26 February 2019
EMA/PDCO/69021/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 26 February-01 March 2019

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

26 February 2019, 14:00- 19:00, room 3A

27 February 2019, 08:30- 19:00, room 3A

28 February 2019, 08:30- 19:00, room 3A

01 March 2019, 08:30- 13:00, room 3A

Health and safety information

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

Disclaimers

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

Note on access to documents

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

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1. Introductions

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PDCO plenary session to be held 26 February - 01 March 2019. See 26 February -01 March 2019 PDCO minutes (to be published post 26-29 March 2019 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 26 February -01 March 2019.

1.3. Adoption of the minutes

PDCO minutes for 29 January-01 February 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. EMEA-002378-PIP01-18

Treatment of acute heart failure

Day 120 opinion

Action: For adoption

Cardiovascular Diseases

2.1.2. EMEA-001710-PIP03-17

Treatment of ulcerative colitis

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.3. EMEA-002374-PIP01-18

Treatment of systemic lupus erythematosus (SLE)

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.4. Voclosporin - EMEA-002264-PIP01-17

Treatment of systemic lupus erythematosus / Treatment of active lupus nephritis

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.5. Oteseconazole - EMEA-002392-PIP01-18

Treatment of vulvovaginal candidiasis

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.6. Ofatumumab - EMEA-002397-PIP01-18

Treatment of multiple sclerosis / Treatment of relapsing remitting multiple sclerosis

Day 120 opinion

Action: For adoption

Neurology

2.1.7. Abemaciclib - EMEA-002342-PIP01-18

Ewing's sarcoma (ES) / Treatment of relapsed/refractory Ewing sarcoma in children and young adults, in combination with irinotecan and temozolomide

Day 120 opinion

Action: For adoption

Oncology

2.1.8. EMEA-002348-PIP01-18

B-cell acute lymphoblastic leukemia / Treatment of relapse or refractory B-cell acute

lymphoblastic leukemia

Day 120 opinion

Action: For adoption

Oncology

2.1.9. 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 signalling domains - Orphan - EMEA-002369-PIP01-18

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

Day 120 opinion

Action: For adoption

Oncology

2.1.10. Vinorelbine - EMEA-002365-PIP01-18

Treatment of rhabdomyosarcoma / Maintenance therapy after first relapse treatment, Treatment of relapsed or refractory rhabdomyosarcoma, Maintenance therapy for high-risk rhabdomyosarcoma patients achieving complete remission after frontline treatment

Day 120 opinion

Action: For adoption

Oncology

2.1.11. Aflibercept - EMEA-000236-PIP05-18

Treatment of retinopathy of prematurity (ROP)

Day 120 opinion

Action: For adoption

Ophthalmology

2.1.12. Nintedanib - Orphan - EMEA-001006-PIP05-18

Boehringer Ingelheim International GmbH; Treatment of fibrosing interstitial lung diseases (ILD) / Treatment of fibrosing interstitial lung diseases (ILD) in paediatric patients

Day 120 opinion

Action: For adoption

Pneumology - Allergology / Oncology

2.1.13. EMEA-002307-PIP01-17

Prevention of Ebola virus disease (EVD) / Prevention of EVD in children aged ≥1 year

Day 120 opinion

Action: For adoption

Vaccines / Infectious Diseases

2.1.14. EMEA-002308-PIP01-17

Prevention of Ebola virus disease (EVD) / Prevention of EVD in children aged ≥1 year

Day 120 opinion

Action: For adoption

Vaccines / Infectious Diseases

2.1.15. Rosuvastatin calcium / fenofibrate - EMEA-002509-PIP01-18

Mixed dislipidemia, i.e. hypertriglyceridemia combined with hypercholesterolemia

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.16. Serlopitant - EMEA-002496-PIP01-18

Treatment of prurigo nodularis

Day 60 opinion

Action: For adoption

Dermatology

2.1.17. Delafloxacin - EMEA-001080-PIP03-18

Treatment of community-acquired pneumonia (CAP)

Day 60 opinion

Action: For adoption

Infectious Diseases

2.1.18. EMEA-002419-PIP02-18

Prostate-specific membrane antigen (PSMA)-expressing metastatic, castration-resistant, prostate cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.19. L-asparaginase - Orphan - EMEA-000341-PIP03-18

ERYTECH Pharma S.A.; Treatment of pancreatic cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.20. Rivoceranib mesylate - Orphan - EMEA-002489-PIP01-18

LSK BioPharma Limited; Treatment of gastric cancer / Treatment of adult patients with advanced or metastatic gastric cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.21. Rogaratinib - EMEA-002439-PIP01-18

Treatment of urothelial carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.22. EMEA-002504-PIP01-18

Treatment of all conditions included in the category of malignant neoplasms expressing CEACAM5 protein

Day 60 opinion

Action: For adoption

Oncology

2.1.23. Tislelizumab - EMEA-002480-PIP01-18

Treatment of all conditions included in the category of malignant neoplasms (except central

nervous system, haematopoietic and lymphoid tissue)

Day 60 opinion

Action: For adoption

Oncology

2.1.24. Cenergermin - Orphan - EMEA-001729-PIP02-18

Dompé farmaceutici S.p.A.; Treatment of dry eye disease

Day 60 opinion

Action: For adoption

Ophthalmology

2.1.25. Orvepitant - EMEA-002510-PIP01-18

Treatment of refractory chronic cough

Day 60 opinion

Action: For adoption

Pneumology - Allergology

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. Sebelipase alfa - EMEA-C-001331-PIP01-12-M02

Alexion Europe SAS; Treatment of lysosomal acid lipase deficiency

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism / Gastroenterology-Hepatology

2.2.2. Denosumab - EMEA-C-000145-PIP01-07-M09

Amgen Europe B.V.; Treatment of giant cell tumour of bone

Day 60 opinion

Action: For adoption

Oncology

2.2.3. Conestat alfa - EMEA-C-000367-PIP01-08-M08

Pharming Group N.V.; Treatment of hereditary angioedema (HAE)

Day 60 opinion

Action: For adoption

Other

2.2.4. Peanut allergen extract - EMEA-C1-001481-PIP01-13-M03

DBV Technologies S.A.; Treatment of peanut allergy

Day 60 letter

Action: For adoption

Pneumology - Allergology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Corifollitropin alfa - EMEA-000306-PIP01-08-M04

Merck Sharp & Dohme B.V.; Inability to achieve pregnancy, Treatment of hypogonadotrophic hypogonadism / female adults, boys

Day 60 opinion

Action: For adoption

2.3.2. Rivaroxaban - EMEA-000430-PIP01-08-M11

Bayer AG; Treatment of thromboembolic events, Prevention of thromboembolic events / Treatment (secondary prevention) of venous thromboembolism

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.3. Ertugliflozin L-PGA - EMEA-001533-PIP01-13-M02

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

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.4. Migalstat hydrochloride - Orphan - EMEA-001194-PIP01-11-M04

Amicus Therapeutics UK Limited; Treatment of Fabry disease

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.5. Recombinant parathyroid hormone: rhPTH (1-84) - Orphan - EMEA-001526-PIP01-13-M03

Shire Pharmaceuticals Ireland Limited; Treatment of hypoparathyroidism

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.6. Luspatercept - Orphan - EMEA-001521-PIP01-13-M03

Celgene Europe B.V.; Anaemias due to chronic disorders / Treatment of anaemia in patients with beta-thalassemia intermedia and major

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.7. Nonacog beta pegol (glycopegylated recombinant coagulation factor IX) - Orphan - EMEA-000731-PIP01-09-M03

Novo Nordisk A/S; ICD10-D67-Hereditary factor IX deficiency / Treatment and prophylaxis of bleeding in patient with Haemophilia B (congenital factor IX deficiency)

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.8. Roxadustat - EMEA-001557-PIP01-13-M03

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

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.9. 2Tofacitinib citrate - EMEA-000576-PIP01-09-M10

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

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.10. Ceftolozane / tazobactam - EMEA-001142-PIP01-11-M03

Merck Sharp & Dohme (Europe), Inc.; Treatment of abdominal and gastrointestinal infections, Treatment of urinary tract infections / Treatment of complicated urinary tract infections (cUTI), Treatment of complicated intra-abdominal infections (cIAI)

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.11. Etravirine - EMEA-000222-PIP01-08-M09

Janssen-Cilag International NV; Treatment of HIV-1 virus infection / Indicated in combination with boosted protease inhibitor and other antiretroviral medicinal products for the Treatment of HIV-1 infection in antiretroviral treatment-experienced adolescents and children from 2 months of age and older

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.12. Oritavancin diphosphate - EMEA-001270-PIP01-12-M02

Rempex London Ltd; Treatment of skin and subcutaneous tissue bacterial infections

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.13. Inebilizumab - Orphan - EMEA-001911-PIP01-15-M02

Viela Bio; Neuromyelitis optica spectrum disorder (NMOSD)

Day 60 opinion

Action: For adoption

Neurology

2.3.14. Teriflunomide - EMEA-001094-PIP01-10-M05

Genzyme Europe B.V. / Sanofi-Aventis groupe; Multiple sclerosis / Treatment of children and adolescents from 10 to less than 18 years of age with relapsing forms of multiple sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.3.15. Regorafenib - EMEA-001178-PIP01-11-M04

Bayer AG; Treatment of all conditions contained in the category of malignant neoplasms (except haematopoietic and lymphoid tissue) / Treatment of paediatric patients with a solid malignant tumour(s) integrated with anti-cancer therapy

Day 60 opinion

Action: For adoption

Oncology

2.3.16. Idarucizumab - EMEA-001438-PIP01-13-M01

Boehringer Ingelheim international GmbH; Prevention of dabigatran associated haemorrhage / Treatment of dabigatran associated haemorrhage

Day 60 opinion

Action: For adoption

Other

2.3.17. Selexipag - EMEA-000997-PIP01-10-M02

Janssen Cilag International NV; Treatment of pulmonary arterial hypertension

Day 60 opinion

Action: For adoption

Other

2.3.18. Fevipiprant - EMEA-001315-PIP02-16-M01

Novartis EuroPharm Limited; Treatment of uncontrolled persistent asthma

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.19. Peanut flour - EMEA-001734-PIP01-14-M04

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

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.20. 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-M01

Sanofi Pasteur; Prevention of meningococcal disease

Day 60 opinion

Action: For adoption

Vaccines

2.4. Opinions on Re-examinations

2.4.1. Chemically modified recombinant human sulfamidase - Orphan - EMEA-002380-PIP01-18

Swedish Orphan Biovitrum AB (publ); Mucopolysaccharidosis type IIIA (MPS IIIA)

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.5. Opinions on Review of Granted Waivers

No items.

2.6. Finalisation and adoption of opinions

2.7. Partial Compliance Checks completed by EMA

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

2.7.1. Avelumab - EMEA-C2-001849-PIP02-15-M02

Merck KGaA; Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumors, haematopoetic and lymphoid tissue neoplasms)

Day 1 letter

Action: For information

Oncology

2.7.2. Tisagenlecleucel - EMEA-C2-001654-PIP01-14-M03

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

Day 1 letter

Action: For information

Oncology

2.7.3. Vericiguat - EMEA-C1-001636-PIP01-14-M01

Bayer AG; Treatment of left ventricular failure

Day 1 letter

Action: For information

Cardiovascular Diseases

2.7.4. Osilodrostat - EMEA-C2-000315-PIP02-15-M02

Novartis Europharm Limited; Treatment of adrenal cortical hyperfunctions

Day 1 letter

Action: For information

Endocrinology-Gynaecology-Fertility-Metabolism

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-PIP01-18

Anaesthetic and allied procedures / Intensive care unit (ICU) sedation /Sedation during medical procedures / General Anaesthesia

Day 90 discussion

Action: For discussion

Anaesthesiology

3.1.2. Efpeglenatide - EMEA-001903-PIP01-15

Type 2 diabetes mellitus

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.3. Dusquetide - EMEA-002306-PIP02-18

Prevention of severe oral mucositis

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.4. 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

Genzyme Europe B.V.; Treatment of Haemophilia B, Treatment of Haemophilia A / 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 / 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 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.5. Ustekinumab - EMEA-000311-PIP06-18

ICD10: M32 Treatment of systemic lupus erythematosus (SLE)

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.6. Tafenoquine - EMEA-002301-PIP01-17

Prevention of malaria

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.7. Benzimidazole-containing ENaC inhibitor - EMEA-002394-PIP01-18

Treatment of cystic fibrosis (CF) / Indicated to improve lung function and reduce pulmonary exacerbations for patients with CF in conjunction with standard therapies.

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.8. Glycopyrronium bromide / formoterol fumarate dihydrate / beclometasone dipropionate - EMEA-001875-PIP02-18

Treatment of asthma / Regular treatment of asthma in patients not controlled with medium-high doses of inhaled corticosteroids and long-acting beta2-agonists

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.9. EMEA-002481-PIP01-18

Moderate to severe atopic dermatitis

Day 60 discussion

Action: For discussion

Dermatology

3.1.10. Gadopiclenol - EMEA-001949-PIP02-18

Diagnostic / Detection and visualization of disorders or lesions with suspected abnormal vascularity in various body regions.

Day 60 discussion

Action: For discussion

Diagnostic

3.1.11. Levonorgestrel - EMEA-002474-PIP02-18

Contraception

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

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

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

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

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

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.14. 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 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.15. Secukinumab - EMEA-000380-PIP05-18

Hidradenitis suppurativa

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.16. 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 60 discussion

Action: For discussion

Infectious Diseases

3.1.17. Equine Immunoglobulin F(ab')2 fragments targeting Shiga toxin - Orphan - EMEA-002444-PIP02-18

Chemo Research, S.L.; Prevention of Shiga-Toxin Producing Escherichia Coli Haemolytic Uremic Syndrome

Day 60 discussion

Action: For discussion

Infectious Diseases

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

Treatment of complicated urinary tract infections (cUTI)

Day 60 discussion

Action: For discussion

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

3.1.19. 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 60 discussion

Action: For discussion

Oncology

3.1.20. Flucytosine - Orphan - EMEA-002437-PIP02-18

Tocagen Inc; Treatment of glioma

Day 60 discussion

Action: For discussion

Oncology

3.1.21. Vocimagene amiretrorepvec - Orphan - EMEA-002505-PIP02-18

Tocagen Inc.; Treatment of glioma

Day 60 discussion

Action: For discussion

Oncology

3.1.22. EMEA-002484-PIP01-18

Asthma / Use as an add-on controller medication in the treatment of adults, adolescents and children (>5 years of age) with inadequately controlled asthma

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.23. 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 60 discussion

Action: For discussion

Uro-nephrology

3.1.24. Atorvastatin / amlodipine / candesartan - EMEA-002520-PIP01-18

Treatment of essential hypertension (ICD9: 401, ICD10: I10),/ Treatment of familial hypercholesterolemia (ICD9: 272.0, ICD10: E78.0) / For adults with hypertension and elevated cholesterol already controlled with ramipril, amlodipine and atorvastatin given concurrently at the same dose level as in the fixed dose combinations (FDC) (substitution indication).

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.25. Recombinant human lecithin cholesterol acyltransferase - Orphan - EMEA-002497-PIP01-18

AstraZeneca AB; Acute ST-segment elevation myocardial infarction (STEMI)

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.26. Glycerol / urea - EMEA-002511-PIP01-18

Treatment of atopic dermatitis / Treatment of dry skin / Prevention of relapse of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.1.27. Inactivated patient's own (autologous) microorganism (e.g. Escherichia coli, Candida spp., Enterococcus spp., Streptococcus spp., Staphylococcus spp., Prevotella intermedia, Fusobacterium nucleatum and others) - EMEA-002442-PIP01-18

Prevention and treatment of chronic or recurrent dermal or mucosal inflammation / Prevention and treatment of chronic or recurrent skin and/or mucosa inflammation in the urogenital, otorhinolaryngeal, bronchial, oral, gingiva or periodontal tract, resistant to treatment or not sufficiently treatable with topical or systemic antibiotics, antivirals, antifungals or anti-inflammatory compounds

Day 30 discussion

Action: For discussion

Dermatology / Pneumology - Allergology / Oto-rhino-laryngology / Uro-nephrology

3.1.28. Seladelpar - Orphan - EMEA-002527-PIP01-18

CymaBay Ireland Limited; Treatment of primary biliary cholangitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.29. EMEA-002501-PIP01-18

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

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.30. EMEA-002529-PIP01-18

Treatment of respiratory syncytial virus infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.31. Cladribine - EMEA-000383-PIP02-18

Treatment of multiple sclerosis / Adults and Paediatrics

Day 30 discussion

Action: For discussion

Neurology

3.1.32. Phenobarbital - EMEA-002532-PIP01-18

Epilepsy

Day 30 discussion

Action: For discussion

Neurology

3.1.33. Abemaciclib - EMEA-002342-PIP02-18

High grade glioma (HGG), neuroblastoma (NBL) / Treatment of relapsed or refractory neuroblastoma in combination with irinotecan and temozolomide in paediatric patients /

Treatment of newly diagnosed high grade glioma in combination with temozolomide in paediatric patients

Day 30 discussion

Action: For discussion

Oncology

3.1.34. Humanized antibody targeting B cell maturation antigen conjugated with maleimidocaproyl monomethyl auristatin F - Orphan - EMEA-002468-PIP02-18

GlaxoSmithKline Trading Services; Treatment of multiple myeloma

Day 30 discussion

Action: For discussion

Oncology

3.1.35. Mosunetuzumab - EMEA-002524-PIP01-18

Treatment of follicular lymphoma

Day 30 discussion

Action: For discussion

Oncology

3.1.36. Niraparib - Orphan - EMEA-002268-PIP03-18

Janssen Research & Development; Treatment of prostate malignant neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.1.37. Carfilzomib - Orphan - EMEA-001806-PIP03-18

Amgen Europe BV; Treatment of multiple myeloma

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.1.38. Amoxicillin - EMEA-002548-PIP01-19

Adults / Combination therapy for the eradication of Helicobacter pylori in patients with peptic ulceration, with the aim of reducing the frequency of recurrence of duodenal ulcer disease (ulcera duodeni) and gastric ulcer (ulcer ventriculi) caused by this pathogen.

Day 30 discussion

Action: For discussion

Other

3.1.39. Clarithromycin - EMEA-002549-PIP01-19

Adults / Combination therapy for the eradication of Helicobacter pylori in patients with peptic ulceration, with the aim of reducing the frequency of recurrence of duodenal ulcer disease (ulcera duodeni) and gastric ulcer (ulcer ventriculi) caused by this pathogen.

Day 30 discussion

Action: For discussion

Other

3.1.40. Colecalciferol - EMEA-002553-PIP01-19

Treatment of osteoporosis

Day 30 discussion

Action: For discussion

Other

3.1.41. Ibandronic acid - EMEA-002331-PIP01-18

Treatment of osteoporosis

Day 30 discussion

Action: For discussion

Other

3.1.42. Pantoprazole - EMEA-002512-PIP01-18

Adults / Combination therapy for the eradication of Helicobacter pylori in patients with peptic ulceration, with the aim of reducing the frequency of recurrence of duodenal ulcer disease (ulcera duodeni) and gastric ulcer (ulcer ventriculi) caused by this pathogen

Day 30 discussion

Action: For discussion

Other

3.1.43. Olopatadine hydrochloride / mometasone furoate - EMEA-002514-PIP01-18

Treatment of allergic rhinitis / rhino-conjunctivitis

Day 30 discussion

Action: For discussion

Oto-rhino-laryngology

3.1.44. Atogepant - EMEA-002530-PIP01-18

G43 Migraine / Prophylaxis of migraine

Day 30 discussion

Action: For discussion

Pain

3.1.45. (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 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.46. Budesonide / salbutamol sulfate - EMEA-002533-PIP01-18

Treatment of asthma / as-needed treatment or prevention of bronchoconstriction in children aged 6 years and older with reversible obstructive airway disease. The reduction of exacerbations in children aged 6 years and older with asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.47. Tosatoxumab - Orphan - EMEA-002506-PIP01-18

Aridis Pharmaceuticals Inc; Pneumonia caused by Staphylococcus aureus

Day 30 discussion

Action: For discussion

Pneumology – Allergology

3.1.48. EMEA-002398-PIP01-18

Cystic Fibrosis / Treatment of cystic fibrosis in individuals with cystic fibrosis who are homozygous for the F508del mutation and are receiving treatment with a CFTR modulator

Day 90 discussion

Action: For discussion

Pneumology – Allergology

3.2. Discussions on Compliance Check

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

3.2.1. Lurasidone hydrochloride - EMEA-C-001230-PIP01-11-M04

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

Day 30 discussion

Action: For discussion

Psychiatry

3.2.2. Potassium hydrogen carbonate / potassium citrate monohydrated - EMEA-C1-001357-PIP01-12-M02

ADVICENNE; Treatment of renal tubular acidosis

Day 30 discussion

Action: For discussion

Uro-nephrology

3.2.3. Fc- and CDR-modified humanised monoclonal antibody against C5 - EMEA-C1-001943-PIP01-16-M01

Alexion Europe SAS; Treatment of atypical haemolytic uremic syndrome

Day 30 discussion

Action: For discussion

Uro-nephrology / Haematology-Hemostaseology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Angiotensin II - EMEA-001912-PIP02-16-M02

La Jolla Pharmaceutical II B.V.; Hypotension associated with distributive or vasodilatory shock

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. Omecamtiv mecarbil - EMEA-001696-PIP01-14-M01

Amgen Europe B.V.; Treatment of heart failure / Treatment of chronic heart failure New York Association (NYHA) class II-IV with systolic dysfunction, in children and adolescents 6 to <18 years, in combination with standard pharmacological therapy, including angiotensin converting enzyme inhibitors (ACE inhibitors), angiotensin II receptor blockers, and/or beta-blockers

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.3. Asfotase alfa - Orphan - EMEA-000987-PIP01-10-M04

Alexion Europe SAS; Treatment of hypophosphatasia

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. Deferiprone - Orphan - EMEA-001126-PIP01-10-M03

Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF) - Coordinator for DEEP Project (HEALTH-F4-2010-261483); Treatment of chronic iron overload requiring chelation therapy / Treatment of iron overload in paediatric patients affected by haemoglobinopathies requiring chronic transfusions and iron chelation

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.5. Ravulizumab - Orphan - EMEA-002077-PIP01-16-M02

Alexion Europe SAS; Treatment of paroxysmal nocturnal haemoglobinuria

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.6. Baricitinib - EMEA-001220-PIP01-11-M05

Eli Lilly and Company Limited; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis) / Treatment of juvenile idiopathic arthritis / Treatment of JIA-associated uveitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.7. Adalimumab - EMEA-000366-PIP02-09-M06

AbbVie Limited; Treatment of moderate to severe ulcerative colitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Ophthalmology / Dermatology / Gastroenterology-Hepatology

3.3.8. Imipenem monohydrate / relebactam monohydrate / cilastatin sodium - EMEA-001809-PIP01-15-M01

Merck Sharp & Dohme (Europe), Inc.; Treatment of bacterial infections caused by gram-negative bacteria

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.9. Pibrentasvir / glecaprevir - EMEA-001832-PIP01-15-M02

AbbVie Ltd; Treatment of Chronic Hepatitis C

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.10. Tenofovir alafenamide - EMEA-001584-PIP01-13-M04

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.11. Onasemnogene abeparvovec - Orphan - EMEA-002168-PIP01-17-M01

AveXis Netherlands B.V.; Treatment of spinal muscular atrophy / Treatment of spinal muscular atrophy Type 1

Day 30 discussion

Action: For discussion

Neurology

3.3.12. Quizartinib - Orphan - EMEA-001821-PIP01-15-M03

Daiichi Sankyo Europe GmbH; Treatment of acute myeloid leukaemia (AML) / 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

3.3.13. Ruxolitinib phosphate - EMEA-000901-PIP03-16-M01

Novartis Europharm Limited; Treatment of acute 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

3.3.14. Gilteritinib (as fumarate) - Orphan - EMEA-002064-PIP01-16-M01

Astellas Pharma Europe B.V.; Treatment of acute myeloid leukemia (AML) / Treatment of patients from 6 months to less than 18 years of age with relapsed or refractory FLT3/ITD positive acute myeloid leukaemia or newly-diagnosed FLT3/ITD positive acute myeloid

leukaemia

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.3.15. Clostridium botulinum neurotoxin type A (150 kD), free from complexing proteins - EMEA-001039-PIP02-12-M03

Merz Pharmaceuticals GmbH; Treatment of chronic troublesome sialorrhea associated with neurological conditions (e.g. cerebral palsy, traumatic brain injury) and/or intellectual disability in children and adolescents aged 2 – 17 years.

Day 30 discussion

Action: For discussion

Ophthalmology / Neurology

3.3.16. Agomelatine - EMEA-001181-PIP01-11-M04

Les Laboratoires Servier; Major Depressive Episodes

Day 30 discussion

Action: For discussion

Psychiatry

3.3.17. Finerenone - EMEA-001623-PIP01-14-M02

Bayer AG; Chronic Kidney Disease / Treatment of chronic kidney disease associated with proteinuria in addition to a therapy with ACEi or ARB

Day 30 discussion

Action: For discussion

Uro-nephrology

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 30 April 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

Disclosure of 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

Disclosure of 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)

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. Fezolinetant- EMEA-18-2018

Astellas Pharma Europe BV; All classes of medicinal products for treatment of climacteric symptoms associated with decreased oestrogen levels, as occurring at menopause / Treatment of moderate to severe vasomotor symptoms associated with menopause in women

Action: For adoption

6.1.2. Estetrol- EMEA-02-2019

Donesta Bioscience B.V.; All classes of medicinal products for treatment of climacteric symptoms associated with decreased oestrogen levels, as occurring at menopause / Treatment of moderate to severe vasomotor symptoms associated with menopause in women

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. Human Papillomavirus type 6 L1 protein / Human Papillomavirus type 11 L1 protein / Human Papillomavirus type 16 L1 protein / Human Papillomavirus type 18 L1 protein – Gardasil - EMEA-000375-PIP01-08-M02

MSD (Europe) Inc; Infection by Human Papillomavirus

Proposed indication: prevention of head & neck cancers (HNC) caused by vaccine HPV types

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

Update on PDCO member(s)/alternate(s) mandate status

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: Comments on ICH S11 – Nonclinical safety testing in support of development paediatric medicines

PDCO member: Karen van Malderen

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.3.3. Modelling and Simulation Working Party: the outlining of the key element form (KEF) for the modelling & simulation (M&S) study

MSWP Chair: Kirstin 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): Outcome of Working Group on Trial Preparedness

PDCO member: Angeliki Siapkara

Action: For information

9.5. Cooperation with International Regulators

9.5.1. Report from the Paediatric Cluster Teleconference

Action: For information

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

9.6.1. Outcome of the WHO/Paediatric HIV Vatican Meeting

Action: For information

9.7. PDCO work plan

No items

9.8. Planning and reporting

9.8.1. Strategic Review and Learning Meeting (SRLM) under the Romanian Presidency to be held in Malta on 13-14 June 2019

PDCO members: Dana Gabriela Marin, John Joseph Borg

Action: For information

10. Any other business

10.1.1. Survey on additional information requested during PIP procedures

Action: For information

10.1.2. EMA relocation to Amsterdam, the Netherlands – Questions & Answers (Q&As)

Action: For discussion

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 3G

11.1.3. Inventory

Action: For discussion on Thursday, 14:00 - 15:00, room 3A

11.1.4. Juvenile Idiopathic Arthritis

Action: For discussion on Thursday, 12:30 - 13:30, room 3L

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/