17 September 2019
EMA/PDCO/477081/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 17-20 September 2019

Chair: Koenraad Norga – Vice-Chair: to be elected

17 September 2019, 14:00- 19:00, room 2D

18 September 2019, 08:30- 19:00, room 2D

19 September 2019, 08:30- 19:00, room 2D

20 September 2019, 08:30- 13:00, room 2D

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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Address for visits and deliveries refer to www.ema.europa.eu/how-to-find-us
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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 17-19 September 2019. See 17-19 September 2019 PDCO minutes (to be published post 15-18 October 2019 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 17-19 September 2019

1.3. Adoption of the minutes

PDCO minutes for 20-23 August 2019

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

No items

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. N. meningitidis serogroup A polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid - EMEA-C1-001930-PIP01-16-M01

Sanofi Pasteur; Prevention of meningococcal disease

Day 60 letter

Action: For adoption

Vaccines

2.2.2. Tapentadol - EMEA-C-000018-PIP01-07-M13

Grünenthal GmbH; Treatment of acute pain

Day 30 letter

Action: For adoption

Pain

2.2.3. Sucroferric oxyhydroxide EMEA-C-001061-PIP01-10-M03

Vifor Fresenius Medical Care Renal Pharma France; Treatment of hyperphosphataemia in patients with chronic kidney disease

Day 30 letter

Action: For adoption

Uro-nephrology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

No items.

2.3.1. Sitagliptin phosphate - EMEA-000470-PIP01-08-M11

Merck Sharp and Dohme (Europe), Inc.; Type 2 diabetes mellitus / Treatment of type 2 diabetes mellitus

Day 30 letter

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.4. Opinions on Re-examinations

2.4.1. Reslizumab - EMEA-001202-PIP02-13-M03

Teva Pharmaceuticals Europe; Treatment of asthma / Add-on treatment to reduce exacerbations, relieve symptoms and improve lung function in paediatric patients from 6 to less than 18 years of age with inadequately controlled severe asthma who have a blood eosinophil count greater than equal to 300 micro litre

Day 30 Opinion

Action: For adoption

Pneumology - Allergology

2.4.2. Mirabegron - EMEA-000597-PIP02-10-M07

Astellas Pharma Europe B.V.; Treatment of idiopathic overactive bladder / Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome

Day 30 Opinion

Action: For adoption

Uro-nephrology

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

For the following partial compliance checks, no need to refer them to PDCO Committee for discussion, were identified by the PME coordinator and PDCO Rapporteur. The PDCO has been informed in writing.

2.7.1. Golimumab - EMEA-C2-000265-PIP02-11-M02

Janssen Biologics B.V.; Treatment of ulcerative colitis

Day 1 letter

Action: For information

Immunology-Rheumatology-Transplantation

2.7.2. Baricitinib - EMEA-C2-001220-PIP03-16-M01

Eli Lilly and Company; Treatment of atopic dermatitis

Day 1 letter

Action: For information

Immunology-Rheumatology-Transplantation

2.7.3. Inebilizumab - EMEA-C2-001911-PIP01-15-M02

Viela Bio; Treatment of neuromyelitis optica spectrum disorders

Day 1 letter

Action: For information

Neurology

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. Remimazolam - EMEA-001880-PIP02-19

Sedation during medical procedures / General anaesthesia and post-operative sedation up to 24h /Sedation in the intensive care unit (ICU) / Sedation for short procedures

Day 90 discussion

Action: For discussion

Anaesthesiology

3.1.2. Ralinepag - Orphan - EMEA-002432-PIP01-18

United Therapeutics Corporation; Treatment of pulmonary arterial hypertension / Treatment of pulmonary arterial hypertension WHO Group I to improve exercise capacity and to delay clinical worsening

Day 90 discussion

Action: For discussion

Cardiovascular Diseases

3.1.3. Recombinant human monoclonal antibody against mannan-binding lectin-associated serine protease-2 - Orphan - EMEA-002479-PIP01-18

Omeros London Limited; Treatment in haematopoietic stem cell transplantation / Treatment of haematopoietic stem cell transplant associated thrombotic microangiopathy (HSCT-TMA)

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.4. Artesunate - Orphan - EMEA-002402-PIP02-18

ACE Pharmaceuticals BV; Plasmodia infections / Treatment of severe malaria caused by plasmodium falciparum in children aged 1 month to 18 years

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.5. Iclaprim mesylate - EMEA-002391-PIP02-19

Infection with gram-positive bacteria

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.6. Hydrocortisone - EMEA-002305-PIP01-17

Prevention of bronchopulmonary dysplasia

Day 90 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.1.7. Ganaxolone - EMEA-002341-PIP01-18

Cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder / Adjunctive treatment of seizures in paediatric patients aged 6 months to < 18 years old with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder

Day 90 discussion

Action: For discussion

Neurology

3.1.8. Padsevonil - EMEA-002466-PIP01-18

Treatment of focal-onset seizures (FOS) in patients with epilepsy / Treatment of FOS in adults and paediatric patients (≥1 month to <18 years of age) with epilepsy

Day 90 discussion

Action: For discussion

Neurology

3.1.9. Phenobarbital - EMEA-002532-PIP01-18

Epilepsy

Day 90 discussion

Action: For discussion

Neurology

3.1.10. Recombinant human arylsulfatase A (rhASA) - Orphan - EMEA-002050-PIP01-16

Shire Pharmaceuticals Ireland Limited; Treatment of metachromatic leukodystrophy (MLD)

Day 90 discussion

Action: For discussion

Neurology

3.1.11. 6-(2-hydroxy-2-methylpropoxy)-4-(6-(6-((6-methoxypyridin-3-yl)methyl)-3,6-diazabicyclo[3.1.1]heptan-3-yl)pyridin-3-yl)pyrazolo[1,5-a]pyridine-3-carbonitrile - Orphan - EMEA-002544-PIP01-18

Eli Lilly and Company Limited; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms) / Treatment of paediatric patients from ≥6 months to <18 years of age with rearranged during transfection (RET)-altered, locally advanced or metastatic, solid tumours or primary central nervous system (CNS) tumours

Day 90 discussion

Action: For discussion

Oncology

3.1.12. Crizotinib - EMEA-001493-PIP03-18

ALK-positive inflammatory myofibroblastic tumour (IMT) / ALK-positive anaplastic large cell lymphoma (ALCL) / Treatment of paediatric patients with relapsed/refractory systemic ALK-positive ALCL, Treatment of paediatric patients with unresectable or relapsed/refractory ALK-positive IMT

Day 90 discussion

Action: For discussion

Oncology

3.1.13. Iodine (^{131}I) murine IgG1 monoclonal antibody against B7-H3 - Orphan - EMEA-002101-PIP02-18

Y-mAbs Therapeutics A/S; Treatment of paediatric neuroblastoma patients with central nervous system (CNS) relapse as evidenced by CNS/ leptomeningeal (LM) metastases

Day 90 discussion

Action: For discussion

Oncology

3.1.14. Ivosidenib - Orphan - EMEA-002247-PIP02-17

Agios Pharmaceuticals, Inc.; Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours, haematopoietic and lymphoid tissue neoplasms) / Treatment of malignant neoplasms of the central nervous system / Treatment of 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 90 discussion

Action: For discussion

Oncology

3.1.15. Larotrectinib - EMEA-001971-PIP03-18

Treatment of malignant neoplasms of the central nervous system / Treatment of paediatric patients with a primary central nervous system (CNS) tumour with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion

Day 90 discussion

Action: For discussion

Oncology

3.1.16. Marizomib - EMEA-002452-PIP01-18

Treatment of malignant glial tumors / Treatment of patients (paediatric) with diffuse intrinsic pontine glioma (DIPG) who have received radiation therapy

Day 90 discussion

Action: For discussion

Oncology

3.1.17. Zanubrutinib - EMEA-002354-PIP02-18

Treatment of mature B-cell neoplasms excluding lymphoplasmacytic lymphoma (Waldenström's macroglobulinaemia) / Treatment of lymphoplasmacytic lymphoma

(Waldenström's macroglobulinaemia) / Treatment of primary mediastinal B-cell lymphoma / Treatment of Burkitt lymphoma / Treatment of diffuse large B-cell lymphoma

Day 90 discussion

Action: For discussion

Oncology

3.1.18. Atropine sulphate - EMEA-002538-PIP01-18

Treatment of myopia

Day 90 discussion

Action: For discussion

Ophthalmology

3.1.19. Ketamine hydrochloride / sufentanil citrate - EMEA-001739-PIP02-16

ICD10:R52 Treatment of pain

Day 90 discussion

Action: For discussion

Pain

3.1.20. EMEA-001976-PIP02-18

Asthma / Treatment to control persistent asthma

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.21. Synthetic double-stranded siRNA oligonucleotide directed against lactate dehydrogenase A mRNA and containing four modified nucleosides which form a ligand cluster of four N-acetylgalactosamine residues - Orphan - EMEA-002493-PIP01-18

Dicerna EU Limited; Treatment of primary hyperoxaluria

Day 90 discussion

Action: For discussion

Uro-nephrology

3.1.22. Ezetimibe / atorvastatin - EMEA-002649-PIP01-19

Treatment of hypercholesterolemia / The combination of atorvastatin 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 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.23. EMEA-002616-PIP01-19

Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.1.24. EMEA-002582-PIP01-19

Treatment of chronic spontaneous urticaria

Day 30 discussion

Action: For discussion

Dermatology

3.1.25. Ruxolitinib - EMEA-002618-PIP01-19

Vitiligo

Day 30 discussion

Action: For discussion

Dermatology

3.1.26. ^{68}Ga-satoreotide trizoxetan - Orphan - EMEA-002632-PIP01-19

Ipsen Pharma; Small cell lung cancer / Neuroendocrine tumours / Breast cancer

Day 30 discussion

Action: For discussion

Diagnostic / Oncology

3.1.27. EMEA-002622-PIP01-19

Diagnosis of biochemical recurrence of prostate cancer

Day 30 discussion

Action: For discussion

Diagnostic / Uro-nephrology

3.1.28. Ladarixin - EMEA-002642-PIP01-19

Treatment of type 1 diabetes / Treatment of new-onset type 1 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.29. Pegzilarginase - Orphan - EMEA-001925-PIP02-19

Aeglea BioTherapeutics, Inc.; Arginase 1 deficiency

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.30. Ambrisentan - EMEA-002613-PIP01-19

Portal Hypertension secondary to decompensated cirrhosis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.31. Benralizumab - EMEA-001214-PIP05-19

Treatment of eosinophilic esophagitis (EoE)

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.32. Guselkumab - EMEA-001523-PIP04-19

Ulcerative colitis: ICD K51 / Treatment of ulcerative colitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.33. Guselkumab - EMEA-001523-PIP05-19

Crohn's disease: ICD K50 / Treatment of Crohn's disease

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.34. EMEA-002640-PIP01-19

Eosinophilic esophagitis / Treatment of eosinophilic esophagitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.35. Relamorelin - EMEA-002323-PIP02-19

Gastroparesis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.36. Benralizumab - EMEA-001214-PIP04-19

Treatment of hypereosinophilic syndrome (HES)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.37. EMEA-001312-PIP02-19

Prevention of acute graft-versus-host disease (GVHD)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.38. Ravagalimab - EMEA-002617-PIP01-19

Ulcerative colitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.39. Ritonavir / atazanavir - EMEA-002588-PIP01-19

Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.40. The whole range of unmanipulated autologous mononuclear cells derived from human umbilical cord blood (Hau-UCB-mnc) - Orphan - EMEA-001799-PIP03-19

BrainRepair UG (haftungsbeschränkt); Periventricular leukomalacia (PVL) ICD-10-CM P91.2

Day 30 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.1.41. Cenobamate - EMEA-002563-PIP02-19

Treatment of epilepsy

Day 30 discussion

Action: For discussion

Neurology

3.1.42. Gaboxadol - Orphan - EMEA-002620-PIP01-19

Ovid Therapeutics; Angelman syndrome

Day 30 discussion

Action: For discussion

Neurology

3.1.43. Chimeric 2'-O-(2-methoxyethyl) modified antisense oligonucleotide - Orphan - EMEA-002546-PIP01-19

Roche Registration GmbH; Huntington’s disease

Day 30 discussion

Action: For discussion

Neurology

3.1.44. EMEA-002631-PIP01-19

Treatment of acute myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.1.45. ^{177}Lu-satoreotide tetraxetan - Orphan - EMEA-002629-PIP01-19

Ipsen Pharma; Small cell lung cancer / Neuroendocrine tumours / Breast cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.46. EMEA-002615-PIP01-19

Multiple myeloma

Day 30 discussion

Action: For discussion

Oncology

3.1.47. Autologous inactivated glioma cells - Orphan - EMEA-002661-PIP01-19

ERC Belgium; Recurrent high grade glioma / Treatment of recurrent high grade glioma

Day 30 discussion

Action: For discussion

Oncology

3.1.48. Autologous inactivated glioma cells - Orphan - EMEA-002662-PIP01-19

ERC Belgium; Recurrent high grade glioma / Treatment of recurrent high grade glioma

Day 30 discussion

Action: For discussion

Oncology

3.1.49. Autologous inactivated glioma cells - Orphan - EMEA-002663-PIP01-19

ERC Belgium; Recurrent high grade glioma / Treatment of recurrent high grade glioma

Day 30 discussion

Action: For discussion

Oncology

3.1.50. Autologous inactivated glioma cells - Orphan - EMEA-002664-PIP01-19

ERC Belgium; Recurrent high grade glioma / Treatment of recurrent high grade glioma

Day 30 discussion

Action: For discussion

Oncology

3.1.51. Duvelisib - Orphan - EMEA-002587-PIP01-19

Verastem, Inc.; Treatment of chronic lymphocytic leukaemia/small lymphocytic lymphoma / Treatment of follicular lymphoma

Day 30 discussion

Action: For discussion

Oncology

3.1.52. Savolitinib - EMEA-002627-PIP01-19

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

Day 30 discussion

Action: For discussion

Oncology

3.1.53. Sitravatinib malate - EMEA-002633-PIP01-19

Treatment of non-small cell lung cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.54. Sulindac / eflornithine hydrochloride monohydrate - Orphan - EMEA-001518-PIP03-19

CANCER PREVENTION PHARMA (IRELAND) LIMITED; Treatment of familial adenomatous polyposis

Day 30 discussion

Action: For discussion

Oncology

3.1.55. Temozolomide - EMEA-002634-PIP01-19

Treatment of malignant glioma / Children from the age of three years and adolescent patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy, who have difficulty swallowing

Day 30 discussion

Action: For discussion

Oncology

3.1.56. Atropine - EMEA-002545-PIP01-19

Myopia

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.57. Propranolol - EMEA-002625-PIP01-19

Retinopathy of prematurity

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.58. Ondansetron - EMEA-002623-PIP01-19

Treatment of alcohol use disorder (AUD)

Day 30 discussion

Action: For discussion

Other / Neurology

3.1.59. Loxoprofen - EMEA-002626-PIP01-19

Local treatment of pain

Day 30 discussion

Action: For discussion

Pain

3.1.60. Thiocolchicoside / diclofenac - EMEA-002580-PIP01-19

Acute low back pain / treatment of acute low back pain in adults

Day 30 discussion

Action: For discussion

Pain

3.1.61. Gefapixant - EMEA-002267-PIP02-19

Treatment of cough

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.62. EMEA-002639-PIP01-19

Cystic fibrosis / Treatment of cystic fibrosis in children from birth to <18 years

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.63. EMEA-002638-PIP01-19

Cystic fibrosis / Treatment of cystic fibrosis in children from birth to <18 years

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.64. EMEA-002641-PIP01-19

Prevention of pneumococcal disease caused by *S. pneumoniae* / For the active immunisation for the prevention of invasive pneumococcal diseases (IPD) caused by *S. pneumoniae* in infants, children and adolescents from 6 weeks to < 18 years of age

Day 30 discussion

Action: For discussion

Vaccines

3.2. Discussions on Compliance Check

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

3.2.1. Rivaroxaban - EMEA-C-000430-PIP01-08-M11

Bayer AG; Treatment of thromboembolic events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.2.2. Tedizolid phosphate- EMEA-C1-001379-PIP01-12-M04

Merck Sharp & Dohme (Europe), Inc.; Treatment of acute bacterial skin and skin structure infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.3. Tenofovir alafenamide / emtricitabine - EMEA-C-001577-PIP03-17

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.4. Atezolizumab - EMEA-C-001638-PIP01-14-M02

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

Day 30 discussion

Action: For discussion

Oncology

3.2.5. Decitabine - EMEA-C-000555-PIP01-09-M06

Janssen-Cilag International NV; Treatment of acute myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.2.6. Sildenafil citrate - EMEA-C-000671-PIP01-09-M10

Pfizer Limited; Treatment of pulmonary arterial hypertension (PAH)

Day 30 discussion

Action: For discussion

Other

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Rubidium (^{82}Rb) chloride - EMEA-000882-PIP03-11-M04

Jubilant DraxImage Inc.; Visualization of myocardial perfusion for diagnostic purposes / Rubidium chloride (^{82}Rb) injection is a radiopharmaceutical to be used in positron-emission tomography (PET) imaging for the assessment of myocardial perfusion abnormalities

Day 30 discussion

Action: For discussion

3.3.2. Chloroprocaine hydrochloride - EMEA-000639-PIP03-16-M01

Sintetica GmbH; Peripheral nerve block (local anesthesia by perineural injection)

Day 30 discussion

Action: For discussion

Anaesthesiology

3.3.3. Ambrisentan - Orphan - EMEA-000434-PIP01-08-M06

Glaxo Group Limited; Treatment of pulmonary arterial hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.4. Aciclovir - EMEA-001066-PIP02-11-M03

VECTANS PHARMA; Herpes simplex labialis

Day 30 discussion

Action: For discussion

Dermatology

3.3.5. Bimekizumab - EMEA-002189-PIP01-17-M01

UCB Biopharma SPRL; 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

3.3.6. Dupilumab - EMEA-001501-PIP01-13-M06

Regeneron Pharmaceuticals, Inc; Atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.3.7. Volanesorsen - Orphan - EMEA-001915-PIP01-15-M01

Akcea Therapeutics; Familial chylomicronemia syndrome

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.8. Liraglutide - EMEA-000128-PIP02-09-M03

Novo Nordisk A/S; E66 Obesity / Treatment of obesity

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.9. Lubiprostone - EMEA-000245-PIP01-08-M06

Sucampo AG; Chronic idiopathic constipation

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.10. Maralixibat chloride - Orphan - EMEA-001475-PIP03-17-M01

SFL Regulatory Services GmbH; Treatment of progressive familial intrahepatic cholestasis (PFIC)

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.11. Naloxegol - EMEA-001146-PIP01-11-M05

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

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.12. Teduglutide ([gly2] recombinant human glucagon-like peptide) - Orphan - EMEA-000482-PIP01-08-M05

Shire Pharmaceuticals Ireland Limited; ICD-9-CM Diagnosis 579.3 - Other and unspecified post surgical non absorption - short bowel syndrome / Treatment of short bowel syndrome

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.13. Avatrombopag maleate - EMEA-001136-PIP01-11-M01

Dova Pharmaceuticals Ireland Limited; Chronic immune thrombocytopenia / Treatment of thrombocytopenia in patients with chronic immune thrombocytopenia

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.14. Crizanlizumab - Orphan - EMEA-002141-PIP01-17-M02

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

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.15. Mepolizumab - Orphan - EMEA-000069-PIP01-07-M05

GSK Trading Services Limited; Hypereosinophilic syndrome / Treatment of hypereosinophilic syndrome (HES)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.16. Synthetic double-stranded siRNA oligonucleotide directed against antithrombin mRNA and covalently linked to a ligand containing three N-acetylgalactosamine residues - Orphan - EMEA-001855-PIP01-15-M01

Genzyme Europe B.V.; Treatment of haemophilia B / Treatment of heamophilia A / Indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in children aged ≥ 1 year with severe Haemophilia B, including patients who express neutralizing antibodies to exogenous factor IX substitution / Indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in children aged ≥ 1 year with severe haemophilia A, including patients who express neutralizing antibodies to exogenous factor VIII substitution

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.17. Vonicog alfa - EMEA-001164-PIP01-11-M03

Baxalta Innovations GmbH; Von Willebrand disease / Prevention and treatment of bleeding episodes and for surgical and invasive procedures in paediatric patients (less than 18 years of age) with von Willebrand disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.18. Apremilast - EMEA-000715-PIP02-11-M04

Celgene Europe B.V.; Treatment of juvenile idiopathic arthritis (JIA) / Treatment of juvenile psoriatic a (JPsA)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.19. Apremilast - EMEA-000715-PIP05-13-M04

Celgene Europe B.V.; Treatment of Behçet's disease / Treatment of oral ulcers associated with Behçet's disease

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.20. Avacopan - Orphan - EMEA-002023-PIP01-16-M03

ChemoCentryx Ireland Ltd.; Treatment of antineutrophil cytoplasmic antibody (ANCA)-associated vasculitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.21. Ibrutinib - Orphan - EMEA-001397-PIP04-17-M01

Janssen-Cilag International N.V.; Treatment of chronic graft versus host disease (cGVHD) / Indicated for the treatment of cGVHD in children 1 year of age and older

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.22. Itacitinib - Orphan - EMEA-002178-PIP01-17-M01

Incyte Biosciences Distribution B.V; Treatment of acute graft versus host disease (D89.810, ICD-10-CM) / Treatment of steroid naïve paediatric population with acute graft versus host disease after allogeneic hematopoietic stem cell transplantation

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.23. Rimiducid - Orphan - EMEA-001870-PIP01-15-M02

Beliicum Pharma Ltd; Treatment of graft Versus host disease / Treatment of graft versus host disease in paediatric patients who have received a mismatched, related, allogeneic haematopoietic stem cell transplantation together with rivogenlecleucel

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.24. Rivogenlecleucel - Orphan - EMEA-001869-PIP01-15-M02

Bellicum Pharma Ltd; Adjunctive treatment in haematopoietic stem cell transplantation / Treatment of immunodeficiency after mismatched, related, allogeneic transplantation in

paediatric patients with malignant and non-malignant disorders amenable to haematopoietic stem cell transplantation

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.25. Tofacitinib citrate - EMEA-000576-PIP01-09-M11

Pfizer Europe MA EEIG; Juvenile idiopathic arthritis / 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

3.3.26. Daclatasvir - EMEA-001191-PIP01-11-M03

Bristol-Myers Squibb Pharma EEIG; Treatment of chronic viral hepatitis C

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.27. Dalbavancin HCL - EMEA-000016-PIP01-07-M07

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.28. Letermovir - Orphan - EMEA-001631-PIP01-14-M04

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.29. Zanamivir - EMEA-001318-PIP01-12-M03

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.30. Fremanezumab - EMEA-001877-PIP01-15-M02

Teva GmbH; Prevention of migraine headaches

Day 30 discussion

Action: For discussion

Neurology

3.3.31. Peginterferon beta-1a - EMEA-001129-PIP01-11-M04

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

Day 30 discussion

Action: For discussion

Neurology

3.3.32. Abemaciclib - EMEA-002342-PIP01-18-M01

Eli Lilly and Company Limited; Treatment of Ewing sarcoma (ES) / Treatment of relapsed/refractory Ewing sarcoma in combination with irinotecan and temozolomide

Day 30 discussion

Action: For discussion

Oncology

3.3.33. Autologous T lymphocyte-enriched population of cells transduced with a lentiviral vector encoding a chimeric antigen receptor targeting human B cell maturation antigen with 4-1BB and CD3-zeta intracellular signaling domains - Orphan - EMEA-002369-PIP01-18-M01

Celgene Europe B.V.; Treatment of mature B-cell neoplasms / Treatment of paediatric patients with relapsed or refractory B cell maturation antigen + (BCMA+) B-cell non-Hodgkin lymphoma

Day 30 discussion

Action: For discussion

Oncology

3.3.34. Pevonedistat - Orphan - EMEA-002117-PIP01-17-M01

Takeda Pharma A/S; Treatment of acute myeloid leukaemia (AML) / Treatment of myelodysplastic syndromes (MDS) / Treatment of paediatric patients with newly diagnosed high risk AML or relapsed or refractory (R/R) AML / Treatment of relapsed/refractory (R/R) myelodysplastic syndromes (MDS)

Day 30 discussion

Action: For discussion

Oncology

3.3.35. Ruxolitinib phosphate - EMEA-000901-PIP04-17-M01

Novartis Europharm Limited; Chronic graft versus host disease / Treatment of chronic graft versus host disease (GvHD) after allogeneic hematopoietic stem cell transplantation (alloSCT) in paediatric patients aged 28 days and above

Day 30 discussion

Action: For discussion

Oncology

3.3.36. Inotuzumab ozogamicin - Orphan - EMEA-001429-PIP01-13-M03

Pfizer Europe MA EEIG; Treatment of acute lymphoblastic leukaemia / For the treatment of relapsed or refractory B cell precursor acute lymphoblastic leukaemia

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.3.37. Bilastine - EMEA-000347-PIP02-16-M01

Faes Farma S.A.; Treatment of allergic conjunctivitis

Day 30 discussion

Action: For discussion

Ophthalmology

3.3.38. Mexiletine hydrochloride - Orphan - EMEA-002012-PIP01-16-M02

Lupin Europe GmbH; Treatment of myotonic disorders

Day 30 discussion

Action: For discussion

Other

3.3.39. Rolapitant - EMEA-001768-PIP02-15-M02

Tesaro Bio Netherlands B.V.; Chemotherapy-induced nausea and vomiting (CINV) in subjects receiving highly emetogenic chemotherapy (HEC)

Day 30 discussion

Action: For discussion

Other

3.3.40. Loxapine - EMEA-001115-PIP01-10-M07

Ferrer Internacional, S.A.; Bipolar disorder / Schizophrenia / For rapid control of agitation in patients with schizophrenia / For rapid control of agitation in patients with bipolar disorder

Day 30 discussion

Action: For discussion

Psychiatry

3.3.41. Lurasidone hydrochloride - EMEA-001230-PIP01-11-M05

AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.p.A.; Schizophrenia

Day 30 discussion

Action: For discussion

Psychiatry

3.3.42. Influenza virus surface antigens (Haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (Haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (Haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (Haemagglutinin and neuraminidase) of strain A (H1N1) - EMEA-001894-PIP01-15-M01

Seqirus GmbH; For the prevention of influenza caused by Influenza virus, types A and B contained in the vaccine

Day 30 discussion

Action: For discussion

Vaccines

3.3.43. *Neisseria meningitidis* serogroup Y polysaccharide conjugated to tetanus toxoid / *Neisseria meningitidis* serogroup W-135 polysaccharide conjugated to tetanus toxoid / *Neisseria meningitidis* serogroup C polysaccharide conjugated to tetanus toxoid / *Neisseria meningitidis* serogroup A polysaccharide conjugated to tetanus toxoid - EMEA-001930-PIP01-16-M02

Sanofi Pasteur; Prevention of meningococcal disease

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 03 December 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

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.

5.1. New Scientific Advice

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

5.2. Ongoing Scientific Advice

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

5.3. Final Scientific Advice (Reports and Scientific Advice letters)

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. Aflibercept- EMEA-11-2019

Bayer AG; All classes of medicinal products for treatment of age-related macular degeneration and diabetic macular oedema / Treatment of neovascular (wet) age- related macular degeneration (AMD) / Visual impairment due to diabetic macular oedema (DME))

Action: For adoption

6.1.2. Tropomyosin receptor kinase B agonistic antibody- EMEA-12-2019

Boehringer Ingelheim International GmbH; All classes of medicinal products for treatment of age-related macular degeneration and diabetic macular oedema / Treatment of patients with geographic atrophy (GA) secondary to age-related macular degeneration (AMD)

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

No items

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

9.1.1. PDCO Vice-Chairperson - election

Action: For adoption

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. Extrapolation: case studies under assessment

MSWP Chair: Kristin Karlsson

Action: For information

9.3.4. Healthcare Professionals Working Party (HCPWP) and Patients and Consumers Working Party (PCWP) – Work Plan 2019-2022

Action: For adoption

9.3.5. Draft Agenda Joint Healthcare Professionals Working Party (HCPWP) and Patients and Consumers Working Party (PCWP) 25 Sep 2019

Action: For information

9.3.6. Draft Agenda Patients and Consumers Working Party (PCWP) 24 Sep 2019

Action: For information

9.3.7. Draft Agenda Healthcare Professionals Working Party (HCPWP) 24 Sep 2019

Action: For information

9.3.8. Scientific advice working party (SAWP) – nomination of a PDCO representative

Action: For information

9.3.9. Summary of Product Characteristics Advisory Group (SmPC AG)– nomination of PDCO representative(s)

Action: For information

9.3.10. Guidance and template for Key Elements for M&S studies: Physiologically based PK (PBPK) and PopPK/PD Studies

MSWP Chair: Kristin Karlsson

Action: For information

9.3.11. Extrapolation – Implementation and follow-up from Malta SLRM

MSWP Chair: Kristin Karlsson

Action: For information

9.4. Cooperation within the EU regulatory network

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

Action: For information

9.5. Cooperation with International Regulators

None

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

9.6.1. Strategic Review and Learning Meeting (SRLM) under the Finnish Presidency to be held in Helsinki on 20-22 November 2019 - Agenda

PDCO members: Pia Annunen, Ann-Marie Tötterman

Action: For information

9.7. PDCO work plan

No items

9.8. Planning and reporting

9.8.1. Marketing authorisation applications (MAA) forecast for 2019 – planning update dated Q3 2019

Action: For information

10. Any other business

No items

11. Breakout sessions

11.1.1. Paediatric oncology

Action: For discussion on Thursday, 14:00 - 15:00, room 0-F

11.1.2. Neonatology

Action: For discussion on Thursday, 14:00 - 15:00, room 0-E

11.1.3. Inventory

Action: For discussion on Thursday, 14:00 - 15:00, room 2-D

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/