18 September 2018
EMA/PDCO/581674/2018 Corr.[1]
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 18-21 September 2018

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

18 September 2018, 14:00-19:00, room 3A

19 September 2018, 08:30- 19:00, room 3A

20 September 2018, 08:30- 19:00, room 3A

21 September 2018, 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).

[1] Correction under point 2.8.1

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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 18-21 September 2018. See September 2018 PDCO minutes (to be published post October 2018 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 18-21 September

1.3. Adoption of the minutes

PDCO minutes for 21-24 August 2018

2. Opinions

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

2.1. Opinions on Products

2.2. 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. Human normal immunoglobulin - EMEA-C-001797-PIP01-15-M01

Octapharma Pharmazeutika Produktionsges.m.b.H; Treatment of primary immunodeficiency

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology

2.2.2. Ranibizumab - EMEA-C1-000527-PIP04-13-M01

Novartis Europharm Limited; Treatment of retinopathy of prematurity

Day 60 letter

Action: For adoption

Ophthalmology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

No items.

2.4. Opinions on Re-examinations

2.4.1. Alicaforsen - Orphan - EMEA-002060-PIP02-17

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

Action: For adoption

Gastroenterology-Hepatology

2.4.2. Tenofovir alafenamide / emtricitabine / cobicistat / darunavir - EMEA-001825-PIP01-15-M02

Janssen-Cilag International NV; Treatment of human immunodeficiency virus type-1 (HIV-1) infection / Treatment of HIV-1 infection in paediatric subjects weighing 25 kg or more above 6 years of age

Action: For adoption

Infectious Diseases

2.5. Opinions on Review of Granted Waivers

2.5.1. Clostridium botulinum neurotoxin type A (150 kD), free from complexing proteins- EMEA-001039-PIP03-17

Merz Pharmaceuticals GmbH; Treatment of hemifacial spasm

Day 30 adoption

Action: For adoption

Neurology / Ophtamology

2.6. Finalisation and adoption of opinions

No items.

2.7. Partial Compliance Checks completed by EMA

For the following partial compliance checks, no need to refer them to PDCO Committee for

discussion, were identified by the PME coordinator and PDCO Rapporteur. The PDCO has been informed in writing.

2.7.1. Tenofovir - EMEA-C4-000533-PIP01-08-M07

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

Day 30 adoption

Action: For information

Infectious Diseases

2.8. Revision of the PDCO opinions

2.8.1. Telisotuzumab vedotin - EMEA-002361-PIP01-18

Lung carcinoma (small cell and non-small cell carcinoma)

Action: For information

Oncology

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. Small molecule Janus Kinase -1 inhibitor - EMEA-002312-PIP01-17

Moderate to severe atopic dermatitis

Day 90 discussion

Action: For discussion

Dermatology

3.1.2. Cenicriviroc - EMEA-001999-PIP02-17

NASH with Stage 2-3 fibrosis

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.3. Human monoclonal IgG1 antibody against Tissue Factor Pathway Inhibitor - Orphan - EMEA-002285-PIP01-17

Pfizer Limited; Treatment of haemophilia B, Treatment of haemophilia A

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.4. Upadacitinib Hemihydrate - EMEA-001741-PIP04-17

Treatment of Atopic Dermatitis

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Dermatology

3.1.5. Brincidofovir - Orphan - EMEA-001904-PIP02-17

Chimerix UK Limited; Treatment of AdV in immunocompromised patients

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.6. Brincidofovir - Orphan - EMEA-001904-PIP03-18

Chimerix UK Limited; Treatment of smallpox

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.7. Eubacterial Spores, Purified Suspension, Encapsulated - EMEA-001970-PIP02-17

To reduce recurrence of Clostridium difficile infection (CDI) in paediatric patients who have received antibacterial drug treatment for recurrent CDI.

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.8. Evobrutinib - EMEA-002284-PIP01-17

Treatment of multiple sclerosis

Day 90 discussion

Action: For discussion

Neurology

3.1.9. Brigatinib - EMEA-002296-PIP01-17

Inflammatory Myofibroblastic Tumors (IMT), Non-small cell lung cancer (NSCLC), Anaplastic large cell lymphoma (ALCL) / Treatment of anaplastic lymphoma kinase (ALK) positive advanced non-small cell lung cancer (NSCLC)., Treatment of paediatric patients ≥1 years of age with ALK+ unresectable or recurrent IMT., Treatment in combination with standard chemotherapy in paediatric patients ≥1 years of age with newly diagnosed ALK+ ALCL at high risk for recurrence.

Day 90 discussion

Action: For discussion

Oncology

3.1.10. Calcifediol - EMEA-002093-PIP02-17

Secondary hyperparathyroidism (SHPT) / treatment of secondary hyperparathyroidism (SHPT) in non-dialysis chronic kidney disease (ND-CKD) patients with low serum 25-hydroxyvitamin D levels

Day 90 discussion

Action: For discussion

Uro-nephrology

3.1.11. Remimazolam (as besylate) - EMEA-001880-PIP01-18

Anaesthetic and allied procedures / ICU sedation, General anaesthesia, Procedural sedation

Day 30 discussion

Action: For discussion

Anaesthesiology

3.1.12. Ezetimibe / atorvastatin - EMEA-002410-PIP01-18

Treatment of hypercholesterolaemia

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.13. Flurpiridaz F18 - EMEA-002413-PIP01-18

Coronary artery disease

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.14. Glycopyrronium bromide - EMEA-002383-PIP01-18

Treatment of primary axillary hyperhidrosis

Day 30 discussion

Action: For discussion

Dermatology

3.1.15. Oxalobacter formigenes Strain HC-1 - Orphan - EMEA-000370-PIP02-18

OxThera AB; Treatment of Primary Hyperoxaluria

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology

3.1.16. Dusquetide - EMEA-002306-PIP02-18

Treatment of Severe Oral Mucositis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.17. Adeno-associated viral vector serotype 5 containing a B domain deleted variant of human coagulation factor VIII gene - Orphan - EMEA-002427-PIP01-18

BioMarin International Limited; Treatment of patients with haemophilia A

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.18. Allogeneic CD34+ umbilical cord blood cells cultured ex vivo with Notch ligand Delta1 - Orphan - EMEA-002271-PIP01-17

Nohla Therapeutics, Inc.; Haematopoietic Stem Cell Transplantation (HSCT) / Patients with

high risk haematologic malignancies undergoing myeloablative cord blood transplant (CBT)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.19. C1-esterase inhibitor human - Orphan - EMEA-002316-PIP02-18

CSL Behring GmbH; Treatment of antibody mediated rejection (AMR) in kidney transplantation

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.20. Ixekizumab - EMEA-001050-PIP02-18

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis) / Children with juvenile idiopathic arthritis subtypes of enthesitis-related arthritis (including JoAS) and juvenile psoriatic arthritis.

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.21. Sarilumab - EMEA-001045-PIP04-18

Muscular auto-immune disorder

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.22. Inolimomab - Orphan - EMEA-002372-PIP01-18

ElsaLys Biotech SA; Acute Graft versus Host Disease following heamatopoietic stem cell transplantation

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Oncology / Haematology-Hemostaseology

3.1.23. Entacapone / carbidopa monohydrate / levodopa - EMEA-002421-PIP01-18

Treatment of Parkinson's disease and parkinsonism

Day 30 discussion

Action: For discussion

Neurology

3.1.24. Ganaxolone - EMEA-002341-PIP01-18

Cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder / Adjunctive treatment of seizures in paediatric patients aged 2 to < 18 years old with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder

Day 30 discussion

Action: For discussion

Neurology

3.1.25. Alectinib hydrochloride - EMEA-002431-PIP01-18

Treatment of non-small cell lung cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.26. Avadomide - Orphan - EMEA-002405-PIP01-18

Celgene Europe Limited; Treatment of mature B-cell neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.1.27. Crizotinib - EMEA-001493-PIP02-18

Treatment of lung malignant neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.1.28. Humanized IgG1 monoclonal antibody against GD2 (hu3F8) - EMEA-002346-PIP01-18

Treatment of neuroblastoma

Day 30 discussion

Action: For discussion

Oncology

3.1.29. Ipatasertib - EMEA-002396-PIP01-18

Treatment of prostate cancer, Treatment of breast cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.30. Molibresib - EMEA-002406-PIP01-18

Malignant neoplasm of breast / Oestrogen receptor-positive breast cancer (ER+BC)

Day 30 discussion

Action: For discussion

Oncology

3.1.31. Pemigatinib - EMEA-002370-PIP01-18

Treatment of urothelial carcinoma, Treatment of cholangiocarcinoma

Day 30 discussion

Action: For discussion

Oncology

3.1.32. Aflibercept - EMEA-000236-PIP05-18

Retinopathy of prematurity (ROP) / Aflibercept is indicated for the treatment of retinopathy of prematurity (ROP)

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.33. lentiviral vector containing the human ABCA4 gene for treatment of Stargardt's disease - Orphan - EMEA-002407-PIP01-18

Genzyme Europe B.V.; Treatment of inherited retinal disorders

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.34. Triheptanoin - Orphan - EMEA-001920-PIP03-18

Ultragenyx Pharmaceutical Inc.; Glucose Transporter Type-1 Deficiency Syndrome

Day 30 discussion

Action: For discussion

Other

3.1.35. Ibuprofen - EMEA-002400-PIP01-18

Short-term symptomatic treatment of pain

Day 30 discussion

Action: For discussion

Pain

3.1.36. A fully human, IgG2 mAb - EMEA-002433-PIP01-18

Treatment of severe asthma in patients 6 year-olds and above as an add-on therapy of standard of care

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.37. Dapagliflozin - EMEA-000694-PIP04-18

N18 Chronic Kidney Disease

Day 30 discussion

Action: For discussion

Uro-nephrology

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

Prevention of influenza infection

Day 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. Glycerol Phenylbutyrate - EMEA-C-000297-PIP02-12-M02

Horizon Pharma Ireland Limited; Treatment of Urea Cycle Disorders

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.2. Lubiprostone - EMEA-C4-000245-PIP01-08-M05

Sucampo AG; Treatment of Constipation

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.2.3. Ceftaroline fosamil - EMEA-C2-000769-PIP01-09-M08

Pfizer Limited; Treatment of complicated skin and soft tissue infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.4. Paclitaxel - EMEA-C-001308-PIP01-12-M02

Celgene Europe Ltd; Treatment of solid malignant tumours

Day 30 discussion

Action: For discussion

Oncology

3.2.5. Gilteritinib - EMEA-C1-002064-PIP01-16

Astellas Pharma Europe B.V.; Treatment of acute myeloid leukemia

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Enalapril maleate - EMEA-001706-PIP01-14-M02

Ethicare GmbH; Treatment of Heart Failure

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. Tadalafil - EMEA-000452-PIP02-10-M05

Eli Lilly and Company Ltd; Benign prostatic hyperplasia , Pulmonary arterial hypertension / Treatment of Persistent Pulmonary Hypertension of the Newborn, Treatment of Pulmonary Arterial Hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.3. Dabigatran etexilate mesilate - EMEA-000081-PIP01-07-M11

Boehringer Ingelheim International GmbH; Treatment of thromboembolic events, Prevention of thomboembolic events / Treatment of venous thromboembolic events in paediatric patients (secondary venous thrombotic event prevention)

Day 30 discussion

Action: For discussion

Cardiovascular Diseases / Haematology-Hemostaseology

3.3.4. Edoxaban (tosylate) - EMEA-000788-PIP02-11-M08

Daiichi Sankyo Europe GmbH; Prevention of arterial thromboembolism, Prevention of venous thromboembolism, Treatment of venous thromboembolism / Prevention of arterial thromboembolism in paediatric cardiac patients at risk of thrombotic events, Acute treatment & secondary prevention of symptomatic recurrent venous thrombotic events (VTE) in paediatric patients at risk

Day 30 discussion

Action: For discussion

Cardiovascular Diseases / Haematology-Hemostaseology

3.3.5. Certolizumab pegol - EMEA-001071-PIP03-14-M01

UCB Pharma SA; Treatment of psoriasis / Moderate to severe chronic plaque psoriasis

Day 30 discussion

Action: For discussion

Dermatology

3.3.6. Lixisenatide - EMEA-000916-PIP01-10-M06

Sanofi-aventis R&D; Treatment of type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.7. Migalstat hydrochloride - Orphan - EMEA-001194-PIP01-11-M03

Amicus Therapeutics UK Limited; Fabry Disease

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.8. Tolvaptan - EMEA-001231-PIP02-13-M06

Otsuka Pharmaceutical Europe Ltd.; Polycystic Kidney Disease (PKD) / Treatment of progression of ADPKD

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology

3.3.9. Apremilast - EMEA-000715-PIP05-13-M03

Celgene Europe Limited; Treatment of Behçet's Disease / Treatment of oral ulcers associated with Behçet's Disease in children and adolescents from the age of 6 to less than 18 years

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.10. Autologous CD34+ haematopoietic stem cells transduced ex vivo with EFS lentiviral vector encoding for the human ADA gene - Orphan - EMEA-001974-PIP01-16-M02

Orchard Therapeutics Limited; Treatment of severe combined immunodeficiency due to adenosine deaminase deficiency (ADA-SCID)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.11. Filgotinib - EMEA-001619-PIP04-17-M01

Gilead Sciences International Ltd.; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis, and juvenile idiopathic arthritis) / Treatment of juvenile idiopathic arthritis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.12. Ixekizumab - EMEA-001050-PIP01-10-M04

Eli Lilly & Company Limited; Plaque psoriasis / Treatment of severe chronic plaque psoriasis in paediatric patients from the age of 6 years who are not adequately controlled by topical therapies

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.13. Secukinumab - EMEA-000380-PIP02-09-M04

Novartis Europharm Limited; Chronic Idiopathic Arthritis / Treatment of juvenile psoriatic arthritis, Treatment of enthesitis-related arthritis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.14. Avibactam / ceftazidime - EMEA-001313-PIP01-12-M08

Pfizer Limited; Treatment of bacterial infections / For the treatment of complicated urinary tract infections, For the treatment of complicated intra-abdominal infections, For the treatment of pneumonia, For the treatment of infections due to aerobic Gram-negative organisms

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.15. Letermovir - Orphan - EMEA-001631-PIP01-14-M03

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

3.3.16. Amikacin sulfate - Orphan - EMEA-000525-PIP01-08-M06

Insmed Limited; Treatment of Pseudomonas aeruginosa lung infection/colonisation in cystic fibrosis patients, Treatment of nontubercolous mycobacterial (NTM) lung infection

Day 30 discussion

Action: For discussion

Infectious Diseases / Pneumology - Allergology

3.3.17. Nanobody directed towards the fusion protein of human respiratory syncytial virus - EMEA-001553-PIP01-13-M02

Ablynx NV; Treatment of RSV lower respiratory tract infection

Day 30 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.3.18. D-Sorbitol / Naltrexone HCl / (RS)-Bacoflen - Orphan - EMEA-002164-PIP01-17-M01

Pharnext SA; Treatment of Charcot-Marie-Tooth Type 1A in symptomatic paediatric patients

Day 30 discussion

Action: For discussion

Neurology

3.3.19. Eculizumab - Orphan - EMEA-000876-PIP03-14-M02

Alexion Europe SAS; Neuromyelitis optica spectrum disorders / Treatment of paediatric patients with relapsing neuromyelitis optica spectrum disorders

Day 30 discussion

Action: For discussion

Neurology

3.3.20. Lasmiditan - EMEA-002166-PIP01-17-M01

Eli Lilly and Company Limited; Migraine with and without aura

Day 30 discussion

Action: For discussion

Neurology

3.3.21. Risdiplam - EMEA-002070-PIP01-16-M02

Roche Registration GmbH; Treatment of spinal muscular atrophy

Day 30 discussion

Action: For discussion

Neurology

3.3.22. Daunorubicin (liposomal formulation) / cytarabine (liposomal formulation) - Orphan - EMEA-001858-PIP02-16-M02

JAZZ PHARMACEUTICALS IRELAND LIMITED; acute myeloid leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.3.23. Idasanutlin - Orphan - EMEA-001489-PIP01-13-M01

Roche Registration GmbH; Treatment of acute myeloid leukaemia, Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoietic and lymphoid tissue), Treatment of acute lymphoblastic leukaemia / Treatment of children with first relapse of, or with frontline-refractory acute myeloid leukaemia, Treatment of children with first relapse of, or with frontline-refractory acute lymphoblastic leukaemia, Treatment of children with a solid malignant tumour which is newly-diagnosed and metastatic, or refractory to first-line treatment

Day 30 discussion

Action: For discussion

Oncology

3.3.24. Idelalisib - EMEA-001350-PIP02-13-M04

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

Day 30 discussion

Action: For discussion

Oncology

3.3.25. Ixazomib - Orphan - EMEA-001410-PIP02-17-M01

Takeda Pharm A/S; Treatment of Acute Lymphoblastic Leukaemia (ALL), Treatment of Multiple Myeloma (MM) / Treatment of adult patients with Newly Diagnosed Multiple Myeloma (NDMM), Treatment of paediatric patients diagnosed with relapsed precursor B-ALL or T-ALL

Day 30 discussion

Action: For discussion

Oncology

3.3.26. Lenvatinib - Orphan - EMEA-001119-PIP02-12-M04

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

3.3.27. Dexamethasone / Povidone-Iodine - EMEA-001936-PIP01-16-M01

Shire Pharmaceuticals Ireland Ltd; Treatment of Infectious conjunctivitis (adenoviral and bacterial)

Day 30 discussion

Action: For discussion

Ophthalmology

3.3.28. Ex vivo expanded autologous human corneal epithelium cells containing stem cells - Orphan - EMEA-001082-PIP02-11-M02

Chiesi Farmaceutici S.p.A.; Limbal stem cell deficiency due to ocular burns

Day 30 discussion

Action: For discussion

Ophthalmology

3.3.29. Ketorolac trometamol / phenylephrine hydrochloride - EMEA-001256-PIP02-12-M02

Omeros Corporation; Lens therapeutic procedure

Day 30 discussion

Action: For discussion

Ophthalmology

3.3.30. Conestat alfa - EMEA-000367-PIP01-08-M08

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

Day 30 discussion

Action: For discussion

Other

3.3.31. Ivacaftor - Orphan - EMEA-000335-PIP01-08-M13

Vertex Pharmaceuticals (Europe) Limited; Treatment of Cystic Fibrosis

Day 30 discussion

Action: For discussion

Other

3.3.32. Palonosetron / fosnetupitant - EMEA-001198-PIP03-17-M01

Helsinn Birex Pharmaceuticals Limited; Prevention of Chemotherapy-Induced Nausea and Vomiting

Day 30 discussion

Action: For discussion

Other

3.3.33. Aluminium hydroxide adsorbed, de-pigmented glutaraldehyde polymerised, allergen extract of Betula alba pollen (birch pollen) - EMEA-000630-PIP02-09-M04

LETI Pharma GmbH; 30.1 Allergic rhinitis due to pollen, J30.2 Other seasonal allergic rhinitis, J30.3 Other allergic rhinitis, J30.4 Allergic rhinitis, unspecified H10.1 Acute allergic conjunctivitis / Treatment of patients with allergic rhinoconjunctivitis with or without intermittent allergic asthma due to sensitisation against tree pollens (Betula alba family), Treatment of patients with allergic rhinitis with or without intermittent allergic asthma due to sensitisation against tree pollens (Betula alba family)

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.34. Aluminium hydroxide adsorbed, depigmented glutaraldehyde polymerised, allergen extracts of birch, alder and hazel pollen - EMEA-000662-PIP02-09-M04

LETI Pharma GmbH; J 30.1 Allergic rhinitis due to pollen J 30.2 Other seasonal allergic rhinitis J 30.03 Other allergic rhinitis J 30.4 Allergic rhinitis, unspecified H10.1 Acute allergic conjunctivitis / Treatment of patients with allergic rhinitis with or without intermittent allergic

asthma due to sensitisation against tree pollens (Betula alba family), Treatment of patients with allergic rhino-conjunctivitis with or without intermittent allergic asthma due to sensitisation against tree pollens (Betula alba family)

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.35. Peanut Allergen Extract - EMEA-001481-PIP01-13-M03

DBV Technologies S.A; peanut allergy

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.36. Peanut flour - EMEA-001734-PIP01-14-M03

Aimmune Therapeutics Inc; Peanut Allergy / Peanut oral immunotherapy for the reduction in clinical reactivity to accidental exposure in peanut children and adults

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.37. Tezepelumab - EMEA-001613-PIP01-14-M02

AstraZeneca AB; Treatment of asthma / Tezepelumab is indicated as add-on maintenance treatment of patients with severe asthma aged 5 years and older.

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.38. Potassium hydrogen carbonate / Potassium citrate monohydrated - Orphan - EMEA-001357-PIP01-12-M02

Advicenne Pharma; treatment of renal tubular acidosis

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3.39. Cholera vaccine, live attenuated, oral (Strain CVD 103-HgR) - EMEA-001490-PIP01-13-M01

PaxVax Netherlands B.V.; Prevention of disease caused by V. cholerae serogroup O1

Day 30 discussion

Action: For discussion

Vaccines

3.3.40. 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-001715-PIP01-14-M01

Seqirus Netherlands B.V.; Prevention of influenza

Day 30 discussion

Action: For discussion

Vaccines

3.3.41. 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-M02

Seqirus UK Limited; Prevention of influenza

Day 30 discussion

Action: For discussion

Vaccines

3.3.42. Pneumococcal Polysaccharide Serotype 33F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 23F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 22F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 19A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 18C – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 14 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 9V – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 7F – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6B – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 6A – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 5 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 4 – Diphtheria CRM197 Conjugate / Pneumococcal Polysaccharide Serotype 3 – Diphtheria CRM197 Conjugate /

Merck Sharp & Dohme (Europe), Inc.; Prevention of disease caused by Streptococcus pneumoniae / Active immunisation for the prevention of invasive disease, pneumonia and acute otitis media caused by Streptococcus pneumoniae in infants, children and adolescents from 6 weeks to less than 18 years of age.

Day 30 discussion

Action: For discussion

Vaccines

4. Nominations

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

4.1. List of letters of intent received for submission of applications with start of procedure 04 December 2018 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. Duvelisib - EMEA-15-2018

Verastem Inc; The class of primarily alkylating medicinal products for treatment of myeloproliferative neoplasms and mature B, T and NK cell neoplasms/ 1) Treatment of chronic lymphocytic leukaemia / small lymphocytic lymphoma, including patients with 17p deletion, who have received at least one prior therapy; 2) Treatment of follicular B cell non-Hodgkin lymphoma who have received at least two prior therapies

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. Octenidine dihydrochloride - EMEA-001384-PIP02-17

Schülke & Mayr GmbH; Prevention of oral soft tissue infections

Proposed indication: for temporary reduction of bacterial count in the oral cavity, for inhibition of plaque formation, in cases of insufficient oral hygiene capacity

Action: For adoption

7.1.2. Fully human monoclonal antibody (mAb) directed against the human PD-1 receptor - EMEA-002007-PIP02-17

Regeneron Ireland U.C.; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue)

Proposed indication: indicated as the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-small cell lung cancer, in patients whose tumors express PD-L1 ⩾ 50% of tumor cells; Cemiplimab in combination with ipilimumab and/or platinum-based doublet chemotherapy/ipilimumab, is indicated as the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-small cell lung cancer, in patients whose tumors express PD-L1 ⩾50% of tumor cell; Cemiplimab, in combination with platinum-based doublet chemotherapy and/or ipilimumab/platinum-based doublet chemotherapy, is indicated as the first-line treatment of unresectable, locally advanced, recurrent or metastatic non-small cell lung cancer, in patients whose tumors express PD-L1 <50% of tumor cell

Action: For adoption

8. Annual reports on deferrals

Note: The annual reports on deferrals to be noted by the members of the PDCO are flagged in

the Annex B.

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

No items

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

Action: For information

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

9.3.1. Non-clinical Working Group: D30 Products identified

PDCO member: Karen van Malderen

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.3.3. Request for advice to CHMP and PDCO on orally inhaled products for children

Action: For information

9.4. Cooperation within the EU regulatory network

9.4.1. European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA)

Action: For information

9.5. Cooperation with International Regulators

No items

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

No items

9.7. PDCO work plan

No items

9.8. Planning and reporting

No items

10. Any other business

10.1.1. Regulatory Science Engagement Plan to 2025

Action: For information

10.1.2. EC/EMA action plan to further improve the implementation of the Paediatric Regulation

Scope: Outcomes and action plan

Action: for adoption

10.1.3. Paediatric addendum to anti-cancer guideline: proposal for way forward

Action: for information

10.1.4. Report from the paediatric strategy forum for medicinal product development of checkpoint inhibitors for use in combination therapy in paediatric patients

Action: for information

11. Breakout sessions

11.1.1. Paediatric oncology

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

11.1.2. Neonatology

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

11.1.3. Inventory

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

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/