



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Procedure Management and Committees Support Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 30 March-1 April 2016

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

30 March 2016, 08:30- 19:00, room 3A

31 March 2016, 08:30- 19:00, room 3A

1 April 2016, 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 30 March - 1 April 2016. See March 2016 PDCO minutes (to be published post April 2016 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 30 March - 1 April 2016.

1.3. Adoption of the minutes

PDCO minutes for 24-26 February 2016.

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. KEOC liquid extract ethanolic 30 per cent (w/w) of *Allium cepa* L. (fresh bulb) and *Citrus lemon* (L.) Burm. (fresh fruit), *Paullinia cupana* Kunth, *Theobroma cacao* L. - EMEA-001835-PIP01-15

Treatment of alopecia

Day 120 opinion

Action: For adoption

Dermatology

2.1.2. A derivative of (2S,3S,4R)-3-ethyl-4-hydroxypyrrolidine-2-carboxylic acid / A derivative of (S)-methyl (2-(2-(1H-imidazol-2-yl)pyrrolidin-1-yl)-2-oxoethyl)carbamate / Sofosbuvir - EMEA-001822-PIP01-15

Treatment of chronic hepatitis C / Treatment of chronic Hepatitis C in adolescents and children 3 years of age and older

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.3. [Anti-respiratory syncytial virus human IgG1k monoclonal antibody - EMEA-001784-PIP01-15](#)

Prevention of respiratory syncytial viral infections

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.4. [doravirine - EMEA-001676-PIP01-14](#)

Treatment of human immunodeficiency virus-1 (HIV-1) infection / Antiretroviral therapy, in combination with other antiretroviral agents, for the treatment of HIV-1 infection in children aged from birth to 18 years

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.5. [tenofovir alafenamide / emtricitabine / cobicistat / darunavir - EMEA-001825-PIP01-15](#)

Treatment of human immunodeficiency virus type-1 (HIV-1) infection / Treatment of HIV-1 infection in adolescents aged from 12 years to <18 years, and weighing 40 kg or more

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.6. [tenofovir disoproxil fumarate / lamivudine / doravirine - EMEA-001695-PIP01-14](#)

Treatment of human immunodeficiency virus-1 (HIV-1) infection / Antiretroviral combination therapy, for the treatment of HIV-1 infection in adults and in children aged 2 to 18 years

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.7. [Human recombinant IgG1 monoclonal antibody targeting fibroblast growth factor 23 Orphan - EMEA-001659-PIP01-15](#)

Ultragenyx Pharmaceutical Inc.; X-linked Hypophosphatemia

Day 120 opinion

Action: For adoption

Other

2.1.8. Hydrogen Peroxide - EMEA-001884-PIP02-15

Treatment of seborrhoeic keratosis / Treatment of seborrhoeic keratosis

Day 60 opinion

Action: For adoption

Dermatology

2.1.9. Levodopa - EMEA-001874-PIP01-15

Parkinson's Disease

Day 60 opinion

Action: For adoption

Neurology

2.1.10. Diclofenac sodium / Capsaicin - EMEA-001861-PIP01-15

Treatment of pain

Day 60 opinion

Action: For adoption

Pain

2.1.11. solithromycin - EMEA-001581-PIP02-16

Treatment of gonococcal infection / Treatment of gonococcal infection

Day 30 adoption

Action: For adoption

Infectious Diseases

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. Adalimumab - EMEA-C-000366-PIP04-12

AbbVie Ltd; Treatment of hidradenitis suppurativa

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Dermatology

- 2.2.2. Pneumococcal polysaccharide serotype 6B conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 23F conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 1 conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 18C conjugated to tetanus toxoid / Pneumococcal polysaccharide serotype 19F conjugated to diphtheria toxoid / Pneumococcal polysaccharide serotype 7F conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 9V conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 14 conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 4 conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 5 conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein - EMEA-C5-000673-PIP01-09-M08
-

GlaxoSmithKline Biologicals S.A.; Prevention of diseases caused by streptococcus pneumoniae

Day 30 opinion

Action: For adoption

Vaccines

- 2.2.3. Expanded Human Allogeneic Mesenchymal Adult Stem Cells Extracted from Adipose Tissue - EMEA-C1-001561-PIP01-13
-

TiGenix S.A.U.; Treatment of anal fistula

Opinion adopted via written procedure on 22 March 2016

Action: For information

Gastroenterology-Hepatology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

- 2.3.1. rivaroxaban - EMEA-000430-PIP01-08-M09
-

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

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. Tadalafil - EMEA-000452-PIP02-10-M04

Eli Lilly and Company Ltd; Pulmonary arterial hypertension (already approved in adults) / Treatment of Persistent Pulmonary Hypertension of the Newborn, Treatment of Pulmonary Arterial Hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.3. vorapaxar sulfate - EMEA-000778-PIP02-12-M01

Merck Sharp & Dohme (Europe), Inc.; Prevention of Thromboembolism / Prevention of thromboemboloc events in paediatric patients

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.4. exenatide - EMEA-000689-PIP01-09-M06

AstraZeneca AB; Non insulin dependant diabetes mellitus (treatment including thiazolidinediones), Non insulin dependant diabetes mellitus (excluding treatment with thiazolidinediones) / Treatment of type 2 Diabetes Mellitus

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.5. Lixisenatide - EMEA-000916-PIP01-10-M05

sanofi-aventis R&D; Type 2 diabetes mellitus / Treatment of type 2 diabetes mellitus

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.6. sitagliptin phosphate - EMEA-000471-PIP01-08-M02

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

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.7. sitagliptin phosphate - EMEA-000472-PIP01-08-M02

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

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.8. Denosumab - EMEA-000145-PIP01-07-M08

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

Day 60 opinion

Action: For adoption

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

2.3.9. solithromycin - EMEA-001581-PIP01-13-M02

Triskel EU Services, Ltd; Treatment of community acquired pneumoniae, Treatment of infection by Francisella tularaensis (tularemia), Treatment of infection by Bacillus anthracis (anthrax) / Treatment of community acquired pneumoniae, Treatment of inhalation tularemia following exposure to Francisella tularaensis, Treatment of inhalation anthrax following exposure to Bacillus anthracis

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.10. ataluren - Orphan - EMEA-000115-PIP01-07-M07

PTC Therapeutics International Limited; Treatment of dystrophinopathy ICD-10: G71.0 Muscular dystrophy [of Duchenne and Becker] / Treatment of nonsense-mutation dystrophinopathy

Day 60 opinion

Action: For adoption

Neurology

2.3.11. Dimethyl fumarate - EMEA-000832-PIP01-10-M03

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

Day 60 opinion

Action: For adoption

Neurology

2.3.12. Perampanel - EMEA-000467-PIP01-08-M07

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 60 opinion

Action: For adoption

Neurology

2.3.13. Pitolisant - Orphan - EMEA-001176-PIP01-11-M02

BIOPROJET PHARMA; Narcolepsy / Treatment of narcolepsy with or without cataplexy

Day 60 opinion

Action: For adoption

Neurology

2.3.14. Cabozantinib - Orphan - EMEA-001143-PIP01-11-M01

Exelixis Inc; Cancer

Day 60 opinion

Action: For adoption

Oncology

2.3.15. Selumetinib - EMEA-001585-PIP01-13-M01

AstraZeneca AB; Treatment of Neurofibromatosis-Type 1, Treatment of Thyroid cancer, Treatment of lung carcinoma / , Selumetinib is indicated for the treatment of inoperable NF1 related plexiform neurofibroma in children and adolescents, Selumetinib in combination with adjuvant radioactive iodine therapy is indicated for the treatment of adolescents newly diagnosed with differentiated thyroid cancer who are at high risk of primary treatment failure.

Day 60 opinion

Action: For adoption

Oncology

2.3.16. Drospirenone - EMEA-001495-PIP01-13-M01

LABORATORIOS LEÓN FARMA, S.A.; Contraception / Oral contraception

Day 30 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.17. Allantoin - Orphan - EMEA-001590-PIP01-13-M02

Scioderm, Inc.; Treatment of epidermolysis bullosa

Day 30 opinion

Action: For adoption

Dermatology

2.4. Opinions on Re-examinations

No items.

2.5. Finalisation and adoption of opinions

3. Discussion of applications

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

3.1. Discussions on Products D90-D60-D30

3.1.1. EMEA-001841-PIP01-15

Type 2 Diabetes Mellitus

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.2. Recombinant humanized anti-MMP9 monoclonal antibody IgG4 - EMEA-001813-PIP01-15

Crohn's Disease, Ulcerative Colitis

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.3. octan-6-yl sulfate hydrate / cilastatin sodium / imipinem monohydrate - EMEA-001809-PIP01-15

Treatment of bacterial infections caused by Gram-negative bacteria

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.4. EMEA-001832-PIP01-15

Treatment of Chronic Hepatitis C / Treatment of Chronic Hepatitis C

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.5. pimavanserin - EMEA-001688-PIP02-15

Treatment of schizophrenia and other psychotic disorders

Day 90 discussion

Action: For discussion

Psychiatry

3.1.6. Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) / 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) - EMEA-001715-PIP01-14

Influenza / Prevention of influenza

Day 90 discussion

Action: For discussion

Vaccines

3.1.7. [tralokinumab - EMEA-001900-PIP01-15](#)

Atopic dermatitis

Day 60 discussion

Action: For discussion

Dermatology

3.1.8. [Cathine hydrochloride \(D-Norpseudoephedrine hydrochloride\) - EMEA-001909-PIP01-15](#)

Treatment of obesity / Adjunct therapy for patients with obesity and a body mass index (BMI) of at least 30 for adults and above the 97th percentile for children who failed to achieve adequate therapeutic response with comprehensive weight loss measures alone.

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.9. [Naldemedine Tosylate - EMEA-001893-PIP01-15](#)

Opioid-induced constipation (OIC) / Opioid-induced constipation (OIC)

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.10. [Eculizumab - Orphan - EMEA-000876-PIP07-15](#)

Alexion Europe SAS; Prevention of delayed graft function after solid organ transplantation / Prevention of delayed graft function after kidney transplantation in patients at increased risk of delayed graft function

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.11. [Expanded donor-derived allogenic T cells transduced with the retroviral vector expressing the transgenes for inducible caspase9 and the truncated CD19 selectable marker - EMEA-001869-PIP01-15](#)

ICD-9 code 279.10 Immunodeficiency with predominant T-cell defect, unspecified / Non-malignant disorders amenable to cure by haematopoietic stem cell transplant (HSCT)

Day 60 discussion

Action: For discussion

3.1.12. Rimiducid - EMEA-001870-PIP01-15

Treatment of Graft Versus Host Disease (ICD 279.50) / Treatment of Graft Versus Host Disease (GvHD) in paediatric patients with non-malignant conditions who received BPX-501 T cell replacement

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.13. Omadacycline - EMEA-000560-PIP02-15

Infections of the skin and subcutaneous tissue

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.14. Omadacycline - EMEA-000560-PIP03-15

Bacterial pneumonia

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.15. Humanised, affinity-optimised, afucosylated immunoglobulin G1 kappa monoclonal antibody - EMEA-001911-PIP01-15

Treatment of Neuromyelitis Optica (NMO) and Neuromyelitis Optica Spectrum Disorders (NMOSD)

Day 60 discussion

Action: For discussion

Neurology

3.1.16. Humanized monoclonal calcitonin gene-related peptide neutralizing antibody - EMEA-001860-PIP03-16

Prophylactic treatment of migraine headache

Day 60 discussion

Action: For discussion

Neurology

- 3.1.17. Humanised chimeric antibody with a humanised H chain and a chimeric (mouse V-domain, human C-domain) L chain against epidermal growth factor receptor conjugated to maleimidocaproyl monomethylauristatin F - Orphan - EMEA-001732-PIPO2-15
-

AbbVie Ltd; Treatment of high-grade glioma / Treatment of high-grade glioma.

Day 60 discussion

Action: For discussion

Oncology

- 3.1.18. Sapacitabine - Orphan - EMEA-001901-PIP01-15
-

Cyclacel Limited; Treatment of acute myeloid leukaemia

Day 60 discussion

Action: For discussion

Oncology

- 3.1.19. Angiotensin II - EMEA-001912-PIP01-15
-

Treatment of Catecholamine-resistant hypotension associated with distributive shock.

Day 60 discussion

Action: For discussion

Other

- 3.1.20. esketamine hydrochloride (2S)-2-(2-chlorophenyl)-2-(methylamino) cyclohexanone hydrochloride - EMEA-001428-PIP03-15
-

Major Depressive Disorder (MDD)

Day 60 discussion

Action: For discussion

Psychiatry

- 3.1.21. 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-001894-PIPO1-15
-

Prevention of influenza

Day 60 discussion

Action: For discussion

Vaccines

3.1.22. Rosuvastatin (Calcium) / Olmesartan medoxomil - EMEA-001914-PIP01-15

Hypertension, Dyslipidaemia, Cardiovascular events / Treatment of dyslipidaemia/hypercholesterolaemia, Prevention of cardiovascular events, Treatment of hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.23. A phosphorothioate oligonucleotide targeted to apolipoprotein C-III - Orphan - EMEA-001915-PIP01-15

Ionis Pharmaceuticals; Familial Chylomicronemia Syndrome

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.24. efpeglenatide - EMEA-001903-PIP01-15

Type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.25. Antithrombin alfa - EMEA-001154-PIP02-15

Treatment of congenital antithrombin deficiency, Treatment of acquired antithrombin deficiency (Preeclampsia), Treatment of acquired antithrombin deficiency (ECMO) / Prophylaxis of peri-partum thromboembolic events in congenital antithrombin deficient patients, Antithrombin supplementation during ECMO procedure, Treatment of pregnant women less than 30 weeks GA with preeclampsia to prolong gestation and decrease foetal and neonatal morbidity and mortality

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.26. abatacept - EMEA-000118-PIP03-15

Treatment of childhood-onset SLE / Treatment of childhood-onset lupus nephritis caused by childhood-onset SLE with abatacept in combination with MMF or CY, and CS in pediatric patients 5 years of age and older who have had an insufficient response to MMF or CY, and CS.

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.27. Ciprofloxacin Hydrochloride - EMEA-001563-PIP02-15

Treatment of cystic fibrosis related bronchiectasis associated with P. aeruginosa infection, Treatment of non-cystic fibrosis related bronchiectasis associated with P. aeruginosa infection (NCFBEPA+)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.28. synthetic surfactant protein B analogue / synthetic surfactant protein C analogue / 1-palmitoyl-2-oleoyl-sn-glycero-3-phosphoglycerol sodium salt / dipalmitoylphosphatidylcholine - Orphan - EMEA-001780-PIP01-15

Chiesi Farmaceutici SpA; treatment of respiratory distress syndrome (RDS) / treatment of respiratory distress syndrome (RDS) in preterm neonates of less than 37 weeks of gestational age

Day 30 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.1.29. benzodiazepine - EMEA-001918-PIP01-15

ICD10 F84: Treatment of autism spectrum disorder

Day 30 discussion

Action: For discussion

Neurology

3.1.30. Imetelstat Sodium - Orphan - EMEA-001910-PIP01-15

Janssen-Cilag International N.V; Treatment of Myelofibrosis

Day 30 discussion

Action: For discussion

Oncology

3.1.31. Cyclosporin - EMEA-001916-PIP01-15

Keratoconjunctivitis sicca

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.32. D-stereoisomer of c-Jun N-terminal Kinase Inhibitor 1 (D-JNKI-1; H-D-Asp-D-Gln-D-Ser-D-Arg-D-Pro-D-Val-D-Gln-D-Pro-D-Phe-D-Leu-D-Asn-D-Leu-D-Thr-D-Thr-D-Pro-D-Arg-D-Lys-D-Pro-D-Arg-D-Pro-D-Pro-D-Arg-D-Arg-D-Arg-D-Gln-D-Arg-D-Arg-D-Lys-D-Lys-D-Arg-D-Gly-NH₂) - Orphan - EMEA-001926-PIP01-16

Auris Medical Ltd.; ASNHL comprising idiopathic sudden sensorineural hearing loss (ISSNHL; also called sudden deafness), acute acoustic trauma (AAT), and surgery induced acoustic trauma

Day 30 discussion

Action: For discussion

Oto-rhino-laryngology

3.1.33. Tramadol hydrochloride / Ibuprofen arginine - EMEA-001887-PIP01-15

Acute pain

Day 30 discussion

Action: For discussion

Pain

3.1.34. Peanut flour - EMEA-001753-PIP02-15

Treatment of peanut allergy Z91.010

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.35. [N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup A polysaccharide conjugated to tetanus toxoid - EMEA-001930-PIP01-16](#)

Prevention of Meningococcal Disease

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. [Sirukumab - EMEA-C2-001043-PIP01-10-M02](#)

Janssen-Cilag International N.V.; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.2. [Ceftriaxone \(in the form of sodium salt\) / Sulbactam \(in the form of sodium salt\) - EMEA-C1-001568-PIP03-14](#)

Venus Pharma GmbH; Treatment of bacterial infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.3. [maraviroc - EMEA-C-000020-PIP01-07-M05](#)

ViiV Healthcare UK Limited; Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.4. dasatinib (as monohydrate) - EMEA-C3-000567-PIP01-09-M04

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

Day 30 discussion

Action: For discussion

Oncology

3.2.5. Nilotinib - EMEA-C3-000290-PIP01-08-M04

Novartis Europharm Ltd.; Treatment of chronic myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. dihydroartemisinin / piperazine tetraphosphate - EMEA-000153-PIP01-07-M03

Sigma-Tau SpA; Uncomplicated malaria caused by Plasmodium falciparum (ICD-10 code B50) / Treatment of uncomplicated malaria caused by Plasmodium falciparum

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.2. Liraglutide - EMEA-000128-PIP02-09-M02

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

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.3. retosiban - EMEA-001359-PIP01-12-M03

GlaxoSmithKline Trading Services Limited; Treatment of spontaneous preterm labour / Treatment of spontaneous preterm labour to improve neonatal outcomes by prolonging pregnancy in women with an uncomplicated singleton pregnancy between 24 and less than 34 weeks gestation

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. Tolvaptan - EMEA-001231-PIP02-13-M03

Otsuka Pharmaceutical Europe Ltd.; Polycystic Kidney Disease (PKD), Dilutional hyponatraemia / Treatment of chronic (>48 hours) dilutional hyponatraemia resistant to fluid restriction (i.e., euvoletic and hypervolemic hyponatremia) associated with heart failure, cirrhosis or SIADH., Treatment of progression of ADPKD, Treatment of progression of ARPKD

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. potassium sulphate / magnesium sulphate heptahydrate / sodium sulphate anhydrous - EMEA-000816-PIP02-10-M01

IPSEN Pharma; Diagnostic of organic and/or functional bowel diseases / In adults and children from 6 months of age for bowel cleansing prior to any procedure requiring a clean bowel (e.g. bowel visualisation including endoscopy and radiology or surgical procedure). Izinova is not a treatment for constipation.

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.6. efmorocotocog alfa - EMEA-001114-PIP01-10-M03

Biogen Idec Ltd; Hereditary Factor VIII Deficiency - D66 / Treatment and prophylaxis of bleeding in patients with severe Haemophilia A (congenital FVIII deficiency)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.7. Secukinumab - EMEA-000380-PIP02-09-M03

Novartis Europharm Limited; Chronic Idiopathic Arthritis / Treatment of juvenile psoriatic arthritis, Treatment of enthesitis-related arthritis JIA

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.8. raltegravir - EMEA-000279-PIP01-08-M05

Merck Sharp & Dohme (Europe), Inc.; Human Immunodeficiency Virus (HIV-1) infection / In combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.9. Alemtuzumab - EMEA-001072-PIP01-10-M02

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 30 discussion

Action: For discussion

Neurology

3.3.10. Clostridium Botulinum neurotoxin type A (150 kD), free from complexing proteins - EMEA-001039-PIP02-12-M02

Merz Pharmaceuticals GmbH; Treatment of sialorrhea / 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

Neurology

3.3.11. Melatonin - Orphan - EMEA-000440-PIP02-11-M04

RAD Neurim Pharmaceuticals EEC Ltd; Insomnia - children, Insomnia - adults /Insomnia

Day 30 discussion

Action: For discussion

Neurology

3.3.12. ibrutinib - Orphan - EMEA-001397-PIP03-14-M01

Janssen-Cilag International N.V.; Treatment of mature B-cell neoplasm / Treatment of children from 1 year to less than 18 years of age with newly-diagnosed and relapsed/refractory mature B-cell lymphoma, that is, diffuse large B-cell lymphoma or Burkitt and Burkitt-like lymphoma.

Day 30 discussion

Action: For discussion

Oncology

3.3.13. darbepoetin alfa - EMEA-000329-PIP02-09-M05

Amgen Europe B.V.; Drug-induced aplastic anaemia, Treatment of anaemia due to chronic disorders / Treatment of symptomatic anaemia in adult and paediatric cancer patients with non-myeloid malignancies receiving chemotherapy, Treatment of symptomatic anaemia associated with chronic renal failure (CRF) in adults and paediatric patients

Day 30 discussion

Action: For discussion

Oncology / Uro-nephrology

3.3.14. tafluprost - EMEA-001187-PIP01-11-M03

Santen Oy; Glaucoma (ICD: H40) / Tafluprost preservative-free is indicated for the treatment of elevated intraocular pressure in paediatric patients 1 month post-natal to less than 18 years of age.

Day 30 discussion

Action: For discussion

Ophthalmology

3.3.15. Clostridium Botulinum neurotoxin type A (150 kD), free from complexing proteins - EMEA-001039-PIP01-10-M02

Merz Pharmaceuticals GmbH; Treatment of muscle spasticity, Treatment of dystonia, Treatment of muscle induced wrinkles / , Treatment of spasticity of the upper and/or lower limb in children and adolescents (aged 2 - 17 years) with cerebral palsy

Day 30 discussion

Action: For discussion

Ophthalmology / Dermatology / Neurology

3.3.16. Atrasentan hydrochloride - EMEA-001666-PIP01-14-M01

AbbVie, Ltd; Nephropathies / Treatment of multidrug-resistant nephrotic syndrome (MDR-NS)

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3.17. Ferric citrate coordination complex - EMEA-001213-PIP02-12-M02

Keryx Biopharma UK Ltd.; Treatment of hyperphosphataemia / The control of hyperphosphataemia in patients with chronic kidney disease (CKD)

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 26 May 2016 for Nomination of Rapporteur and Peer reviewer

Action: For adoption

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

Action: For adoption

4.3. Nominations for other activities

Action: For adoption

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

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

6. Discussion on the applicability of class waivers

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

6.1. Discussions on the applicability of class waiver for products

6.1.1. Dutasteride and Tamsulosin hydrochloride - EMEA-20-2015

Treatment of benign prostatic hyperplasia/ Treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH), Reduction in the risk of acute urinary retention(AUR) and surgery in patients with moderate to severe symptoms of BPH

Action: For adoption

6.1.2. EMEA-07-2016

Treatment of chronic lymphocytic leukaemia/ Treatment of chronic lymphocytic leukaemia

Action: For adoption

6.1.3. EMEA-08-2016

Treatment of follicular lymphoma/ Treatment of follicular lymphoma

Action: For adoption

6.1.4. Niraparib - EMEA-09-2016

Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)- Treatment of Fallopian tube carcinoma ((excluding rhabdomyosarcoma and germ cell tumours) - Treatment of peritoneal carcinoma (excluding blastomas and sarcomas)/ Treatment of ovarian cancer including fallopian tube cancer and peritoneal cancers

Action: For adoption

6.1.5. EMEA-10-2016

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

Action: For adoption

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

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

None.

8. Annual reports on deferrals

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

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. PDCO plenary meeting duration - survey results

PDCO Chair: Dirk Mentzer

Action: For discussion

9.2. Coordination with EMA Scientific Committees or CMDh-v

9.2.1. Committee for Medicinal Products for Human Use (CHMP)

Action: For information

9.2.2. Guideline on the development of new medicinal products for the treatment of Crohn's Disease

PDCO members: Peter Szitanyi and Johannes Taminiau

Action: For adoption

9.2.3. Guideline on the development of new medicinal products for the treatment of Ulcerative Colitis

PDCO members: Peter Szitanyi and Johannes Taminiau

Action: For adoption

9.2.4. Sodium-glucose co-transporter-2 (SGLT2) inhibitors: canagliflozin – INVOKANA (CAP); canagliflozin, metformin – VOKANAMET (CAP); dapagliflozin – FORXIGA (CAP); dapagliflozin, metformin – XIGDUO (CAP); empagliflozin - JARDIANCE (CAP); empagliflozin, metformin – SYNJARDY (CAP) - EMA/H/A-20/1419

Applicant: AstraZeneca AB (Forxiga, Xigduo), Boehringer Ingelheim International GmbH (Jardiance, Synjardy), Janssen-Cilag International N.V. (Invokana, Vokanamet)

Scope: Review of the benefit-risk balance following notification by the European Commission of a referral under Article 20 of Regulation (EC) No 726/2004, based on pharmacovigilance data

Action: For information

9.2.5. Reflection paper on extrapolation of efficacy and safety in paediatric medicine development

Action: For adoption

9.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

9.3.1. Non-clinical Working Group: D30 Products identified

PDCO member: Jacqueline Carleer

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.4. Cooperation within the EU regulatory network

9.4.1. Report on the status of the revision of the 'Ethical considerations for clinical trials on medicinal products conducted with the paediatric population'

Action: For information

9.5. Cooperation with International Regulators

None.

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

None.

9.7. PDCO work plan

None.

9.8. Planning and reporting

9.8.1. PDCO Chair's report to Management Board - March 2016

PDCO Chair: Dirk Mentzer

Action: For information

9.9. PDCO ORGAM

9.9.1. PDCO ORGAM Draft Minutes for 16 March 2016

Action: For adoption

9.10. Other

9.10.1. Launch of PRIME (PRiority MEdicines) scheme

Action: For information

9.11. Harmonisation - Referral procedure under Article 30 of Directive 2001/83/EC

9.11.1. Haldol and associated names (EMEA/H/A-30/1393) (haloperidol), Janssen-Cilag Group of companies and associated companies

CHMP List of Questions to the PDCO

Rapporteur: Martina Weise, Co-Rapporteur: Katarina Vučić

Action: For discussion

9.11.2. Haldol decanoate and associated names (EMEA/H/A-30/1405) (haloperidol) Janssen-Cilag Group of companies and associated companies

CHMP List of Questions to the PDCO

Rapporteur: Martina Weise, Co-Rapporteur: Katarina Vučić

Action: For discussion

10. Any other business

10.1. None.

11. Breakout sessions

11.1.1. Paediatric oncology

Action: For discussion on Thursday, 18:00 - 19:00, room 3M

11.1.2. Neonatology

Action: For discussion on Thursday, 18:00 - 19:00, room 3L

11.1.3. Inventory

Action: For discussion on Thursday, 18:00 - 19:00, room 3K

11.1.4. 10-Year Report Drafting Group

Action: For discussion on Thursday, 18:00 - 19:00, room tbc

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/