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SCIENCE MEDICINES HEALTH

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Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 12-14 October 2016

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

12 October 2016, 08:30- 19:00, room 3A

13 October 2016, 08:30- 19:00, room 3A

14 October 2016, 08:30- 13:00, room 3A

Health and safety information

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

Disclaimers

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

Note on access to documents

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



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1. Introductions

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PDCO plenary session to be held 12-14 October 2016. See October 2016 PDCO minutes (to be published post November 2016 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 12-14 October 2016.

1.3. Adoption of the minutes

PDCO minutes for 17-19 October 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. Isopropyl Alcohol / Chlorhexidine Gluconate - EMEA-002011-PIP01-16

Prevention of infections associated with transcutaneous procedures

Day 60 opinion

Action: For adoption

2.1.2. Naldemedine Tosylate - EMEA-001893-PIP01-15

Opioid-induced constipation (OIC)

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

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

Treatment of congenital antithrombin deficiency, Treatment of acquired antithrombin deficiency (Preeclampsia), Treatment of acquired antithrombin deficiency (ECMO) /

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

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.4. [Recombinant Fusion Protein Linking Coagulation Factor VIIa with Albumin \(rVIIa-FP\) - Orphan - EMEA-001886-PIP01-15](#)

CSL Behring GmbH; Treatment of congenital Haemophilia A or B

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.5. [Recombinant Fusion Protein Linking Coagulation Factor VIIa with Albumin \(rVIIa-FP\) - Orphan - EMEA-001886-PIP02-15](#)

CSL Behring GmbH; Treatment of congenital Factor VII Deficiency

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.6. [Galcanezumab - EMEA-001860-PIP03-16](#)

Prophylactic treatment of migraine headache

Day 120 opinion

Action: For adoption

Neurology

2.1.7. [inebilizumab - EMEA-001911-PIP01-15](#)

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

Day 120 opinion

Action: For adoption

Neurology

2.1.8. [EMEA-001978-PIP01-16](#)

Hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.9. [Synthetic double-stranded siRNA oligonucleotide directed against p53 mRNA - Orphan - EMEA-001993-PIP01-16](#)

Quark Pharmaceuticals Inc.; Prevention of delayed graft function (DGF) after kidney transplantation / Prevention of DGF after transplantation of kidneys from deceased donors \geq 45 years old

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.10. [Terguride hydrogenmaleate - Orphan - EMEA-002015-PIP01-16](#)

medac Gesellschaft für klinische Spezialpräparate mbH; Treatment of Systemic scleroderma

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.11. [Teprotumumab - EMEA-001973-PIP01-16](#)

Active thyroid eye disease

Day 60 opinion

Action: For adoption

Ophthalmology

2.1.12. [EMEA-001742-PIP02-16](#)

prevention of psychosis / prevention of first episode of psychosis (FEP) in individuals with attenuated psychotic syndrome (APS)

Day 60 adoption

Action: For adoption

Psychiatry

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. Hydrocortisone - EMEA-C-001283-PIP01-12

DIURNAL LTD; Treatment of adrenocortical insufficiency

Day 30 adoption

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.2.2. dupilumab - EMEA-C1-001501-PIP01-13-M03

Regeneron Pharmaceuticals, Inc.; Treatment of atopic dermatitis

Day 60 opinion

Action: For adoption

Dermatology

2.2.3. Adalimumab - EMEA-C-000366-PIP05-12-M02

AbbVie Ltd; Treatment of non-infectious uveitis

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Ophthalmology / Dermatology /
Gastroenterology-Hepatology

2.2.4. 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-C2-001582-PIP01-13

Vertex Pharmaceuticals (Europe) Limited; Treatment of cystic fibrosis

Day 60 opinion

Action: For adoption

Other

2.2.5. eteplirsen - EMEA-C1-001722-PIP01-14-M01

Sarepta International C.V.; Treatment of Duchenne muscular dystrophy

Day 30 opinion

Action: For adoption

Neurology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. [ambrisentan - Orphan - EMEA-000434-PIP01-08-M04](#)

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

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. [Dobutamine - EMEA-001262-PIP01-12-M02](#)

Proveca Limited; Circulatory impairment / haemodynamic insufficiency

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.3. [Empagliflozin - EMEA-000828-PIP01-09-M05](#)

Boehringer Ingelheim International GmbH; Treatment of type 2 diabetes mellitus

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.4. [linagliptin \(as base\) - EMEA-000498-PIP01-08-M06](#)

Boehringer Ingelheim International GmbH; Type 2 Diabetes Mellitus / Type 2 Diabetes Mellitus

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.5. [migalstat hydrochloride - Orphan - EMEA-001194-PIP01-11-M02](#)

Amicus Therapeutics UK Ltd; Fabry disease

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.6. [Semaglutide - EMEA-001441-PIP01-13-M01](#)

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

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.7. Ceftobiprole medocaril sodium - EMEA-000205-PIP02-11-M02

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.8. daclatasvir - EMEA-001191-PIP01-11-M02

Bristol-Myers Squibb Pharma EEIG; Treatment of chronic viral hepatitis C / indicated in combination with sofosbuvir (SOF) for the treatment of CHC in children 3 years of age and older, and adolescents.

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.9. Eravacycline - EMEA-001555-PIP01-13-M02

Tetraphase Pharmaceuticals, Inc.; Complicated Intra-Abdominal Infection, Complicated Urinary Tract Infection / Complicated Intra-Abdominal Infection, Urinary Tract Infection

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.10. Telavancin hydrochloride - EMEA-000239-PIP01-08-M02

Clinigen Healthcare Ltd; Nosocomial Pneumonia (NP), Complicated skin and soft tissue infections (cSSTI) / Waiver, Nosocomial Pneumonia (NP)

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.11. Tenofovir alafenamide / Emtricitabine / Bictegravir - EMEA-001766-PIP01-15-M01

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

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.12. [tenofovir disoproxil / emtricitabine / cobicistat / elvitegravir - EMEA-000970-PIP01-10-M01](#)

Gilead Sciences International Ltd; B23 Human immunodeficiency virus disease [HIV] resulting in other conditions / indicated for the treatment of HIV-1 infection in paediatric patients aged 12 years and over

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.13. [Autologous haematopoietic stem cells transduced with lentiviral vector Lenti-D encoding the human ATP-binding cassette, sub-family D \(ALD\), member 1 \(ABCD1\) from cDNA - Orphan - EMEA-001244-PIP01-11-M01](#)

bluebird bio France; Treatment of adrenoleukodystrophy

Day 60 opinion

Action: For adoption

Neurology

2.3.14. [Delta-9-tetrahydrocannabinol / Cannabidiol - EMEA-000181-PIP01-08-M03](#)

GW Pharma Ltd; Spasticity / Intractable spasticity due to cerebral palsy or traumatic CNS injury

Day 60 opinion

Action: For adoption

Neurology

2.3.15. [Perampanel - EMEA-000467-PIP01-08-M08](#)

Eisai Europe Limited; Treatment of treatment-resistant epilepsies / Adjunctive therapy in patients with other paediatric epilepsies, Adjunctive therapy in patients with refractory partial onset seizures including secondarily generalised seizures

Day 60 opinion

Action: For adoption

Neurology

2.3.16. [Autologous T cells transduced with lentiviral vector containing a chimeric antigen receptor directed against CD19 - Orphan - EMEA-001654-PIP01-14-M01](#)

Novartis Europharm Limited; B cell acute lymphoblastic leukaemia (ALL) / Treatment of B cell acute lymphoblastic leukaemia (ALL) in paediatric patients who have relapsed after at least two prior regimens or are refractory

Day 60 opinion

Action: For adoption

Oncology

2.3.17. [Bosutinib - Orphan - EMEA-000727-PIP01-09-M02](#)

Pfizer Limited; CML / Treatment of CML in children and adolescents (from 1 to <18 years of age) with resistance or intolerance to prior TKI therapy

Day 60 opinion

Action: For adoption

Oncology

2.3.18. [Eribulin - EMEA-001261-PIP01-11-M03](#)

Eisai Europe Ltd; Soft Tissue Sarcoma / Treatment of non-Rhabdomyosarcoma soft tissue sarcoma, Treatment of Rhabdomyosarcoma

Day 60 opinion

Action: For adoption

Oncology

2.3.19. [pixantrone - EMEA-000713-PIP02-10-M04](#)

CTI Life Sciences Limited; ICD-09. C83 Diffuse Non-Hodgkin's Lymphoma (including C83.7 Burkitt Lymphoma, C83.5 Lymphoblastic Lymphoma, C83.3 Large-cell Lymphoma) / Treatment of Non-Hodgkin's Lymphoma

Day 60 opinion

Action: For adoption

Oncology

2.3.20. [Sunitinib - EMEA-000342-PIP01-08-M05](#)

Pfizer Limited; CD10 code C49.4 malignant neoplasms of connective and soft tissue of abdomen - gastro-intestinal stromal tumours (GIST) / Treatment of gastro-intestinal stromal tumour in paediatric patients aged 6 to less than 18

Day 60 opinion

Action: For adoption

Oncology

2.3.21. Inotuzumab ozogamicin - Orphan - EMEA-001429-PIP01-13-M01

Pfizer Limited; Treatment of Acute Lymphoblastic Leukaemia / For the treatment of relapsed or refractory B cell precursor Acute Lymphoblastic Leukaemia

Day 60 opinion

Action: For adoption

Oncology / Haematology-Hemostaseology

2.3.22. Bupropion HCl / Naltrexone HCl - EMEA-001373-PIP01-12-M02

Orexigen Therapeutics Ireland Limited; Treatment of obesity / Treatment of obesity

Day 60 opinion

Action: For adoption

Other

2.3.23. fentanyl hydrochloride - EMEA-001509-PIP01-13-M01

Incline Therapeutics Europe Ltd. (a wholly owned subsidiary of The Medicines Company); Treatment of acute pain

Day 60 opinion

Action: For adoption

Pain

2.3.24. 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 60 opinion

Action: For adoption

Pain

2.3.25. Tapentadol - EMEA-000018-PIP01-07-M12

Grünenthal GmbH; Acute pain / Treatment of acute pain

Day 60 opinion

Action: For adoption

Pain

2.3.26. Tapentadol - EMEA-000325-PIP01-08-M06

Grünenthal GmbH; Chronic pain / Treatment of chronic pain

Day 60 opinion

Action: For adoption

Pain

2.3.27. Loxapine - EMEA-001115-PIP01-10-M05

Ferrer Internacional, S.A.; Bipolar disorder, Schizophrenia / For rapid control of agitation in patients with schizophrenia, For rapid control of agitation in patients with bipolar disorder

Day 60 opinion

Action: For adoption

Psychiatry

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. Eculizumab - Orphan - EMEA-000876-PIP03-14

Alexion Europe SAS; Neuromyelitis Optica Spectrum Disorders / Treatment of Relapsing Neuromyelitis Optica Spectrum Disorders in the paediatric population

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.2. Octenidine dihydrochloride - Orphan - EMEA-001384-PIP01-12

Schülke & Mayr GmbH; Skin disinfection

Day 90 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.1.3. [synthetic surfactant protein B analogue / synthetic surfactant protein C analogue / 1-palmitoyl-2-oleoyl-sn-glycero-3-phosphoglycerol sodium salt / dipalmitoylphosphatidylcholine - Orphan - EMEA-001780-PIP01-15](#)

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

Day 90 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.1.4. [Galcanezumab - EMEA-001860-PIP04-16](#)

Prophylactic treatment of cluster headache

Day 90 discussion

Action: For discussion

Neurology

3.1.5. [Dexamethasone / Povidone-Iodine - EMEA-001936-PIP01-16](#)

Treatment of Infectious conjunctivitis (adenoviral and bacterial)

Day 90 discussion

Action: For discussion

Ophthalmology

Dermatology

3.1.6. [Macimorelin - EMEA-001988-PIP01-16](#)

Growth hormone deficiency / Diagnosis of growth hormone deficiency

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Diagnostic

3.1.7. [\(2R,3S\)-2-\(4-Cyclopentylaminophenyl\)-1-\(2-fluoro-6-methylbenzoyl\)piperidine-3-carboxylic acid\(4-methyl-3-trifluoromethylphenyl\)amide - Orphan - EMEA-002023-PIP01-16](#)

ChemoCentryx, Ltd.; Treatment of ANCA-associated vasculitis

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.8. [Atacicept - EMEA-002004-PIP01-16](#)

Treatment of systemic lupus erythematosus

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.9. [Recombinant humanised monoclonal antibody against human complement component C5a - EMEA-002009-PIP01-16](#)

Treatment of acute Graft-versus-Host Disease

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.10. [Edasalonexent \[N-\(2-\(\(4Z,7Z,10Z,13Z,16Z,19Z\)-docosa-4,7,10,13,16,19-hexaenamido\)ethyl\)-2-hydroxybenzamide\] - Orphan - EMEA-001960-PIP02-16](#)

Catabasis Pharmaceuticals Inc.; Duchenne Muscular Dystrophy / Treatment of Duchenne Muscular Dystrophy

Day 60 discussion

Action: For discussion

Neurology

3.1.11. [Daunorubicin \(liposomal combination\) / Cytarabine \(liposomal combination\) - Orphan - EMEA-001858-PIP02-16](#)

Celator (UK) Ltd; Acute myeloid leukemia

Day 60 discussion

Action: For discussion

Oncology

3.1.12. [lenadogene nolparvovec - Orphan - EMEA-001992-PIP02-16](#)

GENSIGHT-BIOLOGICS; Leber Hereditary Optic Neuropathy (LHON)

Day 60 discussion

Action: For discussion

Ophthalmology

3.1.13. Mexiletine hydrochloride - Orphan - EMEA-002012-PIP01-16

Lupin (Europe) Ltd.; Treatment of myotonic disorders / Symptomatic treatment of myotonic disorders

Day 60 discussion

Action: For discussion

Other

3.1.14. Betrixaban - EMEA-001834-PIP02-16

Prevention of venous thromboembolism / Adults and children

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.15. lauromacrogol 400 - EMEA-002026-PIP02-16

venous therapeutic procedures / sclerotherapy of varicose veins

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.16. Botulinum toxin, Type A - EMEA-002038-PIP01-16

Treatment of glabellar lines

Day 30 discussion

Action: For discussion

Dermatology

3.1.17. rAAV8-hUGT1A1 - Orphan - EMEA-002021-PIP01-16

GENETHON; Treatment of Crigler-Najjar syndrome / Treatment of Severe Crigler-Najjar syndrome requiring phototherapy

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.18. Filgotinib - EMEA-001619-PIP03-16

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

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.19. [Peramivir - EMEA-001856-PIP02-16](#)

Treatment of influenza / Treatment of influenza

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.20. [Methyl 3-\(\(2R\)-2-hydroxy-4-\(\(\(\(S\)-1-methoxy-1-oxopropan-2-yl\)amino\)\(phenoxy\)phosphoryl\)oxy\)-3,3-dimethylbutanamido\)propanoate - Orphan - EMEA-002036-PIP01-16](#)

Retrophin Europe Limited; Treatment of Pantothenate Kinase Associated Neurodegeneration (PKAN)

Day 30 discussion

Action: For discussion

Neurology

3.1.21. [Sarizotan hydrochloride - Orphan - EMEA-001808-PIP02-16](#)

Newron Pharmaceuticals SpA; Treatment of Rett syndrome

Day 30 discussion

Action: For discussion

Neurology

3.1.22. [nintedanib - Orphan - EMEA-001006-PIP03-16](#)

Boehringer Ingelheim International GmbH; Treatment of lung carcinoma (small cell and non-small cell carcinoma), Treatment of mesothelioma

Day 30 discussion

Action: For discussion

Oncology

3.1.23. [vemurafenib - EMEA-000978-PIP03-16](#)

Treatment of histiocytic disease

Day 30 discussion

Action: For discussion

Oncology

3.1.24. Netarsudil - EMEA-002037-PIP01-16

Open Angle Glaucoma / Ocular Hypertension

Day 30 discussion

Action: For discussion

Ophthalmology

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

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

Day 30 discussion

Action: For discussion

Other

3.1.26. palonosetron / fosnetupitant (netupitant prodrug) - EMEA-001198-PIP02-16

Chemotherapy-Induced Nausea and Vomiting

Day 30 discussion

Action: For discussion

Other

3.1.27. Ibuprofen - EMEA-002017-PIP01-16

Treatment of pain, Treatment of febrile disorders / Treatment of pain of non-serious arthritic conditions, Treatment of backache, Treatment of dental pain, Treatment of neuralgia, Treatment of headache, Treatment of rheumatic or muscular pain, Treatment of migraine, Treatment of dysmenorrhoea, Treatment of fever

Day 30 discussion

Action: For discussion

Other / Pain

3.1.28. pimavanserin - EMEA-001688-PIP03-16

Treatment of schizophrenia and other psychotic disorders

Day 30 discussion

Action: For discussion

Psychiatry

3.1.29. DNA plasmid encoding HPV type 18 consensus E6 and E7 proteins (pGX3002) / DNA plasmid encoding HPV type 16 consensus E6 and E7 proteins (pGX3001) - EMEA-002022-PIP01-16

Treatment of high grade squamous intraepithelial lesions (HSIL) of the cervix caused by HPV types 16 and 18

Day 30 discussion

Action: For discussion

Vaccines / Infectious Diseases

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. Gemtuzumab linked to Ozogamicin - EMEA-C1-001733-PIP02-15

Pfizer Limited; Treatment of acute myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.2.2. Benralizumab - EMEA-C1-001214-PIP01-11-M05

AstraZeneca AB; 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. sacubitril / valsartan - EMEA-000316-PIP02-11-M03

Novartis Europharm Ltd.; Heart failure / Treatment of heart failure

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. Allantoin - Orphan - EMEA-001590-PIP01-13-M03

Scioderm, Inc.; Treatment of epidermolysis bullosa

Day 30 discussion

Action: For discussion

Dermatology

3.3.3. Liquid extract ethanolic 30 per cent (w/w) of Allium cepa L. (fresh bulb) and Citrus limon (L.) Burm. f. (fresh fruit), Paullinia cupana Kunth, Theobroma cacao L. - EMEA-001835-PIP01-15-M01

Legacy Healthcare; Treatment of alopecia

Day 30 discussion

Action: For discussion

Dermatology

3.3.4. Rubidium Rb-82 Chloride - EMEA-000882-PIP03-11-M02

Jubilant DraxImage Inc.; Visualization of myocardial perfusion for diagnostic purposes

Day 30 discussion

Action: For discussion

Diagnostic

3.3.5. Estetrol & Drospirenone - EMEA-001332-PIP01-12-M02

Estetra SPRL; Prevention of pregnancy

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. deferiprone - Orphan - EMEA-001126-PIP01-10-M02

Conorzio per Valutazioni Biologiche e Farmacologiche (CVBF) - Coordinator for DEEP Project (HEALTH-F4-2010-261483); treatment of chronic iron overload requiring chelation therapy / treatment of iron overload in paediatric patients affected by haemoglobinopathies requiring chronic transfusions and iron chelation

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.7. Ceftaroline fosamil - EMEA-000769-PIP01-09-M06

AstraZeneca AB; Treatment of cSSTI (complicated skin and soft tissue infections), Treatment

of CAP (community-acquired pneumonia) / Treatment of cSSTI (complicated skin and soft tissue infections), Treatment of CAP (community-acquired pneumonia)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.8. Talimogene laherparepvec - EMEA-001251-PIP01-11-M02

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

Day 30 discussion

Action: For discussion

Oncology

3.3.9. Finerenone - EMEA-001623-PIP01-14-M01

Bayer Pharma AG; Chronic Kidney Disease / Treatment of chronic kidney disease associated with proteinuria in addition to a therapy with ACEi or ARB

Day 30 discussion

Action: For discussion

Uro-nephrology

4. Nominations

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

4.1. List of letters of intent received for submission of applications with start of procedure 3 January 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.

5.1.1. PDCO-SAWP interaction training session for PDCO members

Action: For 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. DNA plasmids encoding for HPV type 16 or 18 consensus E6 and E7 antigens - EMEA-28-2016

Treatment of high grade squamous intraepithelial lesions (HSIL) of the vulva caused by HPV types 16 and 18

Action: For adoption

6.1.2. Tremelimumab - EMEA-29-2016

Treatment of lung carcinoma (small cell and non-small cell carcinoma)/ 1) Tremelimumab in combination with durvalumab is indicated for the 1st line treatment of patients with locally advanced or metastatic NSCLC with tumours with no sensitizing EGFR mutation or ALK translocation; 2) Tremelimumab in combination with durvalumab is indicated for the treatment of patients with locally advanced or metastatic NSCLC which has progressed on or after platinum-based chemotherapy

Action: For adoption

6.1.3. Tremelimumab - EMEA-30-2016

Treatment of oropharyngeal, laryngeal or nasal epithelial carcinoma (excluding nasopharyngeal carcinoma or lympho-epithelioma) 1) Tremelimumab in combination with durvalumab is indicated for the 2nd line treatment for recurrent or metastatic squamous cell carcinoma of the head and neck, progressed during or after treatment with 1 platinum-based regimen; 2) Tremelimumab in combination with durvalumab is indicated for the 1st line treatment of recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck

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. Macitentan - EMEA-001032-PIP01-10-M02

Actelion Registration Ltd.; Treatment of idiopathic pulmonary fibrosis Treatment of pulmonary arterial hypertension/ Treatment of systemic sclerosis/Treatment of Eisenmenger's syndrome

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. Outline for Agenda of PDCO November 2016 meeting

PDCO Chair: Dirk Mentzer

Action: For information

9.1.2. Preparations for elections of PDCO Vice-chair

Action: For information

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 on CHMP approach for Extrapolation in Juvenile Idiopathic Arthritis (JIA), Inflammatory bowel disease (IBD) and Psoriasis

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. Report on the updated Paediatric Addendum to the guideline on acute heart failure (AHF)

Action: For information

9.4. Cooperation within the EU regulatory network

9.4.1. European Commission (EC) 10-year report on Paediatric Regulation

Action: For information

9.4.2. Questions of the PDCO for the Enpr-EMA networks to be invited at the November PDCO

PDCO member: Angelika Siapkara

Action: For information

9.5. Cooperation with International Regulators

None

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

None

9.7. PDCO work plan

9.7.1. PDCO Work Plan 2017

Action: For discussion

9.8. Planning and reporting

None

10. Any other business

10.1.1. Discussion on study design/endpoints in Pulmonary Arterial Hypertension (PAH)

Action: For discussion

10.1.2. Report on Workshop on extrapolation of efficacy and safety in medicine development across age groups

Action: For information

11. Breakout sessions

11.1.1. Paediatric oncology

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

11.1.2. Neonatology

Action: For discussion on Thursday, 18:00 - 18:30, room 3L

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/