17 March 2017
EMA/PDCO/146574/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 21-24 March 2017

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

21 March 2017, 14:00- 19:00, room 3A

22 March 2017, 08:30- 19:00, room 3A

23 March 2017, 08:30- 19:00, room 3A

24 March 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 21-24 March 2017. See March 21-24 PDCO minutes (to be published post April 2017 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 21-24 March 2017.

1.3. Adoption of the minutes

PDCO minutes for 21-24 February 2017.

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. Recombinant modified human growth hormone - Orphan - EMEA-001152-PIP02-16

Richardson Associates Regulatory Affairs Ltd; Growth hormone deficiency / Treatment of children with growth failure due to inadequate secretion of endogenous growth hormone

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.2. EMEA-001983-PIP01-16

Monitoring of renal function

Day 120 opinion

Action: For adoption

Diagnostic / Uro-nephrology

2.1.3. avacopan - Orphan - EMEA-002023-PIP01-16

ChemoCentryx, Ltd.; Treatment of ANCA-associated vasculitis

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.4. Indapamide / Ramipril - EMEA-002081-PIP01-16

Treatment of hypertension ICD10 I10-I15 / Treatment of hypertension as substitution therapy in adults whose blood pressure is adequately controlled by the use of ramipril and indapamide with the individual products given concurrently at the same dose level as in the combination, but as separate medicinal products, Treatment of hypertension in adults whose blood pressure is not adequately controlled by the use of ramipril monotherapy and for whom the use of the second medicinal product is an optimal therapeutic procedure.

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.5. Influenza virus surface antigens (haemagglutinin) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin) of strain A (H1N1) / Influenza virus surface antigens (haemagglutinin) of strain B (Victoria lineage) - EMEA-002027-PIP01-16

Prevention of Influenza infection

Day 60 opinion

Action: For adoption; Oral Explanation Meeting

Infectious Diseases

2.1.6. erdafitinib - EMEA-002042-PIP01-16

Treatment of Ureter and Bladder Carcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.7. 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 60 opinion

Action: For adoption

Oncology

2.1.8. Small interfering RNA targeting human TRPV1 - EMEA-002061-PIP01-16

Treatment of dry eye disease

Day 60 opinion

Action: For adoption

Ophthalmology

2.1.9. mepolizumab - Orphan - EMEA-000069-PIP05-16

GSK Trading Services Limited; Treatment of nasal polyposis / indicated for the add-on maintenance treatment of adult patients with severe bilateral nasal polyposis who have had prior nasal polyp surgery

Day 60 opinion

Action: For adoption

Pneumology - Allergology

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. darbepoetin alfa - EMEA-C-000329-PIP02-09-M05

Amgen Ltd.; Treatment of anaemia due to chronic disorders

Day 60 opinion

Action: For adoption

Oncology / Uro-nephrology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Dopamine hydrochloride - EMEA-001105-PIP01-10-M03

BrePco Biopharma Limited; Treatment of vascular hypotensive disorders / Treatment of hypotension in neonates including the extremely low gestational age newborn. Treatment of hypotension in infants and children

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. EMEA-001838-PIP01-15-M01

Janssen-Cilag International NV; Treatment of respiratory tract disease caused by human respiratory syncytial virus (RSV) / Treatment of respiratory tract disease caused by human RSV

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.3. doravirine - EMEA-001676-PIP01-14-M01

Merck Sharp & Dohme (Europe), Inc.; Treatment of human immunodeficiency virus-1 (HIV-1) infection / Antiretroviral therapy, in combination with other antiretroviral agents, for the treatment of HIV-1 infection in children aged from birth to 18 years

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.4. tenofovir disoproxil fumarate / lamivudine / doravirine - EMEA-001695-PIP01-14-M01

Merck Sharp & Dohme (Europe), Inc.; Treatment of human immunodeficiency virus-1 (HIV-1) infection / Antiretroviral combination therapy, for the treatment of HIV-1 infection in adults and children aged 2 to 18 years

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.5. ponatinib (as hydrochloride) - Orphan - EMEA-001186-PIP01-11-M01

Incyte Biosciences UK Ltd.; Treatment of Chronic myeloid leukaemia, Philadelphia chromosome positive acute lymphoblastic leukaemia / Paediatric population with Chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant or intolerant to at least one prior BCR-ABL TKI therapy; or who have the T315I mutation., Paediatric population with Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) who are resistant or intolerant to at least one prior BCR-ABL TKI therapy; or who have the T315I mutation

Day 60 opinion

Action: For adoption

Oncology

2.3.6. Febuxostat - EMEA-001417-PIP01-12-M02

Menarini International Operations Luxembourg S.A.; Prevention/treatment of hyperuricemia / Prevention or treatment of hyperuricemia in patients at intermediate or high risk of Tumor Lysis Sindrome (TLS) affected by hematologic malignancies

Day 60 opinion

Action: For adoption

Other / Oncology

2.3.7. Tapentadol - EMEA-000018-PIP01-07-M13

Grünenthal GmbH; Treatment of acute pain

Day 60 opinion

Action: For adoption

Pain

2.3.8. Melatonin - EMEA-000440-PIP02-11-M05 – opinion at day 30

RAD Neurim Pharmaceuticals EEC Ltd; Treatment of insomnia

Day 0 opinion

Action: For adoption

Neurology

2.4. Opinions on Re-examinations

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

Regeneron Pharmaceuticals, Inc; Treatment of Atopic Dermatitis

Day 30 opinion

Action: For adoption; Oral Explanation Meeting

Dermatology

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

Novartis Europharm Limited; Multiple Sclerosis

Day 30 opinion; Oral Explanation Meeting

Action: For adoption

Neurology

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. Expanded donor-derived allogenic T cells transduced with the retroviral vector expressing the transgenes for inducible caspase9 and the truncated CD19 selectable marker - Orphan - EMEA-001869-PIP01-15

Bellicum Pharma Ltd.; Treatment in haematopoietic stem cell transplantation / Treatment of immunodeficiency after mismatched, related, allogeneic transplantation in paediatric patients with malignant and non-malignant disorders amenable to haematopoietic stem cell transplantation

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.2. Rimiducid - Orphan - EMEA-001870-PIP01-15

Bellicum Pharma Ltd.; Treatment of Graft Versus Host Disease (ICD 279.50) / Treatment of graft versus host disease (GvHD) in paediatric patients who have received a mismatched, related, allogeneic haematopoietic stem cell transplantation together with rivogenlecleucel (expanded T lymphocytes transduced with a retroviral vector containing inducible caspase 9 and truncated CD19).

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.3. EMEA-001975-PIP01-16

Treatment of influenza

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.4. Cannabidiol - Orphan - EMEA-001964-PIP01-16

GW Research Ltd; Treatment of seizures associated with Tuberous Sclerosis Complex (TSC), Treatment of seizures associated with Dravet Syndrome (DS), Treatment of seizures associated with Infantile Spasms (IS), Treatment of seizures associated with Lennox-Gastaut Syndrome (LGS) / Treatment of seizures associated with Tuberous Sclerosis Complex (TSC), Treatment of seizures associated with Dravet Syndrome (DS), Treatment of seizures associated with Infantile Spasms (IS), Treatment of seizures associated with Lennox-Gastaut Syndrome (LGS)

Day 90 discussion

Action: For discussion

Neurology

3.1.5. Polihexanide - Orphan - EMEA-002053-PIP01-16

Società Industria Farmaceutica Italiana (S.I.F.I.) SpA; Treatment of keratitis and keratoconjunctivitis (interstitial) in acanthamoebiasis

Day 90 discussion

Action: For discussion

Ophthalmology

3.1.6. Chloroprocaine Hydrochloride - EMEA-000639-PIP03-16

Peripheral nerve block (local anesthesia by perineural injection)

Day 60 discussion

Action: For discussion

Anaesthesiology

3.1.7. Selonsertib - EMEA-001868-PIP03-16

Treatment of Non-Alcoholic Steatohepatitis (NASH) with moderate to severe fibrosis (F2-F4) in paediatric subjects, 8 to < 18 years of age

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.8. maribavir - Orphan - EMEA-000353-PIP02-16

Shire Pharmaceuticals Ireland Limited; Treatment of CMV infection / Treatment of CMV infection in transplant patients who are ≥2 to <18 years of age

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.9. allopregnanolone - EMEA-002051-PIP01-16

Treatment of Super Refractory Status Epilepticus

Day 60 discussion

Action: For discussion

Neurology

3.1.10. GIVINOSTAT - Orphan - EMEA-000551-PIP03-16

Italfarmaco S.p.A.; Treatment of Duchenne Muscular Dystrophy (DMD)

Day 60 discussion

Action: For discussion

Neurology

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

Kite Pharma EU B.V.; Treatment of B-precursor Acute Lymphoblastic Leukaemia (ALL)

Day 60 discussion

Action: For discussion

Oncology

3.1.12. Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta chimeric antigen receptor - Orphan - EMEA-002010-PIP01-16

Kite Pharma EU B.V.; Treatment of primary mediastinal B cell lymphoma (PMBCL), Treatment of follicular lymphoma (FL), Treatment of diffuse large B cell lymphoma (DLBCL)

Day 60 discussion

Action: For discussion

Oncology

3.1.13. Brimapitide - Orphan - EMEA-001926-PIP02-16

Auris Medical Ltd.; Treatment of Idiopathic Sudden Sensorineural Hearing Loss (ISSNHL)

Day 60 discussion

Action: For discussion

Oto-rhino-laryngology

3.1.14. EMEA-001815-PIP02-16

Treatment of grass pollen induced seasonal allergic rhinoconjunctivitis (SAR)

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.15. ivacaftor / tezacaftor - EMEA-002086-PIP01-16

Treatment of Cystic Fibrosis

Day 60 discussion

Action: For discussion

Pneumology – Allergology

3.1.16. Human normal immunoglobulin - EMEA-002084-PIP01-16

Primary Immunodeficiency Diseases

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.17. Human Normal Immunoglobulin for Intravenous Administration (IVIg) - EMEA-002092-PIP01-16

Treatment of primary immunodeficiency (PID), Treatment of idiopathic thrombocytopenic purpura (ITP) / Primary immunodeficiency syndromes with impaired antibody production, Primary immune thrombocytopenia (ITP), in patients at high risk of bleeding or prior to surgery to correct the platelet count

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.18. Ezetimibe / Rosuvastatin (calcium) - EMEA-002118-PIP01-17

Treatment of hypercholesterolaemia

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.19. Omega-3-carboxylic acids - EMEA-001865-PIP02-16

Treatment of hypertriglyceridaemia or mixed dyslipidaemia to reduce the risk of atherosclerotic cardiovascular disease (ACVD), Treatment of mixed dyslipidaemia with persistent hypertriglyceridaemia

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.20. lucerastat - Orphan - EMEA-002095-PIP01-16

Actelion Registration Ltd.; Treatment of Fabry disease

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.21. Iron hydroxyethyl amylopectin heptonate - EMEA-002094-PIP01-16

Treatment of iron deficiency anemia, Treatment of iron deficiency

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.22. Human anti-interferon gamma monoclonal antibody - Orphan - EMEA-002031-PIP01-16

Novimmune B.V; Treatment of histiocytosis haematophagic conditions

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.23. Nimodipine - Orphan - EMEA-002097-PIP01-16

Edge Therapeutics, Inc.; Treatment of aneurysmal subarchnoidal haemorrhage

Day 30 discussion

Action: For discussion

Neurology

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

Daiichi Sankyo Inc; Treatment of benign soft tissue neoplasms (except tenosynovial giant cell tumour); Treatment of tenosynovial giant cell tumour / Treatment of debilitating tenosynovial giant cell tumour, in paediatric patients from 6 to less than 18 years where there is no other acceptable treatment

Day 30 discussion

Action: For discussion

Oncology

3.1.25. 17α,21-dihydroxy-16α-methyl-pregna-1,4,9(11)-triene-3,20-dione - Orphan - EMEA-001794-PIP02-16

ReveraGen BioPharma Ltd; Treatment of duchenne muscular dystrophy / Treatment of duchenne muscular dystrophy

Day 30 discussion

Action: For discussion

Other

3.1.26. (S)-6-hydroxy-2,5,7,8-tetramethyl-N-((R)-piperidin-3-yl)chroman-2-carboxamide hydrochloride - Orphan - EMEA-002113-PIP01-16

Khondrion BV; Treatment of mitochondrial respiratory chain/oxidative phosphorylation defects

Day 30 discussion

Action: For discussion

Other

3.1.27. Bupivacaine - EMEA-000877-PIP02-16

postsurgical analgesia

Day 30 discussion

Action: For discussion

Pain

3.1.28. allopregnanolone - EMEA-002051-PIP02-16

Treatment of postpartum depression

Day 30 discussion

Action: For discussion

Psychiatry

3.1.29. Buprenorphine hydrochloride - EMEA-002099-PIP01-16

Treatment of opioid dependence

Day 30 discussion

Action: For discussion

Psychiatry

3.1.30. Soybean oil/Medium-chain triglycerides/Olive oil/Fish oil/Acetyl-cysteine/Alanine/Arginine/Glycine/Histidine/Isoleucin/Leucine/Lysine acetate/Methionine/Phenylalanine/Proline/Serine/Threonine/Tryptophan/Tyrosine/Valine/Glucose/Calcium chloride/Sodium glycerophosphate/Magnesium sulphate/Potassium chloride/Sodium acetate/Zinc sulphate/Malic acid - EMEA-002067-PIP02-17

Need for parenteral nutrition/Parenteral nutrition for adult cancer patients when oral or enteral nutrition is impossible, insufficient, or contraindicated

Day 30 discussion

Action: For discussion

Nutrition

3.1.31. calcifediol - EMEA-002093-PIP01-16

Treatment of secondary hyperparathyroidism (SHPT)

Day 30 discussion

Action: For discussion

Uro-nephrology

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. oxymetazoline hydrochloride / Tetracaine hydrochloride - EMEA-C-001764-PIP03-15

St. Renatus, LLC; Local anesthesia

Day 30 discussion

Action: For discussion

Anaesthesiology

3.2.2. Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with lentiviral vector that encodes for the human Wiskott Aldrich Syndrome (WAS) cDNA sequence - EMEA-C-001792-PIP01-15

GlaxoSmithKline Trading Services Ltd; Treatment of Wiskott Aldrich Syndrome

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.3. Certolizumab Pegol - EMEA-C1-001071-PIP03-14

UCB PHARMA S.A.; Treatment of Psoriasis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.2.4. EMEA-C1-001664-PIP02-15

Novartis Europharm Limited; Prevention of migraine headaches

Day 30 discussion

Action: For discussion

Neurology

3.2.5. AAV2-hRPE65v2; voretigene neparvovec - EMEA-C-001684-PIP01-14

Spark Therapeutics Inc.; Treatment of genetic congenital retinal disorders

Day 30 discussion

Action: For discussion

Ophthalmology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Rubidium Rb-82 Chloride - EMEA-000882-PIP03-11-M03

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

Day 30 discussion

Action: For discussion

3.3.2. Enalapril maleate - EMEA-001706-PIP01-14-M01

Ethicare GmbH; Treatment of Heart Failure / Heart failure

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.3. rivaroxaban - EMEA-000430-PIP01-08-M10

Bayer Pharma AG; Treatment of thromboembolic events, Prevention of thromboembolic events, Treatment (secondary prevention) of venous thromboembolism

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.4. Apremilast - EMEA-000715-PIP03-11-M04

Celgene Europe Limited; Treatment of psoriasis in children

Day 30 discussion

Action: For discussion

Dermatology

3.3.5. Telbivudine - EMEA-000065-PIP01-07-M05

Novartis Europharm Limited; Treatment of chronic hepatitis B / Treatment of children and adolescents from 2 to below 18 years of age with compensated HBeAg-positive or HBeAg-negative chronic hepatitis B

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.6. vedolizumab - EMEA-000645-PIP01-09-M05

Takeda Pharma A/S; Treatment of Ulcerative colitis, Treatment of Crohn's disease

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.7. turoctocog alfa pegol - Orphan - EMEA-001174-PIP02-12-M02

Novo Nordisk A/S; ICD10 - D66 - Hereditary factor VIII deficiency

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.8. Sirukumab - EMEA-001043-PIP01-10-M03

Janssen-Cilag International NV; Children:Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondyloarthritis, psoriatic arthritis and juvenile idiopathic arthritis) (ICD: M08), Adults: Rheumatoid Arthritis (ICD: M05) / N.A., Treatment of juvenile idiopathic arthritis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.9. bezlotoxumab - EMEA-001645-PIP01-14-M01

Merck Sharp & Dohme (Europe), Inc.; Treatment of Clostridium difficile infection / indicated for the prevention of recurrence of Clostridium difficile infection (CDI) in paediatric patients at high risk for recurrence of CDI

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.10. Isavuconazonium (sulfate) - Orphan - EMEA-001301-PIP02-12-M01

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.11. Laquinimod - EMEA-000972-PIP01-10-M05

Teva GmbH; Treatment of Multiple Sclerosis (MS) / Treatment of relapsing remitting multiple sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.3.12. olaratumab - Orphan - EMEA-001760-PIP01-15-M02

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

Day 30 discussion

Action: For discussion

Oncology

3.3.13. Human recombinant IgG1 monoclonal antibody targeting fibroblast growth factor 23 (FGF23) - Orphan - EMEA-001659-PIP01-15-M02

Ultragenyx Pharmaceutical Inc.; X-linked Hypophosphatemia

Day 30 discussion

Action: For discussion

Other

3.3.14. ivacaftor - Orphan - EMEA-000335-PIP01-08-M11

Vertex Pharmaceuticals (Europe) Limited; Treatment of Cystic Fibrosis

Day 30 discussion

Action: For discussion

Other

3.3.15. Tapentadol - EMEA-000325-PIP01-08-M07

Grünenthal GmbH; Treatment of chronic pain

Day 30 discussion

Action: For discussion

Pain

3.3.16. Mometasone furoate / Indacaterol acetate (dose expressed as free base) - EMEA-001217-PIP01-11-M03

NOVARTIS EUROPHARM LTD.; Treatment of 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 24 May 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. Melphalan flufenamide (melflufen) - EMEA-03-2017

The class of primarily alkylating medicinal products for treatment of myeloproliferative neoplasms and mature B, T and NK cell neoplasms/ Treatment of multiple myeloma

Action: For adoption

6.1.2. Veliparib - EMEA-04-2017

Treatment of lung carcinoma (small cell and non-small cell carcinoma)/ Veliparib in combination with carboplatin and paclitaxel for the treatment of adult patients with advanced or metastatic squamous non-small cell lung cancer (NSCLC); Veliparib in combination with carboplatin and paclitaxel for the treatment of adult patients with

advanced or metastatic non-squamous non-small cell lung cancer (NSCLC)

Action: For adoption

6.1.3. co-formulation of durvalumab and tremelimumab - EMEA-05-2017

Treatment of oropharyngeal, laryngeal or nasal epithelial carcinoma (excluding nasopharyngeal carcinoma or lympho-epithelioma)/ 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; 1st line treatment of recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck

Action: For adoption

6.1.4. co-formulation of durvalumab and tremelimumab - EMEA-06-2017

Treatment of ureter and bladder carcinoma/ first line treatment of patients with unresectable stage IV urothelial bladder cancer

Action: For adoption

6.1.5. co-formulation of durvalumab and tremelimumab - EMEA-07-2017

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

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

None

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. Joint CHMP-PDCO session

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. Respiratory Drafting Group letter to CHMP and PDCO - Request for advice on how to address issues related to therapeutic equivalence for orally inhaled products for children

PDCO member: Eva Agurell

Action: For adoption

9.4. Cooperation within the EU regulatory network

9.4.1. European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA): Interaction between CROs and networks

Action: For information

9.4.2. Paediatric Curriculum

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

None

9.8. Planning and reporting

9.8.1. Business Pipeline Report for the human scientific committees - Forecast for 2017 - Update Q1/2017

Action: For information

9.8.2. Strategic Review and Learning Meeting (SRLM) to be held in Malta on 10-11 April 2017

PDCO member: John Borg

Action: For information

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

PDCO member: Irja Lutsar / Jana Lass

Action: For discussion

10. Any other business

10.1.1. 'Early Notification System' (ENS) and PDCO

Action: For information

11. Breakout sessions

11.1.1. Paediatric oncology

Action: For discussion on Thursday, 14:00 – 15:00, room 3E

11.1.2. Neonatology

Action: For discussion on Tuesday, 14:00 – 15:00, room 3A

11.1.3. Inventory

Action: For discussion on Tuesday, 14:00 – 15:00, room 3J

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/