of Her- / Epidermal growth factor-receptor antibody medicinal products for the treatment of breast malignant neoplasms

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. Tafamidis meglumine - EMEA-000884-PIP01-10

Pfizer Limited; neuropathic heredofamilial amyloidosis

Proposed indication: cardiomyopathy (due to wild-type or variant transthyretin)

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

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. Coordination Group for Mutual Recognition and Decentralised Procedures - Human (CMDh)

CMDh Question to PDCO

PDCO member: Hugo Tavares

Action: For adoption

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. PDCO confirmation of new NcWG experts: January 2018 PDCO

PDCO member: Karen van Malderen

Action: For information

9.3.3. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

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

Action: For information

9.3.5. Draft Guideline on good pharmacovigilance practices (GVP) Product or Population Specific Considerations IV: Paediatric Pharmacovigilance

Action: For discussion

9.3.6. Pilot phase on the Inventory of unmet needs

PDCO member: Karl-Heinz Huemer

Action: For information

9.3.7. Risk Management Plan and PIP studies: synergies or overlap

Action: For information

9.3.8. Patients and Consumers Working Party (PCWP)

Agenda of the PCWP meeting with all eligible organisations – 22 November 2017

Meeting Summary PCWP meeting with all eligible organisations – 22 November 2017

Action: For information

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

AMR info session report – 19 September 2017

Agenda of the PCO & HCPO training - 21 November 2017

Action: For information

9.3.10. Questions and answers on ethanol used as an excipient in medicinal products for human use

Action: For discussion

9.4. Cooperation within the EU regulatory network

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

Action: For information

9.5. Cooperation with International Regulators

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. Involvement of young people at PDCO

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

11.1.4. Overview of Duchenne PIPs and Spinal Muscular Atrophy PIPs

Action: For information

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/