13 November 2018
EMA/754134/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 13-16 November 2018

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

13 November 2018, 14:00- 19:00, room 3A

14 November 2018, 08:30- 19:00, room 3A

15 November 2018, 08:30- 19:00, room 3A

16 November 2018, 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 13-16 November 2018. See November month 2018 PDCO minutes (to be published post December 2018 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 13-16 November 2018.

1.3. Adoption of the minutes

PDCO minutes for 16-19 October 2018.

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. Evinacumab - EMEA-002298-PIP01-17

Treatment of elevated cholesterol / Treatment of homozygous familial hypercholesterolemia (HoFH)

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.2. Semaglutide - EMEA-001441-PIP03-17

Treatment of obesity

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.3. Ibrutinib - Orphan - EMEA-001397-PIP04-17

Janssen-Cilag International N.V.; Indicated for the treatment of cGVHD in children 1 year of age and older.

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.4. Rezafungin acetate - EMEA-002319-PIP01-17

Treatment of invasive candidiasis

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.5. Bilastine - EMEA-000347-PIP02-16

Treatment of allergic conjunctivitis

Day 120 opinion

Action: For adoption

Ophthalmology

2.1.6. Bupivacaine - EMEA-000877-PIP03-17

Postsurgical analgesia

Day 120 opinion

Action: For adoption

Pain

2.1.7. Meloxicam / Bupivacaine - EMEA-002246-PIP01-17

Acute Post Operative Pain

Day 120 opinion

Action: For adoption

Pain / Anaesthesiology

2.1.8. Synthetic double-stranded siRNA oligonucleotide targeted against transthyretin mRNA, with six phosphorothioate linkages in the backbone, and nine 2'-fluoro and thirty-five 2'-O-methyl nucleoside residues in the sequence, which is covalently

linked via a phosphodiester group to a ligand containing three N-acetylgalactosamine residues - Orphan - EMEA-002425-PIP01-18

Alnylam Netherlands BV; Transthyretin-mediated amyloidosis

Day 60 opinion

Action: For adoption

Cardiovascular Diseases / Neurology

2.1.9. Bruton's tyrosine kinase inhibitor - Orphan - EMEA-002438-PIP01-18

Principia Biopharma, Inc.; Treatment of Pemphigus

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.10. Anti-VEGF and anti-DLL4 dual variable domain immunoglobulin - EMEA-002420-PIP01-18

Treatment of colorectal malignant neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.1.11. Palbociclib - EMEA-002146-PIP02-18

Treatment of breast malignant neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.1.12. Germanium (68Ge) chloride / Gallium (68Ga) chloride - EMEA-002436-PIP01-18

Radiolabelling agent

Day 60 opinion

Action: For adoption

Other

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. Dupilumab - EMEA-C2-001501-PIP01-13-M05

Regeneron Pharmaceuticals, Inc.; Treatment of atopic dermatitis

Day 60 letter

Action: For adoption

Dermatology

2.2.2. Belimumab - EMEA-C-000520-PIP01-08-M05

Glaxo Group Limited; Treatment of systemic lupus erythematosus

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.2.3. Perampanel - EMEA-C5-000467-PIP01-08-M10

Eisai Europe Ltd; Treatment of treatment-resistant epilepsies

Day 60 letter

Action: For adoption

Neurology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Rabeprazole sodium - EMEA-000055-PIP01-07-M06

Eisai Limited; E16.4 Abnormal secretion of gastrin: Zollinger-Ellison Syndrome, K26 Duodenal Ulcer, K25 Gastric Ulcer, B96.8 Helicobacter pylori in patients with peptic ulcer disease, K21.0 Gastro-oesophageal reflux disease / Treatment of symptomatic erosive or ulcerative gastro-oesophageal reflux disease (GORD); symptomatic treatment of moderate to very severe gastro-oesophageal reflux disease (symptomatic GORD), Treatment in combination with appropriate antibacterial therapeutic regimens for the eradication of helicobacter pylori in patients with peptic ulcer disease

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.2. Bedaquiline (fumarate) - Orphan - EMEA-000912-PIP01-10-M04

Janssen-Cilag International NV; Treatment of multi-drug resistant tuberculosis

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.3. Ceftobiprole medocaril sodium - EMEA-000205-PIP02-11-M03

Basilea Pharmaceutica International Ltd.; J15: Bacterial pneumoniae no elsewhere classified, J13: Pneumonia due to Streptococcus pneumoniae, J14: Pneumonia due to Hemophilus influenzae / Treatment of nosocomial pneumonia, Treatment of community acquired pneumonia

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.4. Cobicistat / darunavir - EMEA-001280-PIP01-12-M02

Janssen-Cilag International NV; Treatment of HIV-1 infection in pediatric patients from 3 to less than 18 years.

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.5. Dolutegravir (DTG) - EMEA-000409-PIP01-08-M05

ViiV Healthcare UK Ltd.; B24 Unspecified Human Immunodeficiency Virus (HIV) disease / Treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.6. EMEA-001975-PIP01-16-M02

Janssen-Cilag International NV; Treatment of influenza / To be used in combination with oseltamivir for the treatment of acute influenza A in adults and children < 18 years of age with complicated influenza or at high risk for complications

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.7. Lamivudine (3TC) / Abacavir (ABC) / Dolutegravir (DTG) - EMEA-001219-PIP01-11-M04

ViiV Healthcare UK Limited; Treatment Human Immunodeficiency Virus (HIV-1) infection in paediatric population

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.8. Fenfluramine hydrochloride - Orphan - EMEA-001990-PIP01-16-M02

Zogenix International Ltd; Dravet syndrome / The adjunctive treatment of seizures in paediatric patients at least 1 year of age with Dravet syndrome

Day 60 opinion

Action: For adoption

Neurology

2.3.9. Autologous T cells transduced with lentiviral vector containing a chimeric antigen receptor directed against CD19 - Orphan - EMEA-001654-PIP01-14-M03

Novartis Europharm Limited; Treatment of B cell acute lymphoblastic leukaemia/lymphoblastic lymphoma / Treatment of CD19+ B cell acute lymphoblastic leukaemia (ALL) in paediatric patients whose disease is refractory to a standard chemotherapy regimen, relapsed after stem cell transplantation (SCT) or are ineligible for allogenic SCT.

Day 60 opinion

Action: For adoption

Oncology

2.3.10. Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta chimeric antigen receptor - Orphan - EMEA-001862-PIP01-15-M01

Kite Pharma EU B.V.; Treatment of acute lymphoblastic leukaemia

Day 60 opinion

Action: For adoption

Oncology

2.3.11. Axicabtagene ciloleucel - Orphan - EMEA-002010-PIP01-16-M01

Kite Pharma EU B.V.; Treatment of mature B-cell neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.3.12. Pazopanib - EMEA-000601-PIP01-09-M05

Novartis Europharm Limited; Ewing sarcoma family of tumours, Rhabdomyosarcoma, Non-rhabdomyosarcoma soft tissue sarcoma / Treatment of pediatric patients with rhabdomyosarcoma, Treatment of pediatric patients with Ewing sarcoma family of tumours, Treatment of pediatric patients with non-rhabdomyosarcoma soft tissue sarcoma

Day 60 opinion

Action: For adoption

Oncology

2.3.13. Ivacaftor / lumacaftor - EMEA-001582-PIP01-13-M08

Vertex Pharmaceuticals (Europe) Limited; Treatment of cystic fibrosis

Day 60 opinion

Action: For adoption

Other

2.3.14. Sildenafil - Orphan - EMEA-000671-PIP01-09-M10

Pfizer Limited; Treatment of Pulmonary Arterial Hypertension (PAH)

Day 60 opinion

Action: For adoption

Other

2.4. Opinions on Re-examinations

2.4.1. Autologous CD34+ haematopoietic stem cells transduced ex vivo with EFS lentiviral vector encoding for the human ADA gene - Orphan - EMEA-001974-PIP01-16-M02

Orchard Therapeutics Limited; Treatment of severe combined immunodeficiency due to adenosine deaminase deficiency (ADA-SCID)

Action: For adoption

Immunology-Rheumatology-Transplantation

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. Neisseria meningitidis serogroup B recombinant lipoprotein (subfamily A; Escherichia coli) / Neisseria meningitidis serogroup B recombinant lipoprotein (subfamily B; Escherichia coli) - EMEA-C2-001037-PIP02-11-M04

Pfizer Europe MA EEIG; Prevention of invasive meningococcal disease caused by N. meningitides serogroups B

Day 1 letter

Action: For information

Vaccines

2.7.2. Dupilumab - EMEA-C3-001501-PIP01-13-M05

Regeneron Pharmaceuticals, Inc.; Treatment of atopic dermatitis

Day 1 letter

Action: For information

Dermatology

2.7.3. Fenfluramine hydrochloride - EMEA-C4-001990-PIP01-16-M01

Zogenix International Ltd; Treatment of Dravet syndrome

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. Etripamil - EMEA-002303-PIP01-17

Treatment of supraventricular tachycardia / Treatment of acute paroxysmal supraventricular tachycardia (PSVT)

Day 90 discussion

Action: For discussion

Cardiovascular Diseases

3.1.2. Givosiran sodium - Orphan - EMEA-002048-PIP02-18

Alnylam UK Limited; Treatment of Acute Hepatic Porphyria (AHP)

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.3. EMEA-001710-PIP04-17

Treatment of Crohn's disease

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.4. Filgotinib - EMEA-001619-PIP03-16

Ulcerative colitis (UC), Crohn’s disease (CD) / Treatment of paediatric patients 2 years of age and older with moderately-to-severely active ulcerative colitis, Treatment of paediatric patients 2 years of age and older with moderately-to-severely active Crohn’s disease

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.5. Ianalumab - EMEA-002338-PIP01-18

Autoimmune hepatitis (AIH) / Treatment of autoimmune hepatitis in patients aged 8 years to <18 years in whom steroids and/or azathioprine are contraindicated, are not tolerated, or do not provide an adequate response

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.6. Baricitinib - EMEA-001220-PIP04-17

Treatment of systemic lupus erythematosus

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.7. Iclaprim mesylate - EMEA-002391-PIP01-18

Infection with Gram-positive bacteria / Treatment of acute bacterial skin and skin structure infections

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.8. Rilpivirine (as free base) - EMEA-000317-PIP02-18

Treatment of human immunodeficiency virus (HIV-1) infection / In combination with cabotegravir long acting, treatment of HIV-1 infection in pediatric patients from 6 to less than 18 years of age who are virologically suppressed (HIV-1 RNA <50 copies/mL) and no known or suspected resistance to either rilpivirine or cabotegravir

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.9. Pexidartinib - Orphan - EMEA-001939-PIP03-16

Daiichi Sankyo Inc; Benign soft tissue neoplasms except tenosynovial giant cell tumour, Tenosynovial giant cell tumour / Treatment of debilitating tenosynovial giant cell tumour (TGCT), also known as pigmented villonodular synovitis (PVNS) and giant cell tumour of the tendon sheath (GCT-TS), in paediatric patients from 6 to 18 years where there is no other acceptable treatment

Day 90 discussion

Action: For discussion

Oncology

3.1.10. 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

Prevention of influenza infection

Day 90 discussion

Action: For discussion

Vaccines

3.1.11. Budesonide - EMEA-002417-PIP01-18

Eosinophilic oesophagitis

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.12. Bimekizumab - EMEA-002189-PIP02-18

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondyloarthritis, psoriatic arthritis and juvenile idiopathic arthritis) / Treatment of JIA (enthesitis-related arthritis [ERA] and juvenile psoriatic arthritis [JPsA]) in patients from ≥2 years to <18 years of age.

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.13. Synthetic 47-amino-acid N-myristoylated lipopeptide - Orphan - EMEA-002399-PIP01-18

MYR GmbH; Chronic hepatitis D infection

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.14. Dexamethasone - EMEA-002423-PIP01-18

ICD10 H59.9 Postprocedural disorder of eye and adnexa

Day 60 discussion

Action: For discussion

Ophthalmology

3.1.15. (6aR,10aR)-1-Hydroxy-6,6-dimethyl-3-(2-methyl-2-octanyl)-6a,7,10,10a-tetrahydro-6H-benzo[c]chromene-9-carboxylic acid. - Orphan - EMEA-002069-PIP03-17

Corbus Pharmaceuticals, Inc.; Treatment of Cystic Fibrosis

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.16. Amlodipine / Atorvastatin / Ramipril - EMEA-002416-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 FDC (substitution indication).

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.17. Indapamide / Telmisartan - EMEA-002462-PIP01-18

Treatment of hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.18. Ralinepag - EMEA-002432-PIP01-18

Treatment of pulmonary arterial hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.19. Livoletide - Orphan - EMEA-002455-PIP01-18

Millendo Therapeutics SAS; Treatment of Prader-Willi syndrome

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.20. Emricasan - EMEA-002457-PIP01-18

Non-alcoholic steatohepatitis (NASH) / Treatment of NASH with moderate to severe liver fibrosis (F2-F4) in patients aged 8 to less than 18 years old

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.21. Tropifexor - EMEA-002471-PIP02-18

Non-alcoholic steatohepatitis / Treatment of NASH with moderate to severe liver fibrosis (F2/F3) in paediatric patients from 8 to less than 18 years of age

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.22. Turoctocog alfa pegol - Orphan - EMEA-001174-PIP03-18

Novo Nordisk A/S; Treatment of congenital haemophilia A

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.23. Humanized bispecific antibody against IL-4 and IL-13 - EMEA-001804-PIP03-18

Treatment of systemic sclerosis / Treatment of juvenile systemic sclerosis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.24. Humanized Anti-CD19, Fc Engineered, Monoclonal Antibody - Orphan - EMEA-002414-PIP01-18

Xencor, Inc.; Immunoglobulin G4-Related Disease / The treatment of adults, adolescents and children (> 23 months of age) with Immunoglobulin G4-Related Disease

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.25. Vedolizumab - EMEA-000645-PIP03-18

ICD-9-CM 279.51 / ICD-10-CM D89.810 - Other disorders involving the immune mechanism, not elsewhere classified: acute graft-versus-host disease

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Gastroenterology-Hepatology

3.1.26. Gepotidacin - EMEA-002443-PIP01-18

Treatment of Uncomplicated Urinary Tract Infections (uUTI) / Treatment of uncomplicated urinary tract infections (acute cystitis) in children aged >6 years to <18 years

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.27. Gepotidacin - EMEA-002443-PIP02-18

Treatment of uncomplicated Urogenital Gonorrhea (GC) / Treatment of uncomplicated urogenital gonorrhea in children aged ≥ 14 to <18 years

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.28. Rifamycin sodium - EMEA-002450-PIP01-18

Acute infections diarrhoea

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.29. Amantadine hydrochloride - EMEA-002460-PIP01-18

Treatment of Parkinson's disease and parkinsonism

Day 30 discussion

Action: For discussion

Neurology

3.1.30. Recombinant adeno-associated viral vector serotype 2 carrying the gene for the human aromatic L-amino acid decarboxylase protein - Orphan - EMEA-002435-PIP01-18

PTC Therapeutic International Limited; Aromatic L-Amino Acid Decarboxylase (AADC) Deficiency

Day 30 discussion

Action: For discussion

Neurology

3.1.31. Ronopterin dihydrochloride dihydrate - Orphan - EMEA-002473-PIP01-18

vasopharm GmbH; Treatment of traumatic brain injury / Treatment of moderate and severe Traumatic Brain Injury (TBI) with Glasgow Coma Score (GCS) ≥ 3 and < 8 with presence of structural brain damage on CT (including contusion, mid-line shift) in children and adolescents aged 3-17 years.

Day 30 discussion

Action: For discussion

Neurology

3.1.32. Fibroblast activation protein alpha-targeted interleukin 2 variant immunocytokine - EMEA-002465-PIP01-18

Treatment of Non-small cell lung cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.33. Niraparib (as tosylate monohydrate) - Orphan - EMEA-002268-PIP02-18

Tesaro UK Ltd; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid malignancies)/ combination therapy is for the treatment of patients ≥6 months to <18 years of age who have been diagnosed with recurrent solid tumours that exhibit a breast cancer susceptibility gene (BRCA)ness mutational signature (mutational signature 3).

Day 30 discussion

Action: For discussion

Oncology

3.1.34. Anti PD-1 monoclonal antibody - EMEA-002463-PIP01-18

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

haematopoietic and lymphoid malignancies)/ combination therapy is for the treatment of patients ≥6 months to <18 years of age who have been diagnosed with recurrent solid tumours that exhibit a breast cancer susceptibility gene (BRCA)ness mutational signature (mutational signature 3).

Day 30 discussion

Action: For discussion

Oncology

3.1.35. Technetium (^{99m}Tc) trofolastat chloride - EMEA-002441-PIP01-18

Treatment of prostate carcinoma

Day 30 discussion

Action: For discussion

Oncology / Uro-nephrology

3.1.36. Human ciliary neurotrophic factor - Orphan - EMEA-002477-PIP01-18

LE4D Ltd; Treatment of Macular Telangiectasia Type 2

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.37. EMEA-002446-PIP01-18

Ichtyoses / Treatment of ichthyosis associated with Sjögren-Larsson Syndrome (SLS)

Day 30 discussion

Action: For discussion

Other / Endocrinology-Gynaecology-Fertility-Metabolism / Dermatology

3.1.38. EMEA-001976-PIP02-18

Treatment to control persistent asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.39. Roluperidone - EMEA-002222-PIP02-18

Treatment of Schizophrenia / Treatment of negative symptoms of schizophrenia

Day 30 discussion

Action: For discussion

Psychiatry

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. Ligelizumab - EMEA-C1-001811-PIP02-15-M02

Novartis Europharm Ltd.; Treatment of chronic spontaneous urticaria

Day 30 discussion

Action: For discussion

Dermatology

3.2.2. B/Brisbane/60/2008 (NYMC BX-35) as the B/Brisbane/60/2008-like virus / B/Phuket/3073/2013 as the B/Phuket/3073/2013-like virus / A/California/7/2009(NYMC X-179A) as the A/California/7/2009 (H1N1) pdm09-like virus / A/Hong Kong/4801/2014 (NYMC X-263B) as the A/Hong Kong/4801/2014 (H3N2)-like virus - EMEA-C1-002027-PIP02-17

Adimmune Corporation; Prevention of influenza infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.3. Fidaxomicin - EMEA-C-000636-PIP01-09-M07

Astellas Pharma Europe B.V.; Treatment of enterocolitis caused by clostridium difficile

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.4. Atezolizumab - EMEA-C2-001638-PIP01-14-M01

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

Day 30 discussion

Action: For discussion

Oncology

3.2.5. Cobimetinib - EMEA-C2-001425-PIP01-13-M03

Roche Registration GmbH; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue) with Ras, Raf or MEK pathway activation

Day 30 discussion

Action: For discussion

Oncology

3.2.6. Entrectinib - EMEA-C1-002096-PIP01-16

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

Day 30 Discussion

Action: For discussion

Oncology

3.2.7. Mometasone (furoate) / Indacaterol (acetate) - EMEA-C1-001217-PIP01-11-M05

Novartis Europharm Limited; Treatment of asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Azilsartan medoxomil - EMEA-000237-PIP01-08-M08

Takeda Development Centre (Europe) Ltd.; Treatment of hypertension / Essential (primary) hypertension, Secondary hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. Regadenoson - EMEA-000410-PIP01-08-M04

GE Healthcare AS; Myocardial perfusion disturbances

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.3. Gadopiclenol - EMEA-001949-PIP01-16-M03

GUERBET; Detection and visualization of areas with disruption of the blood brain barrier and/or abnormal vascularity for the central nervous system (CNS) for diagnostic purposes.

Day 30 discussion

Action: For discussion

Diagnostic

3.3.4. 2-hydroxypropyl-ß-cyclodextrin (HP-ß-CD) - Orphan - EMEA-001866-PIP01-15-M03

Mallinckrodt Pharmaceuticals Ireland Ltd; Treatment of Niemann-Pick disease, type C

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. Empagliflozin - EMEA-000828-PIP04-16-M02

Boehringer Ingelheim International GmbH; Treatment of type 1 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. Ethinyl estradiol / Dienogest - EMEA-002229-PIP01-17-M01

Exeltis France S.A.; Oral contraception

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.7. Semaglutide - EMEA-001441-PIP01-13-M02

Novo Nordisk A/S; Treatment of Diabetes Mellitus type 2

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.8. Naloxegol (as naloxegol oxalate) - EMEA-001146-PIP01-11-M04

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

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.9. Potassium sulphate / magnesium sulphate heptahydrate / sodium sulphate anhydrous - EMEA-000816-PIP02-10-M02

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). Not a treatment for constipation.

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.10. Baricitinib - EMEA-001220-PIP01-11-M04

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

3.3.11. Fostemsavir (tromethamine) - EMEA-001687-PIP01-14-M03

ViiV Healthcare UK Ltd; Treatment of human immunodeficiency virus (HIV-1) infection / Treatment of HIV-1 infection as part of a combination therapy in paediatric patients who have no more than 2 remaining available fully active antiretroviral therapies.

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.12. Rilpivirine (RPV) / Dolutegravir (DTG) - EMEA-001750-PIP01-15-M02

ViiV Healthcare UK Limited; B24 Unspecified Human Immunodeficiency Virus (HIV) disease / Treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.13. Bivalent anti-human myostatin adnectin recombinant human IgG1-Fc fusion protein - EMEA-001793-PIP01-15-M03

Roche Registration GmbH; Treatment of Duchenne Muscular Dystrophy / Treatment of Duchenne Muscular Dystrophy in patients aged 2 years and older

Day 30 discussion

Action: For discussion

Neurology

3.3.14. Ocrelizumab - EMEA-000310-PIP03-10-M03

Roche Registration GmBH; Multiple Sclerosis / Treatment of Relapsing Remitting Multiple Sclerosis (RRMS)

Day 30 discussion

Action: For discussion

Neurology

3.3.15. Venetoclax - Orphan - EMEA-002018-PIP02-16-M01

AbbVie Ltd; Treatment of haematopoietic and lymphoid malignant neoplasms, Treatment of solid tumour malignant neoplasms / Treatment of a specific paediatric hematopoietic and lymphoid malignant neoplasm or of a solid malignant neoplasm, in patients from 1 month to 18 years of age

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.3.16. Birch Pollen Extract - EMEA-000809-PIP01-09-M01

Allergy Therapeutics (UK) Ltd; J.30.1 Allergic rhinitis due to pollen H10.1 Acute atopic conjunctivitis / allergic rhinitis/allergic conjunctivitis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.17. Split influenza virus, inactivated containing antigen equivalent to A/ California/7/2009(H1N1)-like strain (A/California/7/2009 (NYMC X-179A)), adjuvanted - EMEA-000669-PIP01-09-M02

Sanofi Pasteur SA; Influenza / Prevention of infection by pandemic influenza virus (H1N1

strain) in the context of a pandemic

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 04 December 2018 for Nomination of Rapporteur and Peer reviewer

Action: For adoption

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

Action: For adoption

4.3. Nominations for other activities

Action: For adoption

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

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

6. Discussion on the applicability of class waivers

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

6.1. Discussions on the applicability of class waiver for products

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

7.1.1. Ticagrelor - EMEA-000480-PIP01-08-M11

AstraZeneca AB; thromboembolic events (children), acute coronary syndrome, history of myocardial infarction / reduction in occurrence of vaso-occlusive crises in paediatric patients with sickle cell disease

Proposed indication: prevention of atherothrombotic events in adult patients with coronary artery disease and type 2 diabetes mellitus without a history of myocardial infarction or stroke

Action: For adoption

Cardiovascular Diseases / Haematology-Hemostaseology

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

None

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. Committee for Medicinal Products for Human Use (CHMP)

CHMP/PDCO joint session

Action: For discussion

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 2019 proposal

PDCO member: Dirk Mentzer;

Action: For discussion

9.8. Planning and reporting

No items.

10. Any other business

10.1.1. Reflection paper on non-infectious liver diseases

PDCO Member: Johannes Taminiau

Action: For adoption

10.1.2. Art.57 database

Action: For information

10.1.3. Report from the FDA cluster TC

Action: For information

11. Breakout sessions

11.1.1. Paediatric oncology

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

11.1.2. Neonatology

Action: For discussion on Thursday, 12:30 - 13:30, room 2H

11.1.3. Inventory

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

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/