



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 December 2018
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Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 11-14 December 2018

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

11 December 2018, 14:00- 19:00, room 3E

12 December 2018, 08:30- 19:00, room 3E

13 December 2018, 08:30- 19:00, room 3E

14 December 2018, 08:30- 13:00, room 3E

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.

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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 11-14 December 2018. See 11-14 December 2018 PDCO minutes (to be published post 29 January – 01 February 2019 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 11-14 December 2018.

1.3. Adoption of the minutes

PDCO minutes for 13-16 November 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. Etripamil - EMEA-002303-PIP01-17

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

Day 120 opinion

Action: For adoption

Cardiovascular Diseases

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

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

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.3. EMEA-001710-PIP04-17

Treatment of Crohn's disease

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.4. 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 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.5. 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 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.6. Baricitinib - EMEA-001220-PIP04-17

Treatment of systemic lupus erythematosus

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.7. Iclaprim Mesylate - EMEA-002391-PIP01-18

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

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.8. 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 120 opinion

Action: For adoption

Infectious Diseases

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

Daiichi Sankyo Inc; Benign soft tissue neoplasms except 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 120 opinion

Action: For adoption

Oncology

2.1.10. 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 120 opinion

Action: For adoption

Vaccines

2.1.11. 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 60 opinion

Action: For adoption

Cardiovascular Diseases

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

Treatment of hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

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

Acute infections diarrhoea

Day 60 opinion

Action: For adoption

Infectious Diseases

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

Treatment of Parkinson's disease and parkinsonism

Day 60 opinion

Action: For adoption

Neurology

2.1.15. Binimetinib - EMEA-001454-PIP05-18

Treatment of colorectal carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.16. Encorafenib - EMEA-001588-PIP03-18

Treatment of colorectal carcinoma

Day 60 opinion

Action: For adoption

Oncology

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

Treatment of Non-small cell lung cancer

Day 60 opinion

Action: For adoption

Oncology

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

Treatment of prostate carcinoma

Day 60 opinion

Action: For adoption

Oncology / Uro-nephrology

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

LE4D Ltd; Treatment of Macular Telangiectasia Type 2

Day 60 opinion

Action: For adoption

Ophthalmology

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. Liraglutide - EMEA-C-000128-PIP01-07-M08

Novo Nordisk; Treatment of type 2 diabetes mellitus

Day 1 opinion

Action: For information

Endocrinology-Gynaecology-Fertility-Metabolism

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

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

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

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

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

GE Healthcare AS; Myocardial perfusion disturbances

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.3. 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 60 opinion

Action: For adoption

Diagnostic

2.3.4. 2-hydroxypropyl- β -cyclodextrin (HP- β -CD) - Orphan - EMEA-001866-PIP01-15-M03

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

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

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

Boehringer Ingelheim International GmbH; Treatment of type 1 diabetes mellitus

Day 60 opinion

Action: For information

Endocrinology-Gynaecology-Fertility-Metabolism

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

Exeltis France S.A.; Oral contraception

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

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

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

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.8. [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 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.9. [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 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.10. [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 60 opinion

Action: For adoption

Infectious Diseases

2.3.11. [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 60 opinion

Action: For adoption

Infectious Diseases

2.3.12. [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 60 opinion

Action: For adoption

Neurology

2.3.13. [Ocrelizumab - EMEA-000310-PIP03-10-M03](#)

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

Day 60 opinion

Action: For adoption

Neurology

2.3.14. [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 60 opinion

Action: For adoption

Oncology / Haematology-Hemostaseology

2.3.15. [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 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.16. [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 60 opinion

Action: For adoption

Vaccines

2.4. Opinions on Re-examinations

No items.

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. Bempedoic acid - EMEA-C1-001872-PIP01-15-M01

Esperion Therapeutics, Inc; Treatment of elevated cholesterol

Day 1 letter

Action: For information

Cardiovascular Diseases

2.7.2. Nivolumab - EMEA-C2-001407-PIP02-15-M02

Bristol-Myers Squibb Pharma EEIG; Treatment of malignant neoplasms of the central nervous system

Day 1 letter

Action: For information

Oncology

2.7.3. Cefiderocol - EMEA-C1-002133-PIP01-17

Shionogi Limited; Treatment of infections due to aerobic Gram-negative bacteria

Day 1 letter

Action: For information

Infectious Diseases

2.7.4. Ceftolozane / Tazobactam - EMEA-C1-001142-PIP02-16

Merck Sharp & Dohme (Europe), Inc.; Treatment of pneumonia

Day 1 letter

Action: For information

Infectious Diseases

2.7.5. Amikacin (sulfate) - EMEA-C4-000525-PIP01-08-M06

Insmed Limited; Treatment of nontuberculous mycobacterial (NTM) lung infection

Day 1 letter

Action: For information

Pneumology - Allergology

2.7.6. Empagliflozin - EMEA-C2-000828-PIP04-16-M01

Boehringer Ingelheim International GmbH; Treatment of type 1 diabetes mellitus

Day 1 letter

Action: For information

Endocrinology-Gynaecology-Fertility-Metabolism

2.7.7. Ivacaftor - EMEA-C9-000335-PIP01-08-M13

Vertex Pharmaceuticals (Europe) Limited; Treatment of cystic fibrosis

Day 1 letter

Action: For information

Other

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

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

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. Mavacamten - EMEA-002231-PIP01-17

Treatment of Hypertrophic Cardiomyopathy / Treatment of obstructive Hypertrophic Cardiomyopathy

Day 90 discussion

Action: For discussion

Cardiovascular Diseases

3.1.2. Dihomo- γ -linolenic acid (DGLA) - EMEA-002364-PIP02-18

Treatment of atopic dermatitis / Treatment of mild to moderate atopic dermatitis

Day 90 discussion

Action: For discussion

Dermatology

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

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

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.4. (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-PIP02-17

Corbus Pharmaceuticals Holdings Inc; Treatment of systemic sclerosis

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.5. [Allogeneic CD34+ umbilical cord blood cells cultured ex vivo with Notch ligand Delta1 - Orphan - EMEA-002271-PIP01-17](#)

Nohla Therapeutics, Inc.; Treatment in Haematopoietic Stem Cell Transplantation (HSCT) in patients with malignant disease / Patients with high risk haematologic malignancies undergoing myeloablative cord blood transplant (CBT)

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.6. [Guselkumab - EMEA-001523-PIP03-18](#)

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondyloarthritis, PsA and juvenile idiopathic arthritis [JIA]) / Treatment of juvenile idiopathic arthritis (juvenile psoriatic arthritis [jPsA])

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.7. [EMEA-002240-PIP02-17](#)

Treatment of Urinary Tract Infections

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.8. [Pretomanid - Orphan - EMEA-002115-PIP01-17](#)

Global Alliance for TB Drug Development; Treatment of multi-drug-resistant tuberculosis

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.9. [Ridinilazole - EMEA-002250-PIP02-17](#)

Treatment of Clostridium difficile Infection (CDI) and reducing the recurrence of CDI

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.10. Isoflurane - EMEA-002320-PIP01-17

Sedation

Day 90 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.1.11. Avapritinib - Orphan - EMEA-002358-PIP02-18

Blueprint Medicines Corporation; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms) / Treatment of paediatric patients with advanced solid tumors harboring mutations in either KIT or PDGFR α .

Day 90 discussion

Action: For discussion

Oncology

3.1.12. Spaltalizumab - EMEA-002351-PIP01-18

Treatment of melanoma / Treatment of adolescent patients with melanoma containing BRAF V600 activating mutations

Day 90 discussion

Action: For discussion

Oncology

3.1.13. (R)-azasetron (as besylate) - Orphan - EMEA-002165-PIP02-18

Sensorion SA; Treatment of Sudden Sensorineural Hearing Loss, Prevention of cisplatin-induced ototoxicity

Day 90 discussion

Action: For discussion

Oto-rhino-laryngology

3.1.14. EMEA-002324-PIP01-17

Treatment of Cystic Fibrosis

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.15. EMEA-002191-PIP02-17

Treatment of Cystic Fibrosis

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.16. Molgramostim - Orphan - EMEA-002282-PIP01-17

Savara ApS; Treatment of pulmonary alveolar proteinosis / Treatment of children from 6 to less than 18 years with autoimmune pulmonary alveolar proteinosis

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.17. Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) / Recombinant Influenza Hemagglutinin-strain B (Victoria lineage) / Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype) / Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype) - EMEA-002418-PIP01-18

Prevention of influenza infection

Day 90 discussion

Action: For discussion

Vaccines

3.1.18. Ralinepag - EMEA-002432-PIP01-18

Treatment of pulmonary arterial hypertension

Day 60 discussion

Action: For discussion

Cardiovascular Diseases

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

Millendo Therapeutics SAS; Treatment of Prader-Willi syndrome

Day 60 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 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.21. Tropifexor - EMEA-002471-PIP01-18

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 60 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 60 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 60 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 60 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 60 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 60 discussion

Action: For discussion

Infectious Diseases

3.1.27. [Gepotidacin - EMEA-002443-PIP02-18](#)

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

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.28. [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; Treatment of Aromatic L-Amino Acid Decarboxylase (AADC) Deficiency

Day 60 discussion

Action: For discussion

Neurology

3.1.29. [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 60 discussion

Action: For discussion

Neurology

3.1.30. [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 60 discussion

Action: For discussion

Oncology

3.1.31. [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 60 discussion

Action: For discussion

Oncology

3.1.32. [EMEA-002446-PIP01-18](#)

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

Day 60 discussion

Action: For discussion

Other / Endocrinology-Gynaecology-Fertility-Metabolism / Dermatology

3.1.33. [EMEA-001976-PIP02-18](#)

Treatment to control persistent asthma

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.34. [Amlodipine besylate / Rosuvastatin calcium - EMEA-002456-PIP01-18](#)

Treatment of Hypertension, Treatment of dyslipidemia, Treatment of ischemic coronary artery disorders, Prevention of cardiovascular events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.35. EMEA-002451-PIP01-18

Alopecia Areata

Day 30 discussion

Action: For discussion

Dermatology

3.1.36. EMEA-002475-PIP01-18

Treatment of Generalized Pustular Psoriasis/ Indicated for treatment of patients with acute or chronic Generalized Pustular Psoriasis (GPP) and for the prevention of flares.

Day 30 discussion

Action: For discussion

Dermatology

3.1.37. EMEA-002470-PIP01-18

Actinic keratosis in adults

Day 30 discussion

Action: For discussion

Dermatology

3.1.38. EMEA-002464-PIP01-18

Treatment of atopic dermatitis / Treatment of patients with moderate-to-severe atopic dermatitis.

Day 30 discussion

Action: For discussion

Dermatology

3.1.39. Trifarotene - EMEA-001492-PIP02-18

Treatment of Lamellar Ichthyosis

Day 30 discussion

Action: For discussion

Dermatology

3.1.40. Norethisterone acetate / estradiol / relugolix - EMEA-002428-PIP01-18

Treatment of symptoms associated with uterine fibroids

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.41. EMEA-002448-PIP01-18

Treatment of NASH / Treatment of NASH with moderate to severe liver fibrosis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.42. C1 esterase inhibitor (human) - EMEA-000568-PIP02-18

Treatment of hereditary angioedema

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.43. Liposomal ciclosporin A (L-CsA) - Orphan - EMEA-002344-PIP02-18

Breath Therapeutics GmbH; Treatment of Bronchiolitis obliterans Syndrome (BOS)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.44. Baloxavir marboxil - EMEA-002440-PIP01-18

Prevention of Influenza, Treatment of Influenza / Treatment of influenza type A/B in otherwise healthy, high risk and hospitalised patients, Prevention (post exposure prophylaxis) of influenza type A/B. Reduction of transmission of influenza type A/B.

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.45. HYDROCORTISONE - EMEA-002305-PIP01-17

Prevention of Bronchopulmonary dysplasia

Day 30 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.1.46. Padsevonil - EMEA-002466-PIP01-18

Treatment of FOS in patients with epilepsy / Treatment of FOS in paediatric patients (≥ 2 to < 18 years of age) with epilepsy.

Day 30 discussion

Action: For discussion

Neurology

3.1.47. Pyrimidinyl-aminopyridine dual leucine zipper kinase inhibitor (GDC-0134) - EMEA-002469-PIP02-18

Treatment of Amyotrophic Lateral Sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.1.48. Genetically modified Mycobacterium bovis BCG - EMEA-002461-PIP01-18

Non-muscle invasive bladder cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.49. Larotrectinib - Orphan - EMEA-001971-PIP03-18

Bayer AG; Treatment of malignant neoplasms of the central nervous system / Treatment of paediatric patients with a primary CNS tumour with a Neurotrophic Tyrosine Receptor Kinase (NTRK) gene fusion

Day 30 discussion

Action: For discussion

Oncology

3.1.50. Marizomib - EMEA-002452-PIP01-18

Treatment of Malignant Glial Tumors / Treatment of patients (pediatric) with diffuse intrinsic

pontine glioma (DIPG) who have received radiation therapy.

Day 30 discussion

Action: For discussion

Oncology

3.1.51. [PEGylated human recombinant IL-2 cytokine \(aldesleukin\)\(to be used in combination with nivolumab or nivolumab and ipilimumab\) - EMEA-002492-PIP01-18](#)

Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoetic, and lymphoid tissue) / In combination with nivolumab (or with nivolumab and ipilimumab) for treatment of a relapsed or refractory paediatric malignant solid tumour in paediatric patients less than 18 years old / In combination with nivolumab (or with nivolumab and ipilimumab) for treatment of patients with unresectable or metastatic melanoma in the age group from 12 to less than 18 years old

Day 30 discussion

Action: For discussion

Oncology

3.1.52. [Zanubrutinib - EMEA-002354-PIP02-18](#)

Treatment of mature B-cell neoplasms excluding lymphoplasmacytic lymphoma (Waldenström's macroglobulinaemia), Treatment of lymphoplasmacytic lymphoma (Waldenström's macroglobulinaemia) / , Treatment of primary mediastinal B-cell lymphoma, Treatment of Burkitt lymphoma, Treatment of diffuse large B-cell lymphoma

Day 30 discussion

Action: For discussion

Oncology

3.1.53. [Empagliflozin - EMEA-000828-PIP06-18](#)

Treatment of chronic kidney disease

Day 30 discussion

Action: For discussion

Uro-nephrology

3.1.54. [Pneumococcal Polyssacharide Serotype 33F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 23F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 22F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 19F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 19A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 18C conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate /](#)

Pneumococcal Polyssacharide Serotype 15B conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 14 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 12F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 11A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 10A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 9V conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 8 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 7F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 6B conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 6A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 5 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 4 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 3 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 1 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate - EMEA-002330-PIP01-18

Disease caused by Streptococcus pneumoniae

Day 30 discussion

Action: For discussion

Vaccines

3.1.55. Recombinant respiratory syncytial virus fusion (RSV F) glycoprotein - EMEA-001985-PIP01-18

Prevention of respiratory syncytial virus (RSV) disease in infants via maternal immunization

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. Semaglutide - EMEA-C1-001441-PIP02-15-M01

Novo Nordisk A/S; Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.2. Avibactam / Ceftazidime - EMEA-C2-001313-PIP01-12-M08

Pfizer Limited; Treatment of Urinary Tract Infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.3. Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) - EMEA-C1-001715-PIP01-14-M01

Seqirus Netherlands B.V.; Prevention of influenza infection

Day 30 discussion

Action: For discussion

Vaccines

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Ambrisentan - Orphan - EMEA-000434-PIP01-08-M05

Glaxo Group Limited; Treatment of Pulmonary Arterial Hypertension / Idiopathic (IPAH) and Familial (FPAH) Pulmonary Hypertension; Associated Pulmonary Hypertension (APAH)

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. Tralokinumab - EMEA-001900-PIP02-17-M02

LEO Pharma A/S; Treatment of Atopic Dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.3.3. Alogliptin benzoate (as alogliptin) - EMEA-000496-PIP01-08-M06

Takeda Development Centre Europe Ltd; Type 2 diabetes melitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. Avalglucosidase alfa - Orphan - EMEA-001945-PIP01-16-M01

Genzyme Europe B.V.; ICD-10: E74.0; Glycogen storage disease (Pompe disease) / Long-term use as an ERT for the treatment of patients with a confirmed diagnosis of Pompe disease (acid α -glucosidase deficiency)

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. Tofacitinib - EMEA-000576-PIP03-12-M02

Pfizer Limited; Ulcerative colitis / Treatment of children and adolescents aged 2 to <18 years of age with moderate to severe ulcerative colitis.

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.6. Ustekinumab - EMEA-000311-PIP04-13-M01

Janssen-Cilag International NV; Treatment of Crohn's Disease

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.7. Crizanlizumab - Orphan - EMEA-002141-PIP01-17-M01

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

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.8. Apremilast - EMEA-000715-PIP02-11-M03

Celgene Europe B.V.; Treatment of Juvenile Idiopathic Arthritis (JIA), Treatment of Juvenile Psoriatic Arthritis (JPsA)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.9. Isavuconazonium (sulfate) - Orphan - EMEA-001301-PIP02-12-M03

Basilea Pharmaceutica International Ltd.; Treatment of mucormycosis, Treatment of invasive aspergillosis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.10. EMEA-001838-PIP01-15-M02

Janssen-Cilag International NV; Treatment of respiratory tract disease caused by human RSV

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.11. Lefamulin - EMEA-002075-PIP01-16-M01

Nabriva Therapeutics AG; Treatment of community-acquired pneumonia

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.12. Erenumab - EMEA-001664-PIP02-15-M03

Novartis Europharm Limited; Prevention of migraine headaches / Prophylaxis of migraine

Day 30 discussion

Action: For discussion

Neurology

3.3.13. Galcanezumab - EMEA-001860-PIP03-16-M02

Eli Lilly and Company Limited; Prevention of migraine headaches

Day 30 discussion

Action: For discussion

Neurology

3.3.14. Humanised anti-IL-6 receptor (IL-6R) monoclonal antibody (satralizumab) - Orphan - EMEA-001625-PIP01-14-M02

CHUGAI PHARMA EUROPE LTD.; Treatment of neuromyelitis optica

Day 30 discussion

Action: For discussion

Neurology

3.3.15. Lacosamide - EMEA-000402-PIP03-17-M03

UCB Pharma S.A.; Treatment of Generalized Epilepsy and Epilepsy Syndromes: Epilepsy - generalized idiopathic epilepsy and epilepsy syndromes [G40.3] Epilepsy - Other generalized epilepsy and epileptic syndromes [G40.4] / Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures (PGTCS) in pediatric patients with idiopathic generalized epilepsy (IGE)(4 years to <18 years)

Day 30 discussion

Action: For discussion

Neurology

3.3.16. Peginterferon beta-1a - EMEA-001129-PIP01-11-M03

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

Day 30 discussion

Action: For discussion

Neurology

3.3.17. Acalabrutinib - Orphan - EMEA-001796-PIP03-16-M01

Acerta Pharma, BV; Treatment of mature B cell neoplasms / Treatment of children from 1 to <18 years of age with previously untreated mature B-cell neoplasms (eg, diffuse large B-cell lymphoma [DLBCL], Burkitt lymphoma [BL] and primary mediastinal B-cell lymphoma [PMBCL]). Treatment of children from 1 to <18 years of age with relapsed/refractory mature B-cell neoplasms (eg, diffuse large B-cell lymphoma [DLBCL], Burkitt lymphoma [BL] and primary mediastinal B-cell lymphoma [PMBCL]).

Day 30 discussion

Action: For discussion

Oncology

3.3.18. Dabrafenib mesylate - EMEA-001147-PIP01-11-M06

Novartis Europharm Limited; Treatment of solid malignant tumours (excluding melanoma), Treatment of melanoma / Treatment of paediatric patients with solid malignant tumours containing BRAF V600 mutations, Treatment of adolescent patients with melanoma with a

BRAF V600 mutation

Day 30 discussion

Action: For discussion

Oncology

3.3.19. Entrectinib - EMEA-002096-PIP01-16-M01

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

Day 30 discussion

Action: For discussion

Oncology

3.3.20. Carotuximab - Orphan - EMEA-002138-PIP01-17-M01

TRACON Pharma Limited-Charles Theuer; Treatment of soft tissue sarcoma

Day 30 discussion

Action: For discussion

Oncology

3.3.21. Olaratumab - Orphan - EMEA-001760-PIP01-15-M03

Eli Lilly and Company Limited; Treatment of Soft Tissue Sarcoma, Treatment of Osteosarcoma / Treatment of recurrent rhabdomyosarcoma in children aged from birth to less than 18 years in combination with a standard-of-care chemotherapy regimen, First-line treatment of osteosarcoma in children aged from 5-18 years in combination with a standard-of-care chemotherapy regimen

Day 30 discussion

Action: For discussion

Oncology

3.3.22. Rituximab - EMEA-000308-PIP01-08-M04

Roche Registration GmbH; Treatment of diffuse large B-cell lymphoma, Treatment of autoimmune arthritis / Treatment of mature B-cell malignancies, that is, diffuse large B-cell lymphoma, Burkitt and Burkitt-like lymphoma/leukaemia.

Day 30 discussion

Action: For discussion

Oncology

3.3.23. Trametinib dimethyl sulfoxide - EMEA-001177-PIP01-11-M05

Novartis Europharm Limited; Treatment of solid malignant tumours (excluding melanoma), Treatment of melanoma / Treatment of paediatric patients with solid malignant tumours containing BRAF V600 mutations, Treatment of adolescent patients with melanoma with a BRAF V600 mutation

Day 30 discussion

Action: For discussion

Oncology

3.3.24. Eltrombopag (eltrombopag olamine) - EMEA-000170-PIP02-10-M03

Novartis Europharm limited; Secondary thrombocytopenia / Treatment of thrombocytopenia secondary to treatment of myeloid or lymphoid malignancies or solid tumours

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.3.25. Autologous cartilage derived cultured chondrocytes - EMEA-001823-PIP01-15-M01

TETEC AG; Treatment of cartilage disorders

Day 30 discussion

Action: For discussion

Other

3.3.26. Methoxyflurane - EMEA-000334-PIP01-08-M08

Medical Developments UK Ltd; Treatment of acute pain / Self administration to conscious patients with minor trauma and associated pain, under supervision of personnel trained in its use. / For the management of acute pain associated with short surgical procedures, such as the change of dressings, dislocations and injections.

Day 30 discussion

Action: For discussion

Pain

3.3.27. Dermatophagoides farinae / Dermatophagoides pteronyssinus - EMEA-001258-PIP01-11-M04

ALK-Abelló A/S; Treatment of allergic rhinitis, Treatment of asthma / Indicated in house dust mite allergic asthma / Indicated in house dust mite allergic rhinitis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.28. Chemically modified extract of grass pollen from *Holcus lanatus*, *Phleum pratense* and *Poa pratensis* - EMEA-001016-PIP01-10-M01

Granzer Regulatory Consulting & Services; Allergic Rhinitis, Allergic Rhinoconjunctivitis

Day 30 discussion

Action: For discussion

Pneumology - Allergology / Oto-rhino-laryngology

3.3.29. Chemically modified extract of grass pollen from *Holcus lanatus*, *Phleum pratense* and *Poa pratensis* - EMEA-001017-PIP01-10-M01

Granzer Regulatory Consulting & Services; Allergic Rhinitis, Allergic Rhinoconjunctivitis

Day 30 discussion

Action: For discussion

Pneumology - Allergology / Oto-rhino-laryngology

3.3.30. Chemically modified extract of trees pollen from Birch and Alder - EMEA-001012-PIP01-10-M01

Granzer Regulatory Consulting & Services; Allergic Rhinitis, Allergic Rhinoconjunctivitis

Day 30 discussion

Action: For discussion

Pneumology - Allergology / Oto-rhino-laryngology

3.3.31. Chemically modified extract of trees pollen from Birch and Alder - EMEA-001013-PIP01-10-M01

Granzer Regulatory Consulting & Services; Allergic Rhinitis, Allergic Rhinoconjunctivitis

Day 30 discussion

Action: For discussion

Pneumology - Allergology / Oto-rhino-laryngology

3.3.32. Chemically modified house dust mites allergen extract of *Dermatophagoides pteronyssinus* and *Dermatophagoides farinae* - EMEA-001011-PIP01-10-M01

Granzer Regulatory Consulting & Services; Allergic Rhinitis, Allergic Rhinoconjunctivitis

Day 30 discussion

Action: For discussion

Pneumology - Allergology / Oto-rhino-laryngology

3.3.33. Chemically modified house dust mites allergen extract of Dermatophagoides pteronyssinus and Dermatophagoides farinae - EMEA-001014-PIP01-10-M01

Granzer Regulatory Consulting & Services; Allergic Rhinitis, Allergic Rhinoconjunctivitis

Day 30 discussion

Action: For discussion

Pneumology - Allergology / Oto-rhino-laryngology

3.3.34. Neisseria meningitidis serogroup B recombinant lipoprotein (subfamily B; Escherichia coli) / Neisseria meningitidis serogroup B recombinant lipoprotein (subfamily A; Escherichia coli) - EMEA-001037-PIP02-11-M05

Pfizer Europe MA EEIG; Invasive meningococcal disease caused by N meningitidis serogroup B.

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 29 January 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.

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. Human embryonic stem-cell derived retinal pigment epithelial (hESC-RPE) cells - EMEA-14-2018

Astellas Pharma Europe B.V.; All classes of medicinal products for treatment of age-related macular degeneration and diabetic macular oedema/Treatment of age-related macular degeneration

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/ Human Papillomavirus Type 31 L1 protein/ Human Papillomavirus Type 33 L1 protein/ Human Papillomavirus Type 45 L1 protein/ Human Papillomavirus Type 52 L1 protein/ Human Papillomavirus Type 58 L1 protein - EMEA-000654-PIP01-09-M02

Sanofi Pasteur MSD SNC; Prevention of premalignant genital lesions (cervical, vulvar and vaginal), cervical cancer and external genital warts (condyloma acuminata) causally related to Human Papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52, 58

Proposed indication: prevention of head and neck cancers 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

No items.

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

Action: For information

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

9.3.1. Non-clinical Working Group: D30 Products identified

PDCO member: Karen van Malderen

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.3.3. Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP)

Meeting Summary PCWP Plenary Meeting 25 Sep 2018

Meeting Summary PCWP/HCPWP Joint Meeting 25 Sep 2018

Meeting Summary HCPWP Plenary Meeting 26 Sep 2018

Action: For information

9.4. Cooperation within the EU regulatory network

9.4.1. CTFG: presentation of CTFG mandate, its activities and potential areas of interaction with PDCO

CTFG Co-Chair: Ann Marie Janson Lang

Action: For information

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 adoption

9.8. Planning and reporting

No items.

10. Any other business

10.1.1. Report from the FDA cluster TC

Action: For information

10.1.2. Feedback on August written procedure

Action: For information

10.1.3. Announcement of the 4th Accelerate Paediatric Strategy Forum (topic: AML) - Call for expression of Interest of PDCO members

PDCO member: Koenraad Norga

Action: For information

11. Breakout sessions

11.1.1. Paediatric oncology

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

11.1.2. Neonatology

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

11.1.3. Inventory

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

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/