24 January 2017
EMA/PDCO/20221/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 24-27 January 2017

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

24 January 2017, 14:00- 19:00, room 3A

25 January 2017, 08:30- 19:00, room 3A

26 January 2017, 08:30- 19:00, room 3A

27 January 2017, 08:30- 13:00, room 3A

Health and safety information

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

Disclaimers

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

Note on access to documents

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

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1. Introductions

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PDCO plenary session to be held 24-27 January 2017. See January 2017 PDCO minutes (to be published post February 2017 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 24-27 January 2017.

1.3. Adoption of the minutes

PDCO minutes for 13-16 December 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. Gadolinium - EMEA-001949-PIP01-16

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

Day 120 opinion

Action: For adoption

Diagnostic

2.1.2. 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 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.3. Somapacitan - EMEA-001469-PIP01-13

Growth Hormone Deficiency

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.4. Testosterone - EMEA-001529-PIP02-14

Male hypogonadism

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.5. 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 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.6. 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 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.7. 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 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Oncology

2.1.8. 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 120 opinion

Action: For adoption

Infectious Diseases

2.1.9. EMEA-001918-PIP01-15

ICD10 F84: Treatment of autism spectrum disorder

Day 120 opinion

Action: For adoption

Neurology

2.1.10. 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 120 opinion

Action: For adoption

Oncology

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

Dyslipidaemia

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.12. EMEA-001868-PIP02-16

K70.1 Alcoholic hepatitis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

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

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

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.14. alpelisib - EMEA-002016-PIP02-16

Treatment of breast cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.15. EMEA-002003-PIP02-16

Treatment of chronic lymphocytic leukaemia

Day 60 opinion

Action: For adoption

Oncology

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

Bayer Pharma AG; Treatment of thromboembolic events

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

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

RAD Neurim Pharmaceuticals EEC Ltd; Treatment of insomnia

Day 60 opinion

Action: For adoption

Neurology

2.2.3. 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 60 opinion

Action: For adoption

Vaccines

2.2.4. 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 60 opinion

Action: For adoption

Vaccines

2.2.5. Tocilizumab - EMEA-C3-000309-PIP01-08-M07 – adoption at day 30

Roche Registration Limited; Chronic Idiopathic Arthritis

Day 30 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.2.6. Peramivir - EMEA-C1-001856-PIP02-16 – letter at Day2

BioCryst UK Ltd; Treatment of influenza

Day 2 letter

Action: For information

Infectious diseases

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Vigabatrin - EMEA-000717-PIP02-13-M02 – Adoption at Day 30

ORPHELIA Pharma SA; Infantile spasms (West syndrome; ICD10: G40.82), Refractory partial epilepsy (ICD10: G40.01, G40.11, G40.21) / Treatment of infantile spasms, Treatment of refractory partial epilepsy

Day 30 opinion

Action: For adoption

Neurology

2.3.2. 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 60 opinion

Action: For adoption

Cardiovascular Diseases

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

Regeneron Pharmaceuticals, Inc; Atopic Dermatitis / Atopic Dermatitis

Day 60 opinion

Action: For adoption

Dermatology

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

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

Day 60 opinion

Action: For adoption

Dermatology

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

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

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.6. 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 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.7. 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 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Oncology

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

Pfizer Limited; Treatment of invasive candidiasis

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.9. 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 60 opinion

Action: For adoption

Infectious Diseases

2.3.10. 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 60 opinion

Action: For adoption

Infectious Diseases

2.3.11. 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 60 opinion

Action: For adoption

Infectious Diseases

2.3.12. 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 60 opinion

Action: For adoption

Infectious Diseases

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

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.14. 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 60 opinion

Action: For adoption

Infectious Diseases

2.3.15. 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 60 opinion

Action: For adoption

Infectious Diseases

2.3.16. 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 60 opinion

Action: For adoption

Neurology

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

Novartis Europharm Limited; Multiple Sclerosis / Multiple Sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.3.18. 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 60 opinion

Action: For adoption

Neurology

2.3.19. 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 60 opinion

Action: For adoption

Oncology

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

Santen Incorporated; Treatment of chronic non-infectious uveitis

Day 60 opinion

Action: For adoption

Ophthalmology

2.3.21. 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 60 opinion

Action: For adoption

Ophthalmology

2.3.22. 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 60 opinion

Action: For adoption

Other

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

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

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.24. 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 60 opinion

Action: For adoption

Uro-nephrology

2.3.25. 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 60 opinion

Action: For adoption

Vaccines

2.3.26. Naldemedine - EMEA-001893-PIP01-15-M01– adoption at day 30

Shionogi Limited; Opioid-induced Constipation (OIC)

Day 30 opinion

Action: For adoption

Gastroenterology-Hepatology

2.4. Opinions on Re-examinations

No items.

2.5. Finalisation and adoption of opinions

3. Discussion of applications

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

3.1. Discussions on Products D90-D60-D30

3.1.1. Levoglutamide - Orphan - EMEA-001996-PIP02-16

Emmaus Medical Europe Ltd.; Sickle cell disease / Levoglutamide is indicated for the prevention of sickle cell crises in adults, adolescents and children older than 5 years suffering from Sickle Cell Disease.

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.2. Macimorelin - EMEA-001988-PIP01-16

Growth hormone deficiency / Diagnosis of growth hormone deficiency

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Diagnostic

3.1.3. Allogeneic, non-expanded, umbilical cord blood-derived, hematopoietic mature myeloid and lymphoid cells (NF) / Allogeneic, ex vivo expanded, umbilical cord blood-derived, hematopoietic CD34+ progenitor cells (CF) - Orphan - EMEA-001913-PIP01-15

Gamida Cell Limited; acute lymphoblastic leukaemia, myelodysplastic syndrome, acute myeloid leukaemia, chronic myeloid leukaemia / treatment of patients with hematological malignancies who are medically indicated for allogeneic haematopoietic stem cell transplantation

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.4. Human fibrinogen concentrate - EMEA-001931-PIP01-16

Treatment of congenital fibrinogen deficiency

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.5. EMEA-001923-PIP01-15

Chronic idiopathic arthritis, including rheumatoid arthritis, axial spondyloarthritis, psoriatic arthritis and juvenile idiopathic arthritis (pJIA indication), Chronic idiopathic arthritis, including rheumatoid arthritis, axial spondyloarthritis, psoriatic arthritis and juvenile idiopathic arthritis (sJIA indication) / Treatment of systemic Juvenile Idiopathic Arthritis (sJIA), Treatment of polyarticular-course Juvenile Idiopathic Arthritis (pJIA)

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.6. Entolimod - Orphan - EMEA-002020-PIP01-16

Cleveland BioLabs Inc; Treatment of acute Radiation Syndrome / Entolimod is indicated for reducing the risk of death following exposure to potentially lethal irradiation occurring as the results of a radiation disaster

Day 90 discussion

Action: For discussion

Other

3.1.7. bempedoic acid - EMEA-001872-PIP01-15

Primary Hypercholesterolemia / Treatment of heterozygous familial hypercholesterolaemia

Day 90 discussion

Action: For discussion

Other / Cardiovascular Diseases

3.1.8. olodaterol hydrochloride - EMEA-001965-PIP01-16

Treatment of cystic fibrosis

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.9. Baclofen - EMEA-001549-PIP02-14

Alcohol use disorders (DSM-5) / Reduction of alcohol consumption as a second line treatment after psychosocial intervention, in 15-17 years adolescents with alcohol use disorders according to DSM 5

Day 90 discussion

Action: For discussion

Psychiatry

3.1.10. rVSVΔG-ZEBOV-GP - EMEA-001786-PIP01-15

Prevention of Ebola disease

Day 90 discussion

Action: For discussion

Vaccines

3.1.11. Crisaborole - EMEA-002065-PIP01-16

Mild to moderate atopic dermatitis

Day 60 discussion

Action: For discussion

Dermatology

3.1.12. lebrikizumab - EMEA-001053-PIP03-16

Treatment of atopic dermatitis

Day 60 discussion

Action: For discussion

Dermatology

3.1.13. (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 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.14. 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 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.15. EMEA-001741-PIP03-16

Treatment of Crohn's Disease

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.16. EMEA-002057-PIP01-16

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

Day 60 discussion

Action: For discussion

Neurology

3.1.17. Deutetrabenazine - EMEA-002052-PIP01-16

Treatment of tics associated with Tourette syndrome

Day 60 discussion

Action: For discussion

Neurology

3.1.18. 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 60 discussion

Action: For discussion

Neurology

3.1.19. (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 therapy.

Day 60 discussion

Action: For discussion

Oncology

3.1.20. 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 60 discussion

Action: For discussion

Oncology

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

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

Day 60 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.1.22. 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 60 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

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

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

Day 60 discussion

Action: For discussion

Ophthalmology

3.1.24. EMEA-002082-PIP01-16

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

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.25. Acetylsalicylic acid / Prasugrel HCl - EMEA-002071-PIP01-16

Prevention of atherosclerosis, thrombosis and thromboembolic events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.26. Amlodipine / Candesartan - EMEA-002090-PIP01-16

Hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.27. Amlodipine / Perindopril - EMEA-002091-PIP01-16

Hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.28. Tetrofosmin - Orphan - EMEA-002019-PIP02-16

proACTINA SA; Diagnosis of malignant Glioma

Day 30 discussion

Action: For discussion

Diagnostic

3.1.29. Alicaforsen - Orphan - EMEA-002060-PIP01-16

Atlantic Pharmaceuticals Ltd; Treatment of gastrointestinal procedural complications / Treatment of active episodes of antibiotic refractory pouchitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.30. Recombinant human monoclonal antibody to GM-CSF - EMEA-001882-PIP02-16

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis) / Treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 1 year of age and older, Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.31. Iclaprim mesylate - EMEA-000345-PIP02-16

Infection with resistant Gram-positive bacteria. / Treatment of acute bacterial skin and skin structure infections caused by susceptible strains of Gram-positive bacteria.

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.32. Lefamulin - EMEA-002075-PIP01-16

Treatment of community-acquired pneumonia

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.33. Tobramycin - Orphan - EMEA-000184-PIP03-16

Novartis Europharm Limited; Treatment of Pseudomonas aeruginosa pulmonary colonisation in patients with bronchiectasis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.34. EMEA-002070-PIP01-16

Treatment of spinal muscular atrophy

Day 30 discussion

Action: For discussion

Neurology

3.1.35. fenfluramine hydrochloride - Orphan - EMEA-001990-PIP01-16

Zogenix International Ltd; Dravet Syndrome / The adjunctive treatment of seizures in paediatric patients at least 2 years of age with Dravet Syndrome

Day 30 discussion

Action: For discussion

Neurology

3.1.36. Methylphenidate hydrochloride - EMEA-002034-PIP01-16

Attention-Deficit/Hyperactivity Disorder (ADHD)

Day 30 discussion

Action: For discussion

Neurology

3.1.37. Autologous CD3+ T Cells Expressing CD19 Chimeric Antigen Receptor - EMEA-001994-PIP01-16

Treatment of B-cell non-Hodgkin's lymphoma, Treatment of B-cell acute lymphoblastic leukemia / Treatment of pediatric patients with relapsed or refractory B-cell acute lymphoblastic leukemia, Treatment of pediatric patients with relapsed or refractory diffuse large B-cell lymphoma, Burkitt lymphoma, and primary mediastinal large B-cell lymphoma

Day 30 discussion

Action: For discussion

Oncology

3.1.38. Autologous CD4+ and CD8+ T cells Expressing a CD19-Specific Chimeric Antigen Receptor - EMEA-001995-PIP01-16

Treatment of B-cell non-Hodgkin's lymphoma, Treatment of B-cell acute lymphoblastic leukemia / Treatment of pediatric patients with relapsed or refractory B-cell acute lymphoblastic leukemia, Treatment of pediatric patients with relapsed or refractory diffuse large B-cell lymphoma, Burkitt lymphoma, and primary mediastinal large B-cell lymphoma

Day 30 discussion

Action: For discussion

Oncology

3.1.39. Enasidenib - Orphan - EMEA-001798-PIP02-16

Celgene Europe Ltd; Treatment of Acute Myeloid Leukaemia / Treatment of patients aged 2 to 21 years old with relapsed or refractory IDH2- mutated AML after at least 2 prior induction attempts.

Day 30 discussion

Action: For discussion

Oncology

3.1.40. Entospletinib - EMEA-002058-PIP01-16

Treatment of Acute myeloid leukemia / Treatment of Acute myeloid leukemia

Day 30 discussion

Action: For discussion

Oncology

3.1.41. epacadostat - EMEA-002072-PIP01-16

Treatment of melanoma / Melanoma >12years - <18 years

Day 30 discussion

Action: For discussion

Oncology

3.1.42. Ramucirumab - EMEA-002074-PIP01-16

Treatment of soft tissue sarcoma, Treatment of intestinal malignant neoplasm, Treatment of gastric cancer and gastro-oesophageal junction adenocarcinoma, Treatment of liver cancer, Treatment of urinary tract malignant neoplasm, Treatment of lung malignant neoplasm / , Treatment of synovial sarcoma and / or desmoplastic small round cell tumour

Day 30 discussion

Action: For discussion

Oncology

3.1.43. ruxolitinib phosphate - EMEA-002056-PIP01-16

acute graft versus host disease / Steroid refractory (SR) acute (a) Graft vs Host Disease (GvHD) after allogeneic hematopoietic stem cell transplantation (alloSCT)

Day 30 discussion

Action: For discussion

Oncology

3.1.44. Vadastuximab Talirine - Orphan - EMEA-002013-PIP01-16

Seattle Genetics UK, Limited; Treatment of Acute Myeloid Leukaemia / Treatment of relapsed or refractory AML

Day 30 discussion

Action: For discussion

Oncology

3.1.45. Angiotensin II - EMEA-001912-PIP02-16

Catecholamine-resistant hypotension associated with distributive shock

Day 30 discussion

Action: For discussion

Other

3.1.46. Ketamine hydrochloride / Sufentanil citrate - EMEA-001739-PIP02-16

ICD10: R52 Pain, unspecified

Day 30 discussion

Action: For discussion

Pain

3.1.47. Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) - EMEA-002068-PIP01-16

Influenza / Prevention of influenza

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. recombinant human beta-glucuronidase - EMEA-C1-001540-PIP01-13-M01

Ultragenyx Germany GmbH; Treatment of Mucopolysaccharidosis type 7 (MPS 7)

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.2. Bictegravir / Tenofovir alafenamide / emtricitabine - EMEA-C1-001766-PIP01-15-M01

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.3. fluticasone furoate / triphenylacetic acid - 4-{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxy}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol - EMEA-C3-000431-PIP01-08-M09

Glaxo Group Limited; Treatment of asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Evolocumab - EMEA-001268-PIP01-12-M04

Amgen Europe B.V.; Treatment of mixed dyslipidaemia, Treatment of elevated cholesterol / , Heterozygous Familial Hypercholesterolaemia (HeFH) and Homozygous Familial Hypercholesterolaemia (HoFH) after Prior Lipid-Lowering Therapy in paediatric subjects aged 10 years and above.

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. Trifarotene - EMEA-001492-PIP01-13-M01

GALDERMA R&D; L70.0 Acne vulgaris / Treatment of acne vulgaris

Day 30 discussion

Action: For discussion

Dermatology

3.3.3. Recombinant human N-acetylglucosaminidase (rhNAGLU) - Orphan - EMEA-001653-PIP01-14-M02

Alexion Europe SAS; Mucopolysaccharidosis IIIB (Sanfilippo B) / Treatment of Mucopolysaccharidosis IIIB (Sanfilippo B)

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. ferric maltol - EMEA-001195-PIP01-11-M02

Shield TX (UK) Limited; Iron deficiency anaemia / Treatment for iron deficiency anaemia (IDA)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.5. ustekinumab - EMEA-000311-PIP03-11-M02

Janssen-Cilag International NV; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondyloarthritis, PsA and juvenile idiopathic arthritis [JIA]) / Treatment of juvenile idiopathic arthritis (jPsA and ERA)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.6. rituximab - EMEA-000308-PIP01-08-M03

Roche Registration Limited; 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

Immunology-Rheumatology-Transplantation / Oncology

3.3.7. letermovir - Orphan - EMEA-001631-PIP01-14-M02

Merck Sharp & Dohme (Europe), Inc.; Prevention of cytomegalovirus infection / Prevention of CMV viremia and/or disease in at-risk patients having undergone an allogeneic HSCT or SOT

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.8. Oseltamivir phosphate - EMEA-000365-PIP01-08-M08

Roche Registration Limited; Treatment and prevention of influenza / Treatment and prevention of influenza in healthy and immunocompromised patients from 0 to less than 18 years of age

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.9. posaconazole - EMEA-000468-PIP02-12-M03

Merck Sharp & Dohme (Europe), Inc.; Prevention of invasive fungal infections, Treatment of invasive fungal infections / For treatment of invasive fungal infections in the following paediatric patients: -Invasive aspergillosis in patients with disease that is refractroy to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products;, Treatment of invasive aspergillosis, -Patients receiving remission-induction chemotherapy for acute myelogenous leukemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high risk of developing invasive fungal infections; - Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease and who are at high risk of developing invasive fungal infections.

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.10. telaprevir - EMEA-000196-PIP01-08-M04

Janssen-Cilag International NV; Chronic viral hepatitis C

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.11. Oritavancin diphosphate - EMEA-001270-PIP01-12-M01

The Medicines Company; Treatment of acute bacterial skin and skin structure infections

Day 30 discussion

Action: For discussion

Infectious Diseases / Dermatology

3.3.12. Bivalent anti-human myostatin adnectin recombinant human IgG1-Fc fusion protein - EMEA-001793-PIP01-15-M01

Bristol-Myers Squibb International Corporation; Treatment of Duchenne Muscular Dystrophy / Treatment of Duchenne Muscular Dystrophy in patients from 2 to less than 18 years of age

Day 30 discussion

Action: For discussion

Neurology

3.3.13. Siponimod hemifumarate - EMEA-000716-PIP01-09-M02

Novartis Europharm Limited; Multiple Sclerosis / Treatment of children/adolescent patients (10-18 years old) with relapsing forms of multiple sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.3.14. HSV-1/ICP34.5-/ICP47-/hGM-CSF - EMEA-001251-PIP01-11-M03

Amgen Europe B.V.; Treatment of solid malignant non-CNS tumours

Day 30 discussion

Action: For discussion

Oncology

3.3.15. ibrutinib - Orphan - EMEA-001397-PIP03-14-M02

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

Day 30 discussion

Action: For discussion

Oncology

3.3.16. Lenvatinib - Orphan - EMEA-001119-PIP02-12-M03

Eisai Europe Ltd; Treatment of papillary thyroid carcinoma, Treatment of Osteosarcoma, Treatment of follicular thyroid carcinoma / Treatment of refractory or relapsed osteosarcoma in children and adolescents, Treatment of progressive, radioiodine-refractory differentiated thyroid cancer in children and adolescents

Day 30 discussion

Action: For discussion

Oncology

3.3.17. Regorafenib - EMEA-001178-PIP01-11-M03

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

Day 30 discussion

Action: For discussion

Oncology

3.3.18. Eliglustat - Orphan - EMEA-000461-PIP02-11-M02

Genzyme Europe B.V.; Treatment of Gaucher disease Type 1 and Type 3 / Treatment of Gaucher disease Type 3, Treatment of Gaucher disease Type 1

Day 30 discussion

Action: For discussion

Other

3.3.19. ivacaftor / lumacaftor - EMEA-001582-PIP01-13-M05

Vertex Pharmaceuticals (Europe) Limited; cystic fibrosis / Treatment of cystic fibrosis

Day 30 discussion

Action: For discussion

Other

3.3.20. Dermatophagoides pteronyssinus/ Dermatophagoides farinae (50%/50%) - EMEA-001258-PIP01-11-M02

ALK-Abelló A/S; Treatment of allergic rhinitis, Treatment of asthma / allergic rhinitis, allergic asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

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 March 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

4.3.1. Nominations of external experts (paediatric neurologists) for ad hoc expert group meeting for (Cerliponase Alfa) to be held on 7 March 2017

Action: For adoption

4.3.2. Participation of PDCO member, Sylvie Benchetrit, at 'Research Roundtable for Epilepsy' to be held on March 2-3, 2017 in Washington

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. Lorlatinib - EMEA-38-2016

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

treatment of adult patients with advanced or metastatic; ALK-positive NSCLC resistant or refractory to one or more prior ALK inhibitor therapies

Action: For adoption

6.1.2. Beta-secretase inhibitor - EMEA-39-2016

All classes of medicinal products for treatment of Alzheimer's disease/ slowing of cognitive decline in asymptomatic individuals at risk for Alzheimer's dementia

Action: For adoption

6.1.3. Pan- fibroblast growth factor receptor inhibitor - EMEA-40-2016

Treatment of ureter and bladder carcinoma/ treatment of FGFR positive locally advanced inoperable or metastatic urothelial bladder cancer patients following platinum based chemotherapy

Action: For adoption

6.1.4. Phosphoinositide 3-kinase delta inhibitor - EMEA-41-2016

All classes of medicinal products for treatment of chronic obstructive pulmonary disease (COPD) (excluding chronic lung diseases associated with long-term airflow limitation, such as asthma, bronchopulmonary dysplasia, primary cilia dyskinesia, obstructive lung disease related to graft-versus -host disease after [bone-marrow] transplantation)

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. baricitinib - EMEA-001220-PIP01-11-M01

Eli Lilly & Company Limited; Treatment of adult patients with psoriatic arthritis (PsA), Treatment of adult patients with ankylosing spondyloarthritis (AxSPA)/Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis)

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

None

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

Action: For information

9.2.2. Report of the PDCO/PRAC joint Working Group

PDCO members: Dirk Mentzer; Sylvie Benchetrit

Action: For discussion

9.2.3. Report of the PDCO/PRAC joint Working Group

Action: For information

9.2.4. PDCO response to CHMP re Proposal for paediatric information for vancomycin medicinal products SmPC

PDCO member: Maria Fernandez Cortizo

Action: For adoption

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

9.3.1. Non-clinical Working Group: D30 Products identified

PDCO member: Jacqueline Carleer

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.3.3. Minutes of the PCWP/HCPWP joint meeting – 20 September 2016 (EMA/625038/2016)

Action: Document tabled for information

9.3.4. Extrapolation – Progress Update

PDCO member: Ine Rusten

Action: For information

9.4. Cooperation within the EU regulatory network

9.4.1. European Network of Paediatric Research (Enpr) – at European Medicines Agency (Enpr-EMA): Presentation of PRINTO by Nicolino Ruperto

Action: For discussion

9.4.2. Update on EDQM PaedForm project

PDCO Member: Siri Wang

Action: For information

9.5. Cooperation with International Regulators

9.5.1. PDCO response to public consultation on ICH S9 Questions and answers

PDCO Members: Jacqueline Carleer, Jaroslav Sterba

Action: For adoption

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 adoption

9.8. Planning and reporting

9.8.1. Strategic Review and Learning Meeting (SRLM) to be held in Tallinn on 4-6 October 2017

PDCO member: Jana Lass

Action: For information

10. Any other business

10.1.1. PEGylated products

PDCO member: Dirk Mentzer

Action: For information

10.1.2. Possible actions and initiatives – lessons learned on the Paediatric Regulation

Action: For information

11. Breakout sessions

11.1.1. Paediatric oncology

Action: For discussion on Wednesday, 19:00 - 19:30, room 3L

11.1.2. Neonatology

Action: For discussion on Tuesday, 19:00 - 19:30, room 2H

11.1.3. Inventory

Action: For discussion on tbd, room tbc

12. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

Paediatric investigation plan (PIP) (section 2.1 Opinion on PIPs and section 3.1 Discussions on PIPs)
A paediatric investigation plan (PIP) is a development plan aimed at ensuring that the necessary data are obtained through studies in children, when it is safe to do so, to support the authorisation of a medicine for children. Pharmaceutical companies submit proposals for PIPs to the European Medicines Agency's Paediatric Committee (PDCO). This Committee is responsible for agreeing or refusing the plan.

Compliance checks (section 2.2 Opinions on Compliance check, section 3.2 Discussions on Compliance check)
A compliance check may be necessary before any application for marketing authorisation (even for an adult indication) can be considered valid, if there was no deferral for at least one of the studies agreed in the PIP, or after the due date of initiation or completion of a study/measure. The same applies to some regulatory applications for authorised products, as described above.

Modification of an Agreed Paediatric Investigation Plan (section 2.3 Opinions on Modification of an agreed PIP, section 3.3 Discussions on Modification of an agreed PIP)
The development plan for a medicine can be modified at a later stage as knowledge increases. Modifications can also be made if the applicant encounters such difficulties with the implementation of a PIP, which render it unworkable or no longer appropriate.
In some cases, studies can be deferred until after the studies in adults have been conducted. This ensures that research in children is done only when it is safe and ethical to do so. Even when studies are deferred, the PIP will include details of the paediatric studies and their timelines.

Class waiver (section 6 Discussion on the applicability of class waiver)
As some diseases do not affect children (for example Parkinson's disease), the development of medicines for these diseases should not be performed in children. In these cases, a PIP is not required and it will be waived**.** For more information on the classes of diseases subject to waivers, see class waivers.

Annual reports on deferrals (section 8)
If the medicinal product is approved in the EU, annual reports on the deferred measures in the PIP must be submitted to the Agency.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/