30 November 2016
EMA/PDCO/801853/2016
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 13-16 December 2016

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

13 December 2016, 14:00 - 17:00, room 3E

14 December 2016, 08:30 - 19:00, room 3E

15 December 2016, 08:30 - 19:00, room 3E

16 December 2016, 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.

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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Table of contents

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 December 2016. See December 2016 PDCO minutes (to be published post January 2017 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 13-16 December 2016.

1.3. Adoption of the minutes

PDCO minutes for 8-11 November 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. 2-hydroxypropyl-ß-cyclodextrin (HP-ß-CD) - Orphan - EMEA-001866-PIP01-15

Vtesse Europe Ltd; Treatment of Niemann-Pick disease, type C

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.2. pegvaliase - Orphan - EMEA-001951-PIP01-16

BioMarin International Limited; For the treatment of hyperphenylalaninaemia / For the treatment of hyperphenylalaninaemia in paediatric patients of all ages with phenylketonuria

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.3. Volanesorsen - Orphan - EMEA-001915-PIP01-15

Ionis Pharmaceuticals; Familial Chylomicronemia Syndrome

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.4. Autologous CD34+ cells transduced with lentiviral vector encoding the human beta-globin gene - Orphan - EMEA-001933-PIP01-16

Fondazione Telethon; Beta-thalassemia major and intermedia / Treatment of Beta thalassemia

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.5. vadadustat - EMEA-001944-PIP01-16

Anaemia secondary to chronic kidney disease / Treatment of anaemia secondary to chronic kidney disease

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.6. 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 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.7. 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 120 opinion

Action: For adoption

Infectious Diseases

2.1.8. Anti-(human calcitonin gene-related peptide receptor) human monoclonal antibody - EMEA-001664-PIP02-15

Migraine headaches / Prophylaxis of migraine

Day 120 opinion

Action: For adoption

Neurology

2.1.9. Esketamine (hydrochloride) - EMEA-001428-PIP03-15

Major Depressive Disorder (MDD)

Day 120 opinion

Action: For adoption

Psychiatry

2.1.10. Fc- and CDR-modified humanized monoclonal antibody against C5 - Orphan - EMEA-001943-PIP01-16

Alexion Europe SAS; Atypical Haemolytic Uremic Syndrome / Treatment of atypical Haemolytic Uremic Syndrome

Day 120 opinion

Action: For adoption

Uro-nephrology / Haematology-Hemostaseology

2.1.11. Varicella-zoster virus (VZV), Oka/Merck, inactivated, vaccine - EMEA-001073-PIP02-14

Prevention of Varicella Zoster Virus disease / Prevention of HZ in immunocompromised patients from 1 to less than 18 years of age

Day 120 opinion

Action: For adoption

Vaccines

2.1.12. Apolipoprotein A-1 (ApoA-1) - EMEA-002040-PIP01-16

Treatment of Acute Myocardial Infarction

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.13. Candesartan cilexetil / Amlodipine besylate / Hydrochlorothiazide - EMEA-002024-PIP01-16

Treatment of essential hypertension (ICD9: 401, ICD10: I10)

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.14. EMEA-002039-PIP01-16

Treatment of uterine leiomyoma (fibroids), Treatment of endometriosis / Treatment of uterine fibroids, Treatment of endometriosis

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.15. Synthetic double-stranded small interfering ribonucleic acid directed against delta-aminolevulinic acid synthase mRNA that is covalently linked to a ligand containing three N-acetylgalactosamine residues - EMEA-002048-PIP01-16

Acute Hepatic Porphyria (AHP)

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.16. Doxorubicin hydrochloride - Orphan - EMEA-002043-PIP01-16

ONXEO S.A.; Treatment of hepatocellular carcinoma / Treatment of hepatocellular carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.17. mirvetuximab soravtansine - Orphan - EMEA-001921-PIP01-16

ImmunoGen Europe Limited; For the treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours), For the treatment of peritoneal carcinoma, For the treatment of fallopian tube carcinoma (excluding rhabdomyosarcoma and germ cell tumours)

Day 60 opinion

Action: For adoption

Oncology

2.1.18. EMEA-002062-PIP01-16

Interstitial Cystitis/Bladder Pain Syndrome

Day 60 opinion

Action: For adoption

Uro-nephrology

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. zanamivir - EMEA-C1-001318-PIP01-12-M01

GlaxoSmithKline Trading Services Limited; Prevention of Influenza

Day 30 opinion

Action: For adoption

Infectious Diseases

2.2.2. Ivacaftor N-(2,4-di-tert-butyl-5-hydroxyphenyl)-4-oxo-1,4-dihydroquinoline-3- carboxamide / Lumacaftor 3 [6 ({[1 (2,2-difluoro 1,3-benzodioxol-5-yl)cyclopropyl]carbonyl}amino)-3 methylpyridin-2-yl]benzoic acid - EMEA-C3-001582-PIP01-13-M04

Vertex Pharmaceuticals (Europe) Limited; Treatment of cystic fibrosis

Day 30 opinion

Action: For adoption

Other

2.2.3. Blinatumomab - EMEA-C2-000574-PIP02-12-M01

Amgen Europe B.V.; Treatment of Acute Lymphoblastic Leukaemia

Day 30 opinion

Action: For adoption

Oncology

2.2.4. Catridecacog - EMEA-C-000185-PIP01-08-M05

Novo Nordisk A/S; Treatment of congenital factor XIII A-subunit deficiency

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.2.5. Fibrinogen (human plasma-derived) - EMEA-C-000457-PIP02-10-M02

LFB Biotechnologies; Treatment of congenital fibrinogen deficiency

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.2.6. tenofovir disoproxil fumarate / emtricitabine - EMEA-C-001091-PIP02-15

Gilead Sciences International Ltd.; Treatment of Human Immunodeficieny (HIV-1) infection

Day 60 opinion

Action: For adoption

Infectious Diseases

2.2.7. natalizumab - EMEA-C-001095-PIP02-12

Biogen Idec Ltd; Treatment of Multiple Sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.2.8. Dinutuximab - EMEA-C-001285-PIP01-12-M02

United Therapeutics Europe Limited; Treatment of Neuroblastoma

Day 60 opinion

Action: For adoption

Oncology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. edoxaban tosilate - EMEA-000788-PIP02-11-M05

Daiichi Sankyo Europe GmbH; 82 Other venous embolism and thrombosis, I74 Arterial embolism and thrombosis, I80 Phlebitis and thrombophlebitis / Prevention of arterial thromboembolism in paediatric cardiac patients at risk of thrombotic events, Acute treatment & secondary prevention of symptomatic recurrent venous thrombotic events (VTE) in paediatric patients at risk

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. Terbinafine hydrochloride - EMEA-001259-PIP02-13-M01

Polichem SA; Treatment of onychomycosis / Treatment of onychomycosis

Day 60 opinion

Action: For adoption

Dermatology

2.3.3. Alirocumab - EMEA-001169-PIP01-11-M02

Sanofi-aventis Recherche & Developpement; Prevention of cardiovascular events / Proposed adult indication: To reduce the risk of cardiovascular events in adult patients with a history of an acute coronary syndrome and elevated LDL cholesterol

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.4. Idursulfase - EMEA-000294-PIP02-12-M01

Shire Human Genetic Therapies AB; ICD10 E76.1: / Treatment of Mucopolysaccharidosis II (Hunter Syndrome)

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.5. Potassium chloride / Sodium chloride / Citric acid, anhydrous / Sodium citrate / Simeticone / Sodium sulphate, anhydrous / Macrogol 4000 - EMEA-001356-PIP02-12-M01

Alfa Wassermann S.p.A.; any clinical procedures requiring a clean bowel e.g. bowel endoscopy or radiology.

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.6. Eltrombopag - EMEA-000170-PIP03-13-M02

Novartis Europharm Limited; Bone Marrow Depression and Hypoplastic Anaemia / Treatment of cytopenias in paediatric patients with severe aplastic anaemia who are no receiving hematopoietic stem cell transplant

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.7. Methoxy polyethylene glycol- epoetin beta - EMEA-000172-PIP01-07-M02

Roche Registration Limited; Anaemia associated with chronic kidney disease

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.8. belatacept - EMEA-000157-PIP01-07-M03

Bristol-Myers Squibb Pharma EEIG; Prevention of rejection of transplanted kidney / NULOJIX, in combination with corticosteroids and a mycophenolic acid (MPA), is indicated for prophylaxis of graft rejection in pediatric patients at least 12 years of age and with a stable renal transplant for at least 6 months, who convert to a CNI-free maintenance immunosuppressive regimen.

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.9. 4-amino-1-[5-chloro-2,5-dideoxy-2-fluoro-3-O-(2-methylpropanoyl)-4-[[(2-methylpropanoyl)oxy]methyl]-a-L-lyxofuranosyl]-2(1H)-pyrimidinone - EMEA-001758-PIP01-15-M01

Janssen-Cilag International NV; Treatment of lower respiratory tract disease caused by human respiratory syncytial virus

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.10. bedaquiline (fumarate) - Orphan - EMEA-000912-PIP01-10-M03

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.11. elbasvir / grazoprevir - EMEA-001604-PIP01-13-M02

Merck Sharp & Dohme (Europe), Inc.; treatment of chronic Hepatitis C infection / Treatment of chronic hepatitis C genotype 1, 4, and 6 infection with the combination regimen of MK-5172 and MK-8742 in children and adolescents from 3 years to less than 18 years of age with compensated liver disease who are previously untreated or who have failed previous Peg-Interferon/Interferon therapy with ribavirin with or without cirrhosis.

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.12. Rilpivirine (RPV) / Dolutegravir (DTG) - EMEA-001750-PIP01-15-M01

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.13. Tenofovir Alafenamide / Emtricitabine - EMEA-001577-PIP02-14-M01

Gilead Sciences International Ltd.; Treatment of human immunodeficiency virus (HIV-1) infection. / Descovy is indicated for the treatment of HIV-1 infection.

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.14. Nanobody directed towards the fusion protein of human respiratory syncytial virus - EMEA-001553-PIP01-13-M01

Ablynx NV; Lower respiratory tract disease caused by RSV / Treatment of RSV lower respiratory tract infection

Day 60 opinion

Action: For adoption

Neonatology - Paediatric Intensive Care

2.3.15. Bumetanide - EMEA-001303-PIP01-12-M01

Neurochlore; Autism Spectrum Disorder / Treatment of AutiSm Spectrum Disorder

Day 60 opinion

Action: For adoption

Neurology

2.3.16. Humanized anti-IL-6 receptor (IL-6R) monoclonal antibody - Orphan - EMEA-001625-PIP01-14-M01

CHUGAI PHARMA EUROPE LTD.; neuromyelitis optica

Day 60 opinion

Action: For adoption

Neurology

2.3.17. Ocrelizumab - EMEA-000310-PIP03-10-M02

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

Day 60 opinion

Action: For adoption

Neurology

2.3.18. Idelalisib - EMEA-001350-PIP02-13-M03

Gilead Sciences International Ltd; Treatment of mature B-cell neoplasm / Treatment of children from 1 year to less than 18 years of age with a relapsed or refractory diffuse large B-cell lymphoma (DLBCL) or mediastinal B-cell lymphoma (MBCL)

Day 60 opinion

Action: For adoption

Oncology

2.3.19. ipilimumab - EMEA-000117-PIP02-10-M07

Bristol-Myers Squibb Pharma EEIG; Treatment of melanoma / Treatment of pre-treated and naive patients with advanced metastatic melanoma.

Day 60 opinion

Action: For adoption

Oncology

2.3.20. midostaurin - Orphan - EMEA-000780-PIP01-09-M03

Novartis Europharm Ltd; C92.0 Acute myeloid leukaemia, C94.3 Mast cell leukaemia, C96.2 Malignant mastocytosis / Treatment of paediatric patients with FLT3 mutated AML, newly diagnosed, A waiver is in place for this condition

Day 60 opinion

Action: For adoption

Oncology

2.3.21. nivolumab - EMEA-001407-PIP02-15-M01

Bristol-Myers Squibb Pharma EEIG; Treatment of malignant neoplasms of lymphoid tissue, Treatment of malignant neoplasms of the central nervous system / Treatment of paediatric patients with relapsed or refractory Hodgkin lymphoma in the age group from 5 years to < 18 years., Treatment of paediatric patients with a relapsed or refractory non-Hodgkin lymphoma in the age group from 6 months to less than 18 years old., Treatment of paediatric patients from 6 months to less than 18 years of age with a recurrent or progressive high-grade glioma.

Day 60 opinion

Action: For adoption

Oncology

2.3.22. paclitaxel - EMEA-001308-PIP01-12-M01

Celgene Europe Limited; Treatment of Solid malignant tumours / Treatment of a paediatric

solid malignant tumour

Day 60 opinion

Action: For adoption

Oncology

2.3.23. ranibizumab - EMEA-000527-PIP04-13-M01

Novartis Europharm Limited; retinopathy of prematurity / Treatment of patients with retinopathy of prematurity

Day 60 opinion

Action: For adoption

Ophthalmology

2.3.24. Patiromer sorbitex calcium - EMEA-001720-PIP01-14-M01

Vifor Fresenius Medical Care Renal Pharma France; Hyperkalaemia

Day 60 opinion

Action: For adoption

Other

2.3.25. CONCENTRATE OF PROTEOLYTIC ENZYMES ENRICHED IN BROMELAIN - Orphan - EMEA-000142-PIP02-09-M05

MediWound Germany GmbH; Treatment of burns of external body surfaces / Removal of eschar in deep partial and/or full thickness burns

Day 60 opinion

Action: For adoption

Other / Dermatology

2.3.26. budesonide - EMEA-001087-PIP02-12-M03

Vectura Limited; Treatment of asthma

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.27. Dupilumab - EMEA-001501-PIP02-13-M02

sanofi-aventis recherche & développement; Asthma

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.28. Formoterol fumarate dihydrate / Beclometasone dipropionate - EMEA-000548-PIP01-09-M06

Chiesi Farmaceutici S.p.A.; COPD, Asthma / Maintenance therapy of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate: - patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting beta2-agonist or - patients already adequately controlled on both inhaled corticosteroids and long-acting beta2-agonists

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.29. Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily B; Escherichia coli) / Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily A; Escherichia coli) - EMEA-001037-PIP02-11-M04

Pfizer Ltd; Prevention of Invasive meningococcal disease caused by N meningitidis serogroup B.

Day 60 opinion

Action: For adoption

Vaccines

2.4. Opinions on Re-examinations

2.4.1. methoxyflurane - EMEA-000334-PIP01-08-M05

Medical Developments UK Ltd; treatment of acute pain / 1. Self administration to conscious patients with minor trauma and associated pain, under supervision of personnel trained in its use 2. For the management of acute pain associated with short surgical procedures, such as the change of dressings, dislocations and injections

Day 30 opinion

Action: For adoption

Pain

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. Gadolinium - EMEA-001949-PIP01-16

Detection and visualisation for areas with disruption of blodd brain barrier and/or abnormal vascularity for diagnostic purposes

Day 90 discussion

Action: For discussion

Diagnostic

3.1.2. Recombinant human alpha-glucosidase conjugated with multiple copies of synthetic bismannose-6-phosphate-tetra-mannose glycan - Orphan - EMEA-001945-PIP01-16

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 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.3. Somapacitan - EMEA-001469-PIP01-13

Growth Hormone Deficiency

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.4. Testosterone - EMEA-001529-PIP02-14

Male hypogonadism

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

Pr Bobby Gaspar; Severe combined immunodeficiency disorder due to adenosine deaminase deficiency [ADA-SCID] / Treatment of severe combined immunodeficiency disorder due to adenosine deaminase deficiency [ADA-SCID]

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.6. Filgotinib - EMEA-001619-PIP02-15

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis, and juvenile idiopathic arthritis) / Treatment of juvenile idiopathic arthritis

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.7. T-lymphocytes enriched leukocyte preparation depleted ex vivo of host host-alloreactive T cells using photodynamic treatment - Orphan - EMEA-001980-PIP01-16

Kiadis Pharma Netherlands B.V.; Adjunctive treatment in haematopoietic stem cell transplantation for a malignant disease / Adjunctive treatment to a haploidentical haematopoietic stem cell transplantation with CD34+ selected cells, in patients with a haematological malignancy, for the reduction of morbidity (i.e. incidences and severity of graft versus host disease) and mortality due to infection and relapse.

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Oncology

3.1.8. Lamivudine (3TC) / Dolutegravir (DTG) - EMEA-001940-PIP01-16

Treatment of human immunodeficiency virus (HIV-1) infection / Treatment of human immunodeficiency virus (HIV-1) infection

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.9. EMEA-001918-PIP01-15

ICD10 F84: Treatment of autism spectrum disorder

Day 90 discussion

Action: For discussion

Neurology

3.1.10. Recommended INN: avelumab (recombinant human monoclonal IgG1 antibody directed against Programmed Death Ligand-1 (anti-PD-L1) - Orphan - EMEA-001849-PIP02-15

Merck KGaA; Treatment of all conditions included in the category of malignant neoplasms

(except central nervous system tumours, haematopoietic and lymphoid tissue neoplasms)

Day 90 discussion

Action: For discussion

Oncology

3.1.11. tadalafil / ambrisentan - EMEA-002030-PIP01-16

Pulmonary Arterial Hypertension

Day 60 discussion

Action: For discussion

Cardiovascular Diseases

3.1.12. Ligelizumab - EMEA-001811-PIP02-15

Treatment of chronic spontaneous urticaria / Treatment of chronic spontaneous urticaria

Day 60 discussion

Action: For discussion

Dermatology

3.1.13. Empagliflozin - EMEA-000828-PIP04-16

Treatment of type 1 diabetes mellitus

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.14. Synthetic double-stranded siRNA oligonucleotide directed against hydroxyacid oxidase 1 mRNA that is covalently linked to a ligand containing three N-acetylgalactosamine residues - Orphan - EMEA-002079-PIP01-16

Alnylam UK Limited; Treatment of Primary Hyperoxaluria Type 1 / Treatment of Primary Hyperoxaluria Type 1

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.15. Plasminogen (human) - Orphan - EMEA-002044-PIP01-16

ProMetic BioTherapeutics Ltd; Plasminogen deficiency

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.16. anifrolumab - EMEA-001435-PIP02-16

Lupus nephritis, Systemic lupus erythematosis / Treatment of

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.17. EMEA-001989-PIP01-16

Staphylococcal skin infection / Treatment of acute bacterial skin and skin structure infections (ABSSSI) due to staphylococcus sensitive or resistant to meticillin

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.18. VIS410 (human immunoglobulin G1 monoclonal antibody directed against a unique, functionally conserved epitope on the influenza A haemagglutinin protein) - EMEA-001924-PIP01-15

Influenza A (ICD10 code: J09) / Treatment of influenza A

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.19. Polihexanide (PHMB) - Orphan - EMEA-002053-PIP01-16

Società Industria Farmaceutica Italiana (S.I.F.I.) SpA; ICD10: B.60.1 Keratitis and keratoconjunctivitis (interstitial) in acanthamoebiasis

Day 60 discussion

Action: For discussion

Ophthalmology

3.1.20. Vosoritide - Orphan - EMEA-002033-PIP01-16

BioMarin International Limited; Treatment of achondroplasia / Treatment of achondroplasia

Day 60 discussion

Action: For discussion

Other

3.1.21. Formoterol Fumarate / Glycopyrronium Bromide / Budesonide - EMEA-002063-PIP01-16

Asthma / For the regular treatment of asthma in children 6 to 11 years of age where use of a triple combination medicinal product (ICS, LAMA and LABA) is appropriate: • patients not adequately controlled with ICS and another controller such as a LABA or LAMA

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.22. Ezetimibe / Atorvastatin Calcium trihydrate - EMEA-002047-PIP01-16

Dyslipidaemia

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.23. Crisaborole - EMEA-002065-PIP01-16

Mild to moderate atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.1.24. lebrikizumab - EMEA-001053-PIP03-16

Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.1.25. (2S)-2-{[(2R)-2-[({[3,3-dibutyl-7-(methylthio)-1,1-dioxido-5-phenyl-2,3,4,5-tetrahydro-1,2,5-benzothiadiazepin-8-l]oxy}acetyl)amino]-2-(4-hydroxyphenyl)acetyl]amino}butanoic acid - Orphan - EMEA-002054-PIP01-16

Albireo AB; Treatment of Progressive Familial Intrahepatic Cholestasis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.26. EMEA-001868-PIP02-16

K70.1 Alcoholic hepatitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.27. Fc- and CDR-modified humanised monoclonal antibody against C5 - Orphan - EMEA-002077-PIP01-16

Alexion Europe SAS; Paroxysmal Nocturnal Haemoglobinuria / Treatment of Paroxysmal Nocturnal Haemoglobinuria

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.28. ABT-494 - EMEA-001741-PIP03-16

Treatment of Crohn's Disease

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.29. riociguat - Orphan - EMEA-000718-PIP02-16

Bayer Pharma AG; M34.9 Treatment of Systemic Sclerosis / Treatment of Diffuse Cutaneous Systemic Sclerosis (dcSSc)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.30. EMEA-002057-PIP01-16

Post ischemic stroke recovery / Treatment of ischemic stroke to improve recovery

Day 30 discussion

Action: For discussion

Neurology

3.1.31. Deutetrabenazine - EMEA-002052-PIP01-16

Treatment of tics associated with Tourette syndrome

Day 30 discussion

Action: For discussion

Neurology

3.1.32. Recombinant human arylsulfatase A (rhASA) - Orphan - EMEA-002050-PIP01-16

Shire Pharmaceuticals Ireland Limited; Treatment of metachromatic leukodystrophy (MLD) / Treatment of metachromatic leukodystrophy (MLD)

Day 30 discussion

Action: For discussion

Neurology

3.1.33. (S)-N-(5-((R)-2-(2,5-difluorophenyl)pyrrolidin-1-yl)pyrazolo[1,5-a]pyrimidin-3-yl)-3-hydroxypyrrolidine-1-carboxamide hydrogen sulfate - Orphan - EMEA-001971-PIP02-16

Loxo Oncology, Inc.; Treatment of solid tumours / The treatment of adults, adolescents and children (> 1 month of age) with advanced solid tumours harbouring an NTRK fusion, as established prior to initiation of LOXO-101 therapy.

Day 30 discussion

Action: For discussion

Oncology

3.1.34. Allogeneic Epstein-Barr virus specific cytotoxic T lymphocytes - Orphan - EMEA-002025-PIP02-16

Atara Biotherapeutics, Inc.; Treatment of Epstein-Barr virus associated post-transplant lymphoproliferative disorder / Treatment of allogeneic haematopoietic cell transplant (alloHCT) patients with Epstein-Barr virus associated Post Transplant Lymphoproliferative Disease (EBV-PTLD) who have failed prior therapy with rituximab

Day 30 discussion

Action: For discussion

Oncology

3.1.35. alpelisib - EMEA-002016-PIP02-16

Treatment of breast cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.36. EMEA-002003-PIP02-16

Treatment of chronic lymphocytic leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.1.37. gilteritinib (as fumarate) - EMEA-002064-PIP01-16

Treatment of acute myeloid leukemia / Treatment of FLT3/ITD positive acute myeloid leukemia

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.1.38. Venetoclax - Orphan - EMEA-002018-PIP02-16

AbbVie Ltd; Treatment of haematopoietic and lymphoid malignant neoplasms, Treatment of solid tumour malignant neoplasms / As monotherapy, or in combination with chemotherapy, for the treatment of relapsed or refractory NHL patients < 18 years of age, who have progressed following autologous stem cell transplantation or who are ineligible for transplantation, As monotherapy or in combination for the treatment of patients with relapsed or refractory neuroblastoma < 18 years of age, As monotherapy, or in combination with chemotherapy, for the treatment of relapsed or refractory ALL in the third line setting in patients < 18 years of age, As monotherapy, or in combination with chemotherapy, for the treatment of relapsed or refractory AML in patients < 18 years of age

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.1.39. Fluocinolone Acetonide - Orphan - EMEA-000801-PIP03-16

CAMPHARM Limited; Chronic non-infectious uveitis affecting the posterior segment of the eye

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.40. EMEA-002082-PIP01-16

Treatment of cystic fibrosis indicated to improve lung function and reduce pulmonary exacerbations for patients in all age groups with cystic fibrosis in conjunction with standard therapies.

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.41. Nintedanib - Orphan - EMEA-001006-PIP04-16

Boehringer Ingelheim International GmbH; Treatment of Progressive Fibrosing Interstitial Lung Disease (PF-ILD)

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.2. Discussions on Compliance Check

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

3.2.1. rivaroxaban - EMEA-C3-000430-PIP01-08-M09

Bayer Pharma AG; Treatment of thromboembolic events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.2.2. Cobicistat / elvitegravir / tenofovir disoproxil / emtricitabine - EMEA-C-000970-PIP01-10-M01

Gilead Sciences International Ltd.; Treatment of human immunodeficiency virus HIV-1 infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.3. Melatonin - EMEA-C-000440-PIP02-11-M04

RAD Neurim Pharmaceuticals EEC Ltd; Treatment of insomnia

Day 30 discussion

Action: For discussion

Neurology

3.2.4. Human recombinant IgGI monoclonal antibody targeting fibroblast growth factor 23 (FGF23) - EMEA-C1-001659-PIP01-15-M01

Ultragenyx Pharmacetical Inc.; X-linked Hypophosphatemia

Day 30 discussion

Action: For discussion

Other

3.2.5. solifenacin succinate - EMEA-C-000573-PIP02-13-M03

Astellas Pharma Europe B.V.; Treatment of neurogenic detrusor overactivity

Day 30 discussion

Action: For discussion

Uro-nephrology

3.2.6. 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-C-000673-PIP01-09-M09

GlaxoSmithKline Biologicals S.A.; Prevention of acute otitis media caused by non-typeable Haemophilus influenzae

Day 30 discussion

Action: For discussion

Vaccines

3.2.7. Purified Pertussis Toxoid (PT) / Hepatitis B Surface Antigen, recombinant (HBsAg) / Purified Filamentous Haemagglutinin (FHA) / Inactivated Type 2 Poliovirus (MEF-1) / Haemophilus influenzae type b polysaccharide conjugated to tetanus protein / Inactivated Type 3 Poliovirus (Saukett) / Purified Diphtheria Toxoid / Inactivated Type 1 Poliovirus (Mahoney) / Purified Tetanus Toxoid - EMEA-C-001201-PIP01-11-M02

Sanofi Pasteur; Prevention of infections caused by Corynebacterium diphtheriae, Clostridium tetani, Bordetella pertussis, poliovirus types 1, 2 and 3, prevention against invasive infections caused by Haemophilus influenzae type b and infection caused by hepatitis B virus

Day 30 discussion

Action: For discussion

Vaccines

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Vericiguat - EMEA-001636-PIP01-14-M01

Bayer Pharma AG; Treatment of left ventricular failure / Treatment of chronic left ventricular failure with reduced ejection fraction in paediatric patients with dilated cardiomyopathies

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. dupilumab - EMEA-001501-PIP01-13-M04

Regeneron Pharmaceuticals, Inc; Atopic Dermatitis / Atopic Dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.3.3. tofacitinib - EMEA-000576-PIP02-11-M04

Pfizer Limited; Treatment of psoriasis / Treatment of severe plaque psoriasis

Day 30 discussion

Action: For discussion

Dermatology

3.3.4. saxagliptin - EMEA-000200-PIP01-08-M07

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

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. Tofacitinib - EMEA-000576-PIP01-09-M06

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

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.6. Treosulfan - Orphan - EMEA-000883-PIP01-10-M03

medac Gesellschaft für klinische Spezialpräparate mbH; Conditioning treatment prior to haematopoietic progenitor cell transplantation / Conditioning treatment prior to haematopoietic progenitor cell transplantation

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Oncology

3.3.7. Anidulafungin - EMEA-000469-PIP01-08-M07

Pfizer Limited; Treatment of invasive candidiasis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.8. avibactam / ceftazidime - EMEA-001313-PIP01-12-M05

AstraZeneca AB; Treatment of bacterial infections / For the treatment of complicated urinary tract infections, For the treatment hospital acquired pneumonia, For the treatment of complicated intra-abdominal infections, For the treatment of Gram-negative bacterial infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.9. Cobicistat - EMEA-000969-PIP01-10-M04

Gilead Sciences International Ltd.; Treatment of human immunodeficiency virus type-1 (HIV-1) infection. / Treatment of human immunodeficiency virus type-1 (HIV-1) infection - pharmacoenhancer for use in combination with antiretroviral agents.

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.10. dasabuvir sodium monohydrate - EMEA-001439-PIP01-13-M01

Abbvie Ltd; Treatment of chronic hepatitis C / Treatment of children and adolescents from >= 3 years to less than 18 years of age with chronic HCV infection with compensated cirrhosis or without compensated cirrhosis in combination with ombitasvir, paritaprevir and ritonavir

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.11. Fidaxomicin - EMEA-000636-PIP01-09-M05

Astellas Pharma Europe B.V.; Treatment of enterocolitis caused by clostridium difficile / Treatment of Clostridium difficile infections (CDI) also known as C. difficile-associated diarrhoea (CDAD).

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.12. ledipasvir / sofosbuvir - EMEA-001411-PIP01-12-M04

Gilead Sciences International Ltd.; Treatment of chronic hepatitis C / Treatment of chronic hepatitis C

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.13. ritonavir / paritaprevir / ombitasvir - EMEA-001440-PIP01-13-M01

Abbvie Ltd; Treatment of chronic hepatitis C / Treatment of children and adolescents from >= 3 years to < 18 years of age with chronic HCV infection with compensated cirrhosis or without compensated cirrhosis in combination with other medicinal products

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.14. tazobactam / ceftolozane - EMEA-001142-PIP01-11-M02

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.15. Brivaracetam - Orphan - EMEA-000332-PIP01-08-M11

UCB Pharma S.A.; treatment of paediatric epilepsy syndromes, Treatment of epilepsy with partial onset seizures, Treatment of neonatal seizures / Treatment of neonatal seizures with adjunctive administration of brivaracetam, Treatment of paediatric patients with partial onset seizures, treatment of refractory paediatric epilepsy syndromes with adjunctive administration of brivaracetam

Day 30 discussion

Action: For discussion

Neurology

3.3.16. Fingolimod hydrochloride - EMEA-000087-PIP01-07-M05

Novartis Europharm Limited; Multiple Sclerosis / Multiple Sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.3.17. lacosamide - EMEA-000402-PIP02-11-M03

UCB Pharma S.A.; Treatment of Epilepsy - Partial-onset seizures [G40.0 - G40.1 - G40.2], 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 partial-onset seizures with or without secondary generalization in pediatric patients with epilepsy (birth to <16 years), Monotherapy in the treatment of partial-onset seizures with or without secondary generalization in pediatric patients (1 month to <18 years), 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), Adjunctive therapy in the treatment of epileptic syndromes associated with generalized seizures in pediatric patients with epilepsy birth to <18 years (specific epileptic syndrome(s) to be based on future clinical development further to exploratory study results)

Day 30 discussion

Action: For discussion

Neurology

3.3.18. cobimetinib - EMEA-001425-PIP01-13-M02

Roche Registration Limited; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue) with Ras, Raf or MEK pathway activation / Treatment of children with a paediatric solid malignant tumour with known or expected Ras, Raf or MEK pathway activation, at first relapse or refractory to initial treatment.

Day 30 discussion

Action: For discussion

Oncology

3.3.19. Sirolimus - Orphan - EMEA-001416-PIP01-12-M01

Santen Incorporated; Treatment of chronic non-infectious uveitis

Day 30 discussion

Action: For discussion

Ophthalmology

3.3.20. tafluprost - EMEA-001187-PIP01-11-M04

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

3.3.21. conestat alfa - EMEA-000367-PIP01-08-M06

Pharming Group N.V.; D84.1 Defects in the complement system C1 esterase inhibitor (C1-INH) deficiency / treatment of acute attacks of angioedema associated with hereditary C1 esterase inhibitor deficiency

Day 30 discussion

Action: For discussion

Other

3.3.22. mepolizumab - Orphan - EMEA-000069-PIP02-10-M07

GSK Trading Services Limited; treatment of asthma / add-on treatment for severe refractory eosinophilic asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.23. mirabegron - EMEA-000597-PIP03-15-M03

Astellas Pharma Europe B.V.; Treatment of neurogenic detrusor overactivity / Treatment of detrusor overactivity in children and adolescents with neurogenic bladder dysfunction

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3.24. Influenza virus surface antigens - A/turkey/Turkey/1/05 (H5N1)-like strain (NIBRG-23) - EMEA-000599-PIP01-09-M05

Seqirus S.r.l.; Prevention of influenza / Active immunization against H5N1 subtype of Influenza A virus

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 21 February 2017 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. EMEA-33-2016

Primary and secondary osteoarthrosis

Action: For adoption

6.1.2. (nanoparticle-drug conjugate (NDC) composed of 20(S)-camptothecin conjugated to a linear, cyclodextrin polyethylene glycol-based copolymer) - EMEA-34-2016

Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumors)/ Treatment of patients with platinum-resistant ovarian carcinoma, fallopian tube carcinoma or primary peritoneal cancer

Action: For adoption

6.1.3. (nanoparticle-drug conjugate (NDC) composed of 20(S)-camptothecin conjugated to a linear, cyclodextrin polyethylene glycol-based copolymer) - EMEA-35-2016

Treatment of fallopian tube carcinoma (excluding rhabdomyosarcoma and germ cell tumors) / (nanoparticle-drug conjugate (NDC) composed of 20(S)-camptothecin conjugated to a linear, cyclodextrin polyethylene glycol-based copolymer)

Action: For adoption

6.1.4. (nanoparticle-drug conjugate (NDC) composed of 20(S)-camptothecin conjugated to a linear, cyclodextrin polyethylene glycol-based copolymer) - EMEA-36-2016

Treatment of peritoneal carcinoma (excluding blastomas and sarcomas)/ (nanoparticle-drug conjugate (NDC) composed of 20(S)-camptothecin conjugated to a linear, cyclodextrin polyethylene glycol-based copolymer)

Action: For adoption

6.1.5. CNP520 (Beta-site-APP-Cleaving Enzyme inhibitor) - EMEA-37-2016

Treatment of Alzheimer's Disease/ Treatment of Alzheimer's Disease

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. Alirocumab - EMEA-001169-PIP01-11-M02

Sanofi-aventis Recherche & Developpement; Treatment of elevated cholesterol / Proposed adult indication: To reduce the risk of cardiovascular events in adult patients with a history of an acute coronary syndrome and elevated LDL cholesterol

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

9.1.1. Rapporteur and peer reviewer comments on Summary Reports

PDCO Chair: Dirk Mentzer

Action: For discussion

9.1.2. Granting deferrals for initiation/completion of measures in PIPs

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

9.3. 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

9.3.3. Patients and Consumers Working Party (PCWP) Workplan 2017

Action: For adoption

9.3.4. Healthcare Professionals Working Party (HCPWP) Workplan 2017

Action: For adoption

9.3.5. Agenda of the Training session for patients and consumers interested in EMA activities held on 29 Nov 2016

Action: Document tabled for information

9.3.6. Agenda of the PCWP meeting with all eligible organisations held on 30 November 2016

Action: Document tabled for information

9.3.7. Report of the PCPWP/ HCPWP workshop on social media held on 19 September 2016

Action: Document tabled for information

9.4. Cooperation within the EU regulatory network

9.4.1. EMA and PDCO during the public consultation phase of 2017 Commission Report on the Paediatric Regulation

PDCO member: Koenraad Norga

Action: For discussion

9.5. Cooperation with International Regulators

9.5.1. Report on the progress of the update of the EMA/FDA strategic document on Gaucher disease

PDCO member: Sylvie Benchetrit

Action: For information

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

None

9.7. PDCO work plan

9.7.1. PDCO Work-plan 2017

Action: For discussion

9.8. Planning and reporting

9.8.1. Business Pipeline Report for the human scientific committees. - Forecast for 2017

Action: Document table for information

10. Any other business

10.1.1. Flow of documents from PDCO members to EMA

Action: For information

10.1.2. Updated policy on handling interests for scientific committees' members and experts

Action: For information

11. Breakout sessions

11.1.1. Paediatric oncology

Action: For discussion on Tuesday, 16:00 - 17:00, room 3H

11.1.2. Neonatology

Action: For discussion on Tuesday, 16:00 - 17:00, room 3J

11.1.3. Inventory

Action: For discussion on Tuesday

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/