



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

09 December 2019
EMA/PDCO/630621/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 09-11 December 2019

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

09 December 2019, 08:30- 19:00, room 2D

10 December 2019, 08:30- 19:00, room 2D

11 December 2019, 08:30- 16:00, 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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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 09-11 December 2019. See 09-11 December 2019 PDCO minutes (to be published post 28-31 January 2020 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 09-11 December 2019

1.3. Adoption of the minutes

PDCO minutes for 12-15 November 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

2.1.1. Asciminib hydrochloride - EMEA-002347-PIP01-18

Treatment of Philadelphia positive chronic myelogenous leukaemia in chronic phase

Day 120 opinion

Action: For adoption

Oncology

2.1.2. EMEA-002568-PIP01-19

Psoriasis / Treatment of moderate to severe chronic plaque-type psoriasis who are candidates for systemic therapy

Day 120 opinion

Action: For adoption

Dermatology

2.1.3. Dupilumab - EMEA-001501-PIP04-19

Treatment of eosinophilic esophagitis

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.4. Norursodeoxycholic acid - Orphan - EMEA-002485-PIP01-18

Dr. Falk Pharma GmbH; Primary sclerosing cholangitis (PSC)

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.5. EMEA-002501-PIP01-18

Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital FVIII deficiency)

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.6. Anti-CD7 mAb conjugated to ricin toxin A chain / anti-CD3 mAb conjugated to ricin toxin A chain - Orphan - EMEA-002087-PIP01-16

Xenikos BV; Steroid refractory acute graft versus host disease

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

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

Premacure AB, a member of the Shire group of companies; Chronic lung disease of prematurity

Day 120 opinion

Action: For adoption

Neonatology - Paediatric Intensive Care

2.1.8. [Atogepant - EMEA-002530-PIP01-18](#)

G43 Migraine / Prophylaxis of migraine

Day 120 opinion

Action: For adoption

Pain

2.1.9. [\(R\)-1-\(3-\(aminomethyl\) phenyl\)-N-\(5-\(\(3 cyanophenyl\)\(cyclopropylmethylamino\)methyl\)-2-fluorophenyl\)-3-\(trifluoromethyl\)-1H-pyrazole-5-carboxamide dihydrochloride - Orphan - EMEA-002449-PIP02-18](#)

BioCryst UK; Treatment of hereditary angioedema (HAE) / Treatment of HAE attacks/
Prevention of HAE attacks

Day 120 opinion

Action: For adoption

Pneumology - Allergology

2.1.10. [EMEA-002484-PIP01-18](#)

Asthma / Use as an add-on controller medication in the treatment of adults, adolescents
and children (>1 year of age) with inadequately controlled asthma

Day 120 opinion

Action: For adoption

Pneumology - Allergology

2.1.11. [EMEA-002515-PIP01-18](#)

Treatment of asthma / Add-on therapy for the maintenance treatment for moderate-severe
asthma

Day 120 opinion

Action: For adoption

Pneumology - Allergology

2.1.12. [Budesonide - Orphan - EMEA-002500-PIP01-18](#)

Calliditas Therapeutics AB; Primary IgA nephropathy

Day 120 opinion

Action: For adoption

Uro-nephrology

2.1.13. EMEA-002657-PIP01-19

Visualisation of prostate-specific membrane antigen in adenocarcinoma of the prostate

Day 60 opinion

Action: For adoption

Diagnostic

2.1.14. EMEA-002682-PIP01-19

Acromegaly and gigantism

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.15. Glibenclamide - EMEA-002651-PIP01-19

Large hemispheric infarction

Day 60 opinion

Action: For adoption

Neurology

2.1.16. Hyoscine / Physostigmine - EMEA-002678-PIP01-19

Poisoning by nervous system stimulants

Day 60 opinion

Action: For adoption

Neurology

2.1.17. EMEA-002679-PIP01-19

Prostate cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.18. Canakinumab - EMEA-000060-PIP08-19

Treatment of lung carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.19. EMEA-002650-PIP01-19

Multiple myeloma

Day 60 opinion

Action: For adoption

Oncology

2.1.20. Loncastuximab tesirine - EMEA-002665-PIP01-19

Treatment of diffuse large B-cell lymphoma (DLBCL)

Day 60 opinion

Action: For adoption

Oncology

2.1.21. 1-[(3S)-3-{4-amino-3-[(3,5-dimethoxyphenyl)ethynyl]-1H-pyrazolo[3,4-d]pyrimidin-1-yl}pyrrolidin-1-yl]-2-propen-1-one - Orphan - EMEA-002647-PIP01-19

Taiho Pharma Europe Lt; Biliary tract cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.22. Ripasudil - EMEA-002676-PIP01-19

Treatment of corneal dystrophy

Day 60 opinion

Action: For adoption

Ophthalmology

2.1.23. EMEA-002658-PIP01-19

Treatment of uveal melanoma

Day 60 opinion

Action: For adoption

Ophthalmology / Oncology

2.1.24. Benzocaine - EMEA-002654-PIP02-19

Sore throat

Day 60 opinion

Action: For adoption

Oto-rhino-laryngology

2.1.25. Levocetirizine / montelukast - EMEA-002646-PIP01-19

Allergic rhinitis

Day 60 opinion

Action: For adoption

Pneumology - Allergology / 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. Selumetinib - EMEA-C1-001585-PIP01-13-M03

AstraZeneca AB; Treatment of neurofibromatosis type 1

Day 60 letter

Action: For adoption

Oncology

2.2.2. Glecaprevir / pibrentasvir - EMEA-C-001832-PIP01-15-M02

AbbVie Ltd; Treatment of chronic hepatitis C

Day 30 letter

Action: For adoption

Infectious Diseases

2.2.3. Sodium thiosulfate - EMEA-C-002147-PIP02-17-M01

Fennec Pharmaceuticals, Inc.; Prevention of platinum-induced ototoxic hearing loss

Day 1 opinion

Action: For adoption

Oncology-Oto-rhino-laryngology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Zoledronic acid - EMEA-000057-PIP01-07-M07

Novartis Europharm Limited; Osteoporosis / Glucocorticoid-induced osteoporosis

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.2. Albutrepenonacog alfa - Orphan - EMEA-001107-PIP01-10-M04

CSL Behring GmbH; Haemophilia B / Treatment of hereditary factor IX deficiency

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.3. Alemtuzumab - EMEA-001072-PIP01-10-M03

Genzyme Europe B.V.; Multiple sclerosis / For paediatric patients with relapsing remitting multiple sclerosis (RRMS) with active disease on prior disease modifying treatment (DMT) defined by clinical or imaging features.

Day 60 opinion

Action: For adoption

Neurology

2.3.4. Cannabidiol - Orphan - EMEA-001964-PIP01-16-M01

GW Pharma (International) B.V.; Lennox Gastaut syndrome / Dravet syndrome / Tuberous sclerosis complex/ Infantile spasms / Treatment of seizures

Day 60 opinion

Action: For adoption

Neurology

2.3.5. (RS)-baclofen /naltrexone HCl / D-Sorbitol - Orphan - EMEA-002164-PIP01-17-M02

Pharnext S.A.; Treatment of Charcot-Marie-Tooth type 1A in symptomatic paediatric patients / Treatment of Charcot-Marie-Tooth disease type 1A in adults and paediatric patients

Day 60 opinion

Action: For adoption

Neurology

2.3.6. Lenvatinib - EMEA-001119-PIP02-12-M06

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

Day 60 opinion

Action: For adoption

Oncology

2.3.7. Lipegfilgrastim - EMEA-001019-PIP01-10-M05

UAB "Sicor Biotech"; Treatment of chemotherapy-induced neutropenia / Prevention of chemotherapy-induced febrile neutropenia

Day 60 opinion

Action: For adoption

Oncology

2.3.8. Nivolumab - EMEA-001407-PIP01-12-M02

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

2.3.9. Nivolumab - EMEA-001407-PIP02-15-M03

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 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 / Treatment of paediatric patients with a relapsed or refractory Hodgkin lymphoma in the age group from 5 years to less than 18 years

Day 60 opinion

Action: For adoption

Oncology

2.3.10. Palonosetron / fosnetupitant - EMEA-001198-PIP03-17-M03

Helsinn Birex Pharmaceuticals Limited; Prevention of chemotherapy-induced nausea and vomiting

Day 60 opinion

Action: For adoption

Other

2.3.11. Vamorolone - Orphan - EMEA-001794-PIP02-16-M02

ReveraGen BioPharma Ltd.; Treatment of Duchenne muscular dystrophy

Day 60 opinion

Action: For adoption

Other

2.3.12. Vosoritide - Orphan - EMEA-002033-PIP01-16-M01

BioMarin International Limited; Treatment of achondroplasia

Day 60 opinion

Action: For adoption

Other

2.3.13. Bupivacaine - EMEA-000877-PIP03-17-M01

Pacira Ltd; Postsurgical analgesia

Day 60 opinion

Action: For adoption

Pain

2.3.14. Vilanterol trifenate / Umeclidinium bromide / Fluticasone furoate - EMEA-002153-PIP01-17-M01

GlaxoSmithKline Trading Services Limited; ICD-10 J45.5x severe persistent asthma

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.15. Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) - EMEA-001715-PIP01-14-M03

Seqirus Netherlands B.V.; Influenza / Prevention of influenza

Day 60 opinion

Action: For adoption

Vaccines

2.4. Opinions on Re-examinations

2.4.1. 3-[5-[(1R,2S)-2-(2,2-difluoropropanoylamino)-1-(2,3-dihydro-1,4-benzodioxin-6-yl)propoxy]indazol-1-yl]-N-[(3R)-tetrahydrofuran-3-yl]benzamide - EMEA-001976-PIP02-18

AstraZeneca AB; Asthma / Treatment to control persistent asthma

Day 30 opinion

Action: For adoption

Pneumology - Allergology

2.5. Opinions on Review of Granted Waivers

No items

2.6. Finalisation and adoption of opinions

No items

2.7. Partial Compliance Checks completed by EMA

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. Teriflunomide - EMEA-C2-001094-PIP01-10-M04

Genzyme Europe B.V. / Sanofi-Aventis groupe; Treatment of multiple sclerosis

Day 1 letter

Action: For information

Neurology

2.7.2. Dupilumab - EMEA-C4-001501-PIP01-13-M06

Regeneron Pharmaceuticals, Inc.; Treatment of atopic dermatitis

Day 1 letter

Action: For information

Dermatology

2.7.3. Eladocagene exuparvovec - EMEA-C1-002435-PIP01-18

PTC Therapeutics International Limited; Aromatic L-amino acid decarboxylase (AADC) deficiency

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. EMEA-002481-PIP01-18

Moderate to severe atopic dermatitis

Day 90 discussion

Action: For discussion

Dermatology

3.1.2. EMEA-002552-PIP01-19

Treatment of non-alcoholic steatohepatitis (NASH)

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.3. Avatrombopag maleate - EMEA-001136-PIP02-19

Chemotherapy-induced thrombocytopenia / Treatment of chemotherapy-induced thrombocytopenia (CIT) in patients receiving myelosuppressive chemotherapy for solid tumours

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.4. CD34+enriched cells from patients with Fanconi anemia subtype A (FA-A) transduced ex vivo with lentiviral vector carrying the FANCA gene - Orphan - EMEA-002578-PIP01-19

Rocket Pharmaceuticals, Inc.; Treatment of Fanconi anemia subtype A

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.5. Allogeneic, non-expanded, umbilical cord blood-derived, haematopoietic mature myeloid and lymphoid cells (NF) / Allogeneic, ex vivo expanded, umbilical cord blood-derived, haematopoietic CD34+progenitor cells (CF) - Orphan - EMEA-001913-PIP02-18

Gamida Cell Ltd; Treatment in haematopoietic stem cell transplantation / Haematopoietic reconstitution of patients who are medically indicated for allogeneic haematopoietic stem cell transplantation

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.6. Baricitinib - EMEA-001220-PIP05-19

Treatment of systemic lupus erythematosus

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.7. Haematopoietic stem cells modified with a lentiviral vector encoding for the human beta 2 integrin/CD18 gene - Orphan - EMEA-002562-PIP01-19

Rocket Pharmaceuticals, Inc.; Severe leukocyte adhesion deficiency type I (LAD-I)

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.8. Zoliflodacin - EMEA-002599-PIP01-19

Treatment of gonococcal infection / Treatment of uncomplicated gonorrhoea

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.9. Tazobactam sodium / cefepime hydrochloride - EMEA-002483-PIP01-18

Treatment of complicated urinary tract infections (cUTI)

Day 90 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care / Infectious Diseases / Uro-nephrology

3.1.10. Cannabidiol - Orphan - EMEA-001964-PIP02-19

GW Pharma (International) B.V; Treatment of Rett syndrome

Day 90 discussion

Action: For discussion

Neurology

3.1.11. Efgartigimod alfa - Orphan - EMEA-002597-PIP01-19

argenx BVBA; Treatment of myasthenia gravis

Day 90 discussion

Action: For discussion

Neurology

3.1.12. EMEA-002572-PIP01-19

Chromosome 15q duplication syndrome / Cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder / Treatment of seizures associated with chromosome 15q duplication syndrome /

Treatment of seizures associated with CDKL5 deficiency disorder

Day 90 discussion

Action: For discussion

Neurology

3.1.13. [Timrepigene emparvovec - Orphan - EMEA-002430-PIP01-18](#)

Nightstar Europa Limited; Treatment of choroideremia

Day 90 discussion

Action: For discussion

Ophthalmology

3.1.14. [Anti-neonatal Fc receptor human monoclonal antibody - Orphan - EMEA-002559-PIP02-19](#)

Momenta Pharmaceuticals, Inc.; Myasthenia gravis

Day 90 discussion

Action: For discussion

Other

3.1.15. [Rebisufligene etispavovec - Orphan - EMEA-002206-PIP02-19](#)

Abeona Therapeutics Inc.; Treatment of mucopolysaccharidosis IIIA (ICD-10 E76.2) / Treatment of mucopolysaccharidosis type IIIA (Sanfilippo A syndrome) in children from 6 months to less than 18 years of age

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.16. [Naltrexone - EMEA-002670-PIP01-19](#)

Treatment of Crohn's disease / treatment of moderate to severe active Crohn's disease as an adjuvant therapy in paediatric patients (from 6 years of age)

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.17. Fidanacogene elaparvovec - Orphan - EMEA-002362-PIP02-19

Pfizer Europe MA EEIG; Treatment of congenital factor IX deficiency (haemophilia B) / Prophylaxis of haemophilia B (congenital factor IX deficiency)

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.18. Evobrutinib - EMEA-002284-PIP02-19

Treatment of systemic lupus erythematosus

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.19. Ritonavir / darunavir - EMEA-002537-PIP02-19

Treatment of human immunodeficiency virus (HIV-1) infection

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.20. Tecovirimat monohydrate - Orphan - EMEA-001205-PIP02-19

SIGA Technologies, Inc.; Orthopoxvirus disease (smallpox, monkeypox, cowpox, and vaccinia complications)

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.21. 1-(2,2-diphenyltetrahydrofuran-3-yl)-n,n-dimethylmethanamine hydrochloride - Orphan - EMEA-002688-PIP01-19

Anavex Germany GmbH; Rett syndrome

Day 60 discussion

Action: For discussion

Other

3.1.22. Fasinumab - EMEA-002059-PIP02-19

Chronic pain / Chronic musculoskeletal pain / Chronic non-musculoskeletal pain / Treatment of chronic cancer pain in a palliative care setting / Treatment of moderate to severe chronic pain associated with osteoarthritis (OA) of the knee or hip in patients who achieve an inadequate response to or are intolerant to currently available analgesics (Adults only)

Day 60 discussion

Action: For discussion

Pain

3.1.23. Sodium alginate oligosaccharide - Orphan - EMEA-002321-PIP01-17

AlgiPharma AS; Symptomatic treatment of cystic fibrosis

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.24. EMEA-002653-PIP01-19

Treatment of Schizophrenia / Treatment of cognitive impairment associated with schizophrenia in patients 13 to <18 years of age

Day 60 discussion

Action: For discussion

Psychiatry

3.1.25. Ezetimibe / Rosuvastatin - EMEA-002257-PIP02-19

Prevention of cardiovascular events / Rosuvastatin/Ezetimibe is indicated to reduce the risk of cardiovascular events as substitution therapy in patients with coronary heart disease (CHD) and a history of acute coronary syndrome (ACS), who are 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

3.1.26. Bilayer, engineered, collagen hydrogel-based skin graft composed of autologous keratinocytes and fibroblasts - Orphan - EMEA-002699-PIP01-19

CUTISS AG; Treatment of burns

Day 30 discussion

Action: For discussion

Dermatology

3.1.27. [Nemolizumab - EMEA-001624-PIP02-19](#)

Prurigo nodularis

Day 30 discussion

Action: For discussion

Dermatology

3.1.28. [EMEA-002689-PIP01-19](#)

Achondroplasia

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.29. [Gefapixant - EMEA-002267-PIP03-19](#)

Treatment of endometriosis

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.30. [Lonapegsomatropin - EMEA-002692-PIP01-19](#)

Growth hormone deficiency

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.31. [Cilofexor - Orphan - EMEA-002554-PIP02-19](#)

Gilead Sciences International Ltd.; Treatment of primary sclerosing cholangitis (PSC) (DB96.2)

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.32. Odevixibat - Orphan - EMEA-002054-PIP02-18

Albireo AB; Biliary atresia

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.33. 2-(2-{[2-(1H-benzimidazol-2-yl)ethyl]amino}ethyl)-N-[(3-fluoropyridin-2-yl)methyl]-1,3-oxazole-4-carboxamide trihydrochloride - Orphan - EMEA-002704-PIP01-19

Vifor France; Beta-thalassaemia / Treatment of beta-thalassaemia

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.34. Efgartigimod alfa - EMEA-002597-PIP02-19

Treatment of immune thrombocytopenia

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.35. Marstacimab - Orphan - EMEA-002285-PIP02-19

Pfizer Europe MA EEIG; Treatment of haemophilia B / Treatment of haemophilia A / Prophylaxis of bleeding in haemophilia B / Prophylaxis of bleeding in haemophilia A

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.36. Mitapivat - EMEA-002684-PIP01-19

Pyruvate kinase deficiency / Treatment of paediatric patients with pyruvate kinase deficiency

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.37. Allogeneic bone marrow derived mesenchymal stromal cells, ex-vivo expanded - Orphan - EMEA-002706-PIP01-19

medac Gesellschaft für klinische Spezialpräparate mbH; Treatment of acute graft-versus-host disease

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.38. Dapirolizumab pegol - EMEA-002702-PIP01-19

Treatment of systemic lupus erythematosus (SLE) / Treatment of children and adolescents ≥7 years to <18 years of age with active SLE despite standard therapy

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.39. Rilzabrutinib - Orphan - EMEA-002438-PIP02-19

Principia Biopharma, Inc.; Immune thrombocytopenia / Treatment of immune thrombocytopenia

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.40. Artesunate - EMEA-002710-PIP01-19

Malaria

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.41. EMEA-002694-PIP01-19

Treatment of chronic viral hepatitis B / Treatment of chronic hepatitis B infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.42. EMEA-002693-PIP01-19

Treatment of chronic viral hepatitis B / Treatment of chronic hepatitis B infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.43. Pritelivir - EMEA-002180-PIP02-19

Treatment of herpes simplex virus disease

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.44. Carbidopa / levodopa - EMEA-002687-PIP01-19

Parkinson's disease

Day 30 discussion

Action: For discussion

Neurology

3.1.45. Elezanumab - EMEA-002675-PIP01-19

Multiple sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.1.46. Soticlestat - EMEA-002572-PIP02-19

Dravet syndrome / Lennox-Gastaut syndrome / Treatment of seizures associated with Dravet syndrome / Treatment of seizures associated with Lennox-Gastaut syndrome

Day 30 discussion

Action: For discussion

Neurology

3.1.47. Verdiperstat - Orphan - EMEA-002708-PIP01-19

Biohaven Pharmaceuticals, Inc.; Multiple system atrophy

Day 30 discussion

Action: For discussion

Neurology

3.1.48. EMEA-002686-PIP01-19

Treatment of breast cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.49. EMEA-002690-PIP01-19

Treatment of non-small cell lung cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.50. Daratumumab - Orphan - EMEA-002152-PIP03-19

Janssen-Cilag International N.V.; Systemic light chain amyloidosis

Day 30 discussion

Action: For discussion

Oncology

3.1.51. Eftilagimod alpha - EMEA-002698-PIP01-19

Treatment of breast tumours / Treatment of benign breast tumours / Treatment of primary breast cancer / Treatment of secondary breast cancer (primary cancer metastasizing to the breast)

Day 30 discussion

Action: For discussion

Oncology

3.1.52. Mosunetuzumab - EMEA-002524-PIP02-19

Treatment of mature B-cell neoplasms / Treatment of children from 6 months to less than 18 years of age with relapsed or refractory high-grade mature B-cell non-Hodgkin lymphoma (B-NHL), including Burkitt lymphoma (BL), Burkitt leukaemia (mature B-cell acute lymphoblastic leukaemia FAB L3; B-AL), and diffuse large B-cell lymphoma (DLBCL)

Day 30 discussion

Action: For discussion

Oncology

3.1.53. [Parsaclisib - Orphan - EMEA-002696-PIP01-19](#)

Incyte Biosciences Distribution B.V.; Treatment of mature B-cell neoplasm

Day 30 discussion

Action: For discussion

Oncology

3.1.54. [Recombinant anti-human CD20 and anti-human CD3 monoclonal antibody - EMEA-002648-PIP01-19](#)

Treatment of mature B-cell neoplasms / Treatment of children from 6 months to less than 18 years of age with relapsed or refractory high-grade mature B-cell non-Hodgkin lymphoma (B-NHL), including Burkitt lymphoma (BL), Burkitt leukaemia (mature B-cell acute lymphoblastic leukaemia FAB L3; B-AL), and diffuse large B-cell lymphoma (DLBCL)

Day 30 discussion

Action: For discussion

Oncology

3.1.55. [Zolbetuximab - Orphan - EMEA-002695-PIP01-19](#)

Astellas Pharma Europe B.V.; Treatment of gastric and gastroesophageal junction adenocarcinoma / Treatment of pancreatic adenocarcinoma

Day 30 discussion

Action: For discussion

Oncology

3.1.56. [Avapritinib - Orphan - EMEA-002358-PIP03-19](#)

Blueprint Medicines (Netherlands) B.V.; Treatment of mastocytosis / Treatment of indolent systemic mastocytosis / Treatment of smoldering systemic mastocytosis

Day 30 discussion

Oncology / Haematology-Hemostaseology

3.1.57. [Brolucizumab - EMEA-002691-PIP01-19](#)

Central retinal vein occlusion (CRVO) / Branch retinal vein occlusion (BRVO)

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.58. [Anti-neonatal Fc receptor human monoclonal antibody - Orphan - EMEA-002559-PIP03-19](#)

Momenta Pharmaceuticals, Inc.; Autoimmune haemolytic anaemia

Day 30 discussion

Action: For discussion

Other

3.1.59. [EMEA-002668-PIP01-19](#)

Treatment of chronic pain in patients, who have not sufficiently responded to different analgesic therapies including at least one opioid (adult population only)

Day 30 discussion

Action: For discussion

Pain

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. [Bimekizumab - EMEA-C1-002189-PIP01-17-M01](#)

UCB Biopharma SPRL; Treatment of psoriasis

Day 30 discussion

Action: For discussion

Dermatology

3.2.2. [Ertugliflozin - EMEA-C2-001533-PIP01-13-M02](#)

MSD (Europe) Inc.; Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.3. [Setmelanotide - EMEA-C1-002209-PIP01-17](#)

Rhythm Pharmaceuticals, Inc.; Treatment of appetite and general nutrition disorders

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.4. [Vestronidase alfa - EMEA-C-001540-PIP01-13-M01](#)

Ultragenyx Germany GmbH; Treatment of mucopolysaccharidosis type 7 (MPS 7)

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.5. [Filgotinib - EMEA-C1-001619-PIP03-16](#)

Gilead Sciences International Ltd.; Treatment of ulcerative colitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.2.6. [Itacitinib - EMEA-C2-002178-PIP01-17-M01](#)

Incyte Biosciences Distribution B.V.; Treatment of acute graft versus host disease

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.7. [Autologous cartilage derived cultured chondrocytes - EMEA-C1-001823-PIP01-15-M01](#)

TETEC AG; Treatment of cartilage disorders

Day 30 discussion

Action: For discussion

Other

3.2.8. [Octenidine \(dihydrochloride\) - EMEA-C-001514-PIP01-13-M01](#)

Cassella-med GmbH & Co. KG; Treatment of upper respiratory tract infections

Day 30 discussion

Action: For discussion

Oto-rhino-laryngology

3.2.9. Lurasidone hydrochloride - EMEA-C-001230-PIP01-11-M05

Aziende Chimiche Riunite Angelini Francesco -ACRAF S.p.A; Treatment of schizophrenia

Day 30 discussion

Action: For discussion

Psychiatry

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Entrectinib - EMEA-002096-PIP01-16-M02

Roche Registration GmbH; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms) / For the treatment of paediatric patients with neurotrophic tyrosine receptor kinase (NTRK) fusion-positive solid tumours

Day 30 discussion

Action: For discussion

3.3.2. Ixekizumab - EMEA-001050-PIP01-10-M05

Eli Lilly Nederland B.V.; Treatment of psoriasis

Day 30 discussion

Action: For discussion

Dermatology

3.3.3. Nemolizumab - EMEA-001624-PIP01-14-M02

Galderma International S.A.; Atopic dermatitis / Treatment of moderate to severe atopic dermatitis not adequately controlled with topical treatments

Day 30 discussion

Action: For discussion

Dermatology

3.3.4. Alogliptin benzoate (as alogliptin) - EMEA-000496-PIP01-08-M07

Takeda Development Centre Europe Ltd; Type 2 diabetes melitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. Dapagliflozin - EMEA-000694-PIP01-09-M08

AstraZeneca AB; E11 Type 2 Diabetes / Treatment of type 2 diabetes

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. Denosumab - EMEA-000145-PIP02-12-M02

Amgen Europe B.V.; Treatment of osteoporosis / Treatment of osteogenesis imperfecta / Treatment of glucocorticoid induced osteoporosis

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.7. Evinacumab - EMEA-002298-PIP01-17-M01

Regeneron Ireland DAC; Treatment of elevated cholesterol / Treatment of homozygous familial hypercholesterolemia (HoFH)

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.8. Sodium zirconium cyclosilicate - EMEA-001539-PIP01-13-M04

AstraZeneca AB; Hyperkalemia / Treatment of hyperkalemia

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.9. Macimorelin - EMEA-001988-PIP01-16-M01

Aeterna Zentaris GmbH; Growth hormone deficiency / Diagnosis of growth hormone deficiency

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Diagnostic

3.3.10. Eluxadolone - EMEA-001579-PIP01-13-M03

Allergan Pharmaceuticals International Limited; Irritable bowel syndrome with diarrhoea

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.11. Eftrenonacog alfa - Orphan - EMEA-000914-PIP01-10-M05

Swedish Orphan Biovitrum AB (publ); Hereditary factor IX deficiency - D67

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.12. Vadadustat - EMEA-001944-PIP01-16-M01

Akebia Therapeutics, Inc.; Treatment of anaemia due to chronic disorders / Treatment of anaemia secondary to chronic kidney disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.13. Avacopan - Orphan - EMEA-002023-PIP01-16-M04

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

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.14. Emapalumab - Orphan - EMEA-002031-PIP01-16-M03

Novimmune BV; Treatment of haemophagocytic lymphohistiocytosis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.15. Bezlotoxumab - EMEA-001645-PIP01-14-M03

Merck Sharp & Dohme (Europe), Inc.; Treatment of clostridium difficile infection /Zinplava is indicated for the prevention of recurrence of clostridium difficile infection (CDI) in paediatric patients at high risk for recurrence of CDI

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.16. Nirsevimab - anti-respiratory syncytial virus human IgG1k monoclonal antibody (MEDI8897) - EMEA-001784-PIP01-15-M02

AstraZeneca AB; Prevention of respiratory syncytial viral infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.17. Posaconazole - EMEA-000468-PIP02-12-M06

Merck Sharp & Dohme (Europe), Inc.; Prevention of invasive fungal infections / Treatment of invasive fungal infections / For treatment of invasive fungal infections in the following paediatric patients: Invasive aspergillosis in patients with disease that is refractory to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products / Treatment of Invasive Aspergillosis / Patients receiving remission-induction chemotherapy for acute myelogenous leukaemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high risk of developing invasive fungal infections / Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease and who are at high risk of developing invasive fungal infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.18. Tenofovir alafenamide - EMEA-001584-PIP01-13-M05

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.19. Vaborbactam / meropenem - EMEA-001731-PIP01-14-M01

Menarini International Operations Luxembourg S.A.; Treatment of gram-negative bacterial infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.20. Eculizumab - Orphan - EMEA-000876-PIP03-14-M04

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

Day 30 discussion

Action: For discussion

Neurology

3.3.21. Eladocagene exuparvovec - Orphan - EMEA-002435-PIP01-18-M01

PTC Therapeutic International Limited; Aromatic L-amino acid decarboxylase (AADC) deficiency / Treatment of aromatic L-amino acid decarboxylase (AADC) deficiency

Day 30 discussion

Action: For discussion

Neurology

3.3.22. Ozanimod - EMEA-001710-PIP02-14-M04

Celgene Europe B.V.; Treatment of multiple sclerosis / Treatment of relapsing remitting forms of multiple sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.3.23. Perampanel - EMEA-000467-PIP01-08-M13

Eisai Europe Limited; Treatment of treatment-resistant epilepsies / Adjunctive therapy in patients with other paediatric epilepsies / Adjunctive therapy in patients with refractory partial onset seizures including secondarily generalised seizures

Day 30 discussion

Action: For discussion

Neurology

3.3.24. Risdiplam - Orphan - EMEA-002070-PIP01-16-M04

Roche Registration GmbH; Treatment of spinal muscular atrophy

Day 30 discussion

Action: For discussion

Neurology

3.3.25. Idasanutlin - Orphan - EMEA-001489-PIP01-13-M02

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

Day 30 discussion

Action: For discussion

Oncology

3.3.26. Sonidegib - EMEA-000880-PIP02-11-M04

Sun Pharmaceutical Industries Europe B.V.; Basal cell carcinoma / Medulloblastoma

Day 30 discussion

Action: For discussion

Oncology

3.3.27. Burosumab - Human recombinant IgG1 monoclonal antibody to fibroblast growth factor 23 (FGF23) - Orphan - EMEA-001659-PIP01-15-M04

Kyowa Kirin Holdings B.V.; X-linked hypophosphataemia / Treatment of X-linked hypophosphataemia

Day 30 discussion

Action: For discussion

Other

3.3.28. Meloxicam / bupivacaine - EMEA-002246-PIP01-17-M01

Heron Therapeutics B.V.; Acute postoperative pain

Day 30 discussion

Action: For discussion

Pain

3.3.29. Ravulizumab (ALXN1210) - Orphan - EMEA-001943-PIP01-16-M04

Alexion Europe SAS; Atypical haemolytic uremic syndrome / Treatment of atypical haemolytic uremic syndrome

Day 30 discussion

Action: For discussion

Uro-nephrology / Haematology-Hemostaseology

3.3.30. Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) - EMEA-002068-PIP01-16-M03

Seqirus UK Limited; Influenza / Prevention of influenza

Day 30 discussion

Action: For discussion

Vaccines

3.3.31. Live, attenuated, chimeric dengue virus, serotype 4 / Live, attenuated, chimeric dengue virus, serotype 3 / Live, attenuated, chimeric dengue virus, serotype 2 / Live, attenuated, chimeric dengue virus, serotype 1 - EMEA-001545-PIP01-13-M02

Sanofi Pasteur; Prevention of dengue disease

Day 30 discussion

Action: For discussion

Vaccines

3.3.32. *Neisseria meningitidis* serogroup B recombinant lipoprotein (rLP2086; subfamily B; *Escherichia coli*) / *Neisseria meningitidis* serogroup B recombinant lipoprotein (rLP2086; subfamily A; *Escherichia coli*) - EMEA-001037-PIP02-11-M06

Pfizer Europe MA EEIG; Invasive meningococcal disease caused by *Neisseria meningitidis* serogroup B

Day 30 discussion

Action: For discussion

Vaccines

- 3.3.33. Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Yamagata lineage) / Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Victoria lineage) / Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain / Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain - EMEA-002359-PIP01-18-M01
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Sanofi Pasteur; Prevention of influenza infection

Day 30 discussion

Action: For discussion

Vaccines

4. Nominations

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

4.1. List of letters of intent received for submission of applications with start of procedure 28 January 2020 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.

No items

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

No items

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

No items

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

9.4. Cooperation within the EU regulatory network

No items

9.5. Cooperation with International Regulators

No items

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

No items

9.7. PDCO work plan

9.7.1. PDCO Work Plan 2020

PDCO Chair: Koenraad Norga;

Action: For adoption

9.8. Planning and reporting

9.8.1. Marketing authorisation applications (MAA) forecast for 2019 – planning update dated Q4 2019

Action: For information

10. Any other business

10.1. Update on EMA relocation

Action: For information

11. Breakout sessions

No items

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/