12 November 2019
EMA/578675/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 12-15 November 2019

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

12 November 2019, 14:00- 19:00, room 2D

13 November 2019, 08:30- 19:00, room 2D

14 November 2019, 08:30- 19:00, room 2D

15 November 2019, 08:30- 13:00, room 2D

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 12-15 November 2019. See 12-15 November 2019 PDCO minutes (to be published post 9-11 December 2019).

1.2. Adoption of agenda

PDCO agenda for 12-15 November 2019.

1.3. Adoption of the minutes

PDCO minutes for 15-18 October 2019.

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. Aztreonam / avibactam - EMEA-002283-PIP01-17

Infections caused by Gram-negative bacteria, including those that produce metallo-β-lactamases, for which there are limited or no treatment options / For the treatment of complicated urinary tract infections / For the treatment of ventilator associated pneumonia / For the treatment of complicated intra-abdominal infections / For the treatment of hospital-acquired pneumonia

Day 120 Opinion

Action: For adoption

Infectious Diseases

2.1.2. Abemaciclib - EMEA-002342-PIP02-18

High grade glioma (HGG), neuroblastoma (NBL) / Treatment of relapsed or refractory neuroblastoma in combination with irinotecan and temozolomide in paediatric patients / Treatment of newly diagnosed high grade glioma in combination with temozolomide in paediatric patients

Day 120 Opinion

Action: For adoption

Oncology

2.1.3. Chloroprocaine - EMEA-000639-PIP04-19

Epidural block (extension of epidural anaesthesia in unplanned caesarean section)

Day 60 Opinion

Action: For adoption

Anaesthesiology

2.1.4. Chloroprocaine - EMEA-000639-PIP05-19

Ocular surface anaesthesia

Day 60 Opinion

Action: For adoption

Anaesthesiology

2.1.5. Ethanol - EMEA-002672-PIP01-19

Treatment of primary hypertension

Day 60 Opinion

Action: For adoption

Cardiovascular Diseases

2.1.6. Masitinib mesilate - Orphan - EMEA-001266-PIP04-19

AB Science; Treatment of amyotrophic lateral sclerosis

Day 60 Opinion

Action: For adoption

Neurology

2.1.7. EMEA-001862-PIP02-19

Treatment of mantle cell lymphoma

Day 60 Opinion

Action: For adoption

Oncology

2.1.8. Iberdomide - EMEA-002636-PIP01-19

Treatment of mature B-cell neoplasms

Day 60 Opinion

Action: For adoption

Oncology

2.1.9. Sacituzumab govitecan - EMEA-002645-PIP01-19

Refractory/relapsed triple-negative breast cancer (TNBC)

Day 60 Opinion

Action: For adoption

Oncology

2.1.10. EMEA-002606-PIP02-19

Treatment of multiple myeloma

Day 60 Opinion

Action: For adoption

Oncology / Haematology-Hemostaseology

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. Valoctocogene roxaparvovec - EMEA-C1-002427-PIP01-18

BioMarin International Ltd.; Treatment of congenital haemophilia A

Day 60 letter

Action: For adoption

Haematology-Hemostaseology

2.2.2. Baloxavir marboxil - EMEA-C1-002440-PIP01-18

Roche Registration GmbH; Treatment of influenza

Day 60 letter

Action: For adoption

Infectious Diseases

2.2.3. Lasmiditan - EMEA-C1-002166-PIP01-17-M02

Eli Lilly and Company Limited; Treatment of migraine headache

Day 60 letter

Action: For adoption

Neurology

2.2.4. Ragweed pollen extract (ambrosia artemisiifolia) - EMEA-C-001881-PIP01-15

ALK Abelló A/S; Treatment of allergic rhinitis / Rhino-conjunctivitis

Day 60 Opinion

Action: For adoption

Pneumology - Allergology

2.2.5. Potassium hydrogen carbonate / Potassium citrate monohydrated - EMEA-C-001357-PIP01-12-M02

ADVICENNE; Treatment of renal tubular acidosis

Day 60 Opinion

Action: For adoption

Uro-nephrology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Edoxaban (tosylate) - EMEA-000788-PIP02-11-M09

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 60 Opinion

Action: For adoption

Cardiovascular Diseases / Haematology-Hemostaseology

2.3.2. Small molecule Janus Kinase -1 inhibitor - EMEA-002312-PIP01-17-M01

Pfizer Europe MA EEIG; Moderate to severe atopic dermatitis

Day 60 Opinion

Action: For adoption

Dermatology

2.3.3. Exenatide - EMEA-000689-PIP01-09-M09

AstraZeneca AB; Non-insulin dependent diabetes mellitus (excluding treatment with thiazolidinediones) / Non-insulin dependent diabetes mellitus (treatment including thiazolidinediones) / Non-insulin dependent diabetes mellitus - in combination with insulin (with or without oral antidiabetics) / Treatment of type 2 diabetes mellitus

Day 60 Opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.4. Tolvaptan - EMEA-001231-PIP02-13-M07

Otsuka Pharmaceutical Netherlands B.V.; Polycystic kidney disease (PKD) /Treatment of progression of autosomal dominant polycystic kidney disease (ADPKD)

Day 60 Opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology

2.3.5. Ozanimod hydrochloride - EMEA-001710-PIP03-17-M01

Celgene Europe B.V.; Treatment of ulcerative colitis / Treatment of moderate to severely active ulcerative colitis

Day 60 Opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.6. Autologous CD34+ haematopoietic stem cells transduced with lentiviral vector encoding the human betaA-T87Q-globin gene - Orphan - EMEA-001665-PIP01-14-M03

bluebird bio (Netherlands) B.V.; Treatment of β-thalassaemia / Treatment of beta-thalassaemia major and severe intermedia

Day 60 Opinion

Action: For adoption

Haematology-Hemostaseology

2.3.7. Human Cell Line recombinant human factor VIII (human-cl rhFVIII) / Human coagulation factor VIII (rDNA) - EMEA-001024-PIP01-10-M02

Octapharma Pharmazeutika Produktionsges.m.b.H; D66: Hereditary factor VIII deficiency, haemophilia A / Haemophilia A

Day 60 Opinion

Action: For adoption

Haematology-Hemostaseology

2.3.8. Luspatercept - Orphan - EMEA-001521-PIP01-13-M04

Celgene Europe B.V.; Anaemias due to chronic disorders / Treatment of anaemia in patients with beta-thalassemia intermedia and major

Day 60 Opinion

Action: For adoption

Haematology-Hemostaseology

2.3.9. Belimumab - EMEA-000520-PIP02-13-M03

Glaxo Group Limited; Systemic lupus erythematosus / Treatment of systemic lupus erythematosus

Day 60 Opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.10. Voxilaprevir / velpatasvir / sofosbuvir - EMEA-001822-PIP01-15-M01

Gilead Sciences Ireland UC; Treatment of chronic hepatitis C / Treatment of chronic hepatitis C in adolescents and children 12 years of age and older

Day 60 Opinion

Action: For adoption

Infectious Diseases

2.3.11. Daclizumab - EMEA-001349-PIP01-12-M03

Biogen Idec Ltd; Multiple sclerosis / Treatment of relapsing remitting forms of multiple

sclerosis

Day 60 Opinion

Action: For adoption

Neurology

2.3.12. Avapritinib - Orphan - EMEA-002358-PIP02-18-M01

Blueprint Medicines (Netherlands) B.V.; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms) / Treatment of paediatric patients from 2 to less than 18 years of age with relapsed/refractory solid tumour harbouring mutations in either KIT or PDGFR-alpha.

Day 60 Opinion

Action: For adoption

Oncology

2.3.13. Brigatinib - EMEA-002296-PIP01-17-M01

Takeda Pharm A/S; 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 60 Opinion

Action: For adoption

Oncology

2.3.14. Lumacaftor / ivacaftor - EMEA-001582-PIP01-13-M09

Vertex Pharmaceuticals (Europe) Ltd; Cystic fibrosis / Treatment of cystic fibrosis

Day 60 Opinion

Action: For adoption

Other

2.3.15. Dupilumab - EMEA-001501-PIP02-13-M04

sanofi-aventis recherche & développement; Treatment of asthma

Day 60 Opinion

Action: For adoption

Pneumology - Allergology

2.3.16. Tezepelumab - EMEA-001613-PIP01-14-M04

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

Day 60 Opinion

Action: For adoption

Pneumology - Allergology

2.3.17. Agomelatine - EMEA-001181-PIP01-11-M05

Les Laboratoires Servier; Major depressive episodes

Day 60 Opinion

Action: For adoption

Psychiatry

2.3.18. Daprodustat - EMEA-001452-PIP01-13-M02

GlaxoSmithKline Trading Services Limited; Treatment of anaemia associated with chronic renal disease

Day 60 Opinion

Action: For adoption

Uro-nephrology / Haematology-Hemostaseology

2.4. Opinions on Re-examinations

No items

2.5. Opinions on Review of Granted Waivers

No items

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. Acalabrutinib - EMEA-C1-001796-PIP03-16-M01

Acerta Pharma B.V.; indicated for the treatment of adult patients with chronic lymphocytic leukaemia (CLL)/small lymphocytic lymphoma (SLL) / Treatment of children from 1 year to less than 18 years of age with newly-diagnosed and relapsed/refractory mature B-cell lymphoma, diffuse large B-cell lymphoma or Burkitt lymphoma or primary mediastinal lymphoma

Day 1 letter

Action: For information

Oncology

2.8. Revision of PDCO Opinions

No items

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. Asciminib hydrochloride - EMEA-002347-PIP01-18

Treatment of Philadelphia positive chronic myelogenous leukemia in chronic phase

Day 90 discussion

Action: For discussion

3.1.2. EMEA-002568-PIP01-19

Psoriasis / Treatment of moderate to severe chronic plaque-type psoriasis who are candidates for systemic therapy

Day 90 discussion

Action: For discussion

Dermatology

3.1.3. Dupilumab - EMEA-001501-PIP04-19

Treatment of eosinophilic esophagitis

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.4. Norursodeoxycholic acid - Orphan - EMEA-002485-PIP01-18

Dr. Falk Pharma GmbH; Primary sclerosing cholangitis (PSC)

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.5. EMEA-002501-PIP01-18

Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital FVIII deficiency)

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.6. Anti-CD7 mAb conjugated to ricin toxin A chain / anti-CD3 mAb conjugated to ricin toxin A chain - Orphan - EMEA-002087-PIP01-16

Xenikos BV; Steroid Refractory acute Graft versus Host Disease

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.7. Mecasermin rinfabate - Orphan - EMEA-000534-PIP03-17

Premacure AB, a member of the Shire group of companies; Chronic lung disease of prematurity

Day 90 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.1.8. Atogepant - EMEA-002530-PIP01-18

G43 Migraine / Prophylaxis of migraine

Day 90 discussion

Action: For discussion

Pain

3.1.9. (R)-1-(3-(aminomethyl) phenyl)-N-(5-((3 cyanophenyl)(cyclopropylmethylamino)methyl)-2-fluorophenyl)-3-(trifluoromethyl)-1H-pyrazole-5-carboxamide dihydrochloride - Orphan - EMEA-002449-PIP02-18

BioCryst UK; Treatment of Hereditary Angioedema (HAE)/ Treatment of HAE attacks /Prevention of HAE attacks

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.10. EMEA-002484-PIP01-18

Asthma / Use as an add-on controller medication in the treatment of adults, adolescents and children (>1 year of age) with inadequately controlled asthma

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.11. EMEA-002515-PIP01-18

Treatment of asthma / Add-on therapy for the maintenance treatment for moderate-severe asthma

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.12. Budesonide - Orphan - EMEA-002500-PIP01-18

Calliditas Therapeutics AB; Primary IgA nephropathy

Day 90 discussion

Action: For discussion

Uro-nephrology

3.1.13. Bis-choline tetrathiomolybdate - Orphan - EMEA-002232-PIP02-19

Alexion Europe S.A.S.; Wilson disease

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.14. Pegfilgrastim - EMEA-002671-PIP01-19

Treatment of chemotherapy-induced neutropenia and prevention of chemotherapy-induced febrile neutropenia / Reduction in the duration of neutropenia and the incidence of febrile neutropenia in paediatric patients treated with cytotoxic chemotherapy for malignancy (with the exception of chronic myeloid leukaemia and myelodysplastic syndromes)

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.15. Taniborbactam / cefepime - EMEA-002576-PIP01-19

Treatment of bacterial infections / Treatment of complicated urinary tract infections (cUTI) / Treatment of hospital acquired and ventilator acquired pneumonia (HAP/VAP) / Treatment of complicated intra-abdominal infections (CIAI)

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.16. Rozanolixizumab - Orphan - EMEA-002681-PIP01-19

UCB Pharma S.A.; Treatment of myasthenia gravis

Day 60 discussion

Action: For discussion

Neurology

3.1.17. EMEA-002635-PIP01-19

Treatment of advanced or metastatic malignancies harbouring anaplastic lymphoma kinase ALK, ROS1, or NTRK1-3 alterations

Day 60 discussion

Action: For discussion

Oncology

3.1.18. Cyclophosphamide - EMEA-002644-PIP01-19

Treatment of malignant disease / Cyclophosphamide is a cytotoxic drug for the treatment of malignant disease in children. As a single agent, it has successfully produced an objective remission in a wide range of malignant conditions / Cyclophosphamide is also frequently used in combination with other cytotoxic drugs, radiotherapy or surgery.

Day 60 discussion

Action: For discussion

Oncology

3.1.19. Imatinib - EMEA-002643-PIP01-19

Treatment of newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy/Treatment of Chronic myelogenous leukaemia: Philadelphia chromosome (Ph1) positive with crisis of blast cells / Paediatric patients with newly diagnosed Philadelphia chromosome (bcr-abl) positive (Ph+) chronic myeloid leukaemia (CML) for whom bone marrow transplantation is not considered as the first line of treatment /Paediatric patients with Ph+ CML in chronic phase after failure of interferon-alpha therapy or in accelerated phase or blast crisis /Paediatric patients with newly diagnosed Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) integrated with chemotherapy

Day 60 discussion

Action: For discussion

Oncology

3.1.20. Lenvatinib - EMEA-001119-PIP03-19

Treatment of all conditions included in the category of malignant neoplasms except haematopoietic and lymphoid tissue

Day 60 discussion

Action: For discussion

Oncology

3.1.21. EMEA-002656-PIP01-19

Chikungunya disease

Day 60 discussion

Action: For discussion

Vaccines

3.1.22. EMEA-002657-PIP01-19

Visualisation of prostate-specific membrane antigen in adenocarcinoma of the prostate

Day 30 discussion

Action: For discussion

Diagnostic

3.1.23. EMEA-002682-PIP01-19

Acromegaly and gigantism

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.24. Rebisufligene etisparvovec - Orphan - EMEA-002206-PIP02-19

Abeona Therapeutics Inc.; Treatment of Mucopolysaccharidosis IIIA (ICD-10 E76.2) / Treatment of mucopolysaccharidosis type IIIA (Sanfilippo A syndrome) in children from 6 months to less than 18 years of age

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.25. Naltrexone - EMEA-002670-PIP01-19

Treatment of Crohn's disease / Treatment of moderate to severe active Crohn's disease as an adjuvant therapy in paediatric patients (from 6 years of age)

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.26. Fidanacogene elaparvovec - Orphan - EMEA-002362-PIP02-19

Pfizer Europe MA EEIG; Treatment of congenital factor IX deficiency (haemophilia B) / Prophylaxis of haemophilia B (congenital factor IX deficiency)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.27. Evobrutinib - EMEA-002284-PIP02-19

Treatment of systemic lupus erythematosus

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.28. Ritonavir / darunavir - EMEA-002537-PIP02-19

Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.29. Tecovirimat monohydrate - Orphan - EMEA-001205-PIP02-19

SIGA Technologies, Inc.; Orthopoxvirus disease (smallpox, monkeypox, cowpox, and vaccinia complications)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.30. Glibenclamide - EMEA-002651-PIP01-19

Large hemispheric infarction

Day 30 discussion

Action: For discussion

Neurology

3.1.31. Hyoscine / physostigmine - EMEA-002678-PIP01-19

Poisoning by nervous system stimulants

Day 30 discussion

Action: For discussion

Neurology

3.1.32. EMEA-002679-PIP01-19

Prostate cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.33. EMEA-002650-PIP01-19

Multiple myeloma

Day 30 discussion

Action: For discussion

Oncology

3.1.34. Loncastuximab tesirine - EMEA-002665-PIP01-19

Treatment of diffuse large B-cell lymphoma (DLBCL)

Day 30 discussion

Action: For discussion

Oncology

3.1.35. 1-[(3S)-3-{4-amino-3-[(3,5-dimethoxyphenyl)ethynyl]-1H-pyrazolo[3,4-d]pyrimidin-1-yl}pyrrolidin-1-yl]-2-propen-1-one - Orphan - EMEA-002647-PIP01-19

Taiho Pharma Europe Lt; Biliary Tract Cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.36. Ripasudil - EMEA-002676-PIP01-19

Treatment of corneal dystrophy

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.37. EMEA-002658-PIP01-19

Treatment of uveal melanoma

Day 30 discussion

Action: For discussion

Ophthalmology / Oncology

3.1.38. 1-(2,2-diphenyltetrahydrofuran-3-yl)-n,n-dimethylmethanamine hydrochloride - Orphan - EMEA-002688-PIP01-19

Anavex Germany GmbH; Rett syndrome

Day 30 discussion

Action: For discussion

Other

3.1.39. Benzocaine - EMEA-002654-PIP02-19

Sore throat

Day 30 discussion

Action: For discussion

Oto-rhino-laryngology

3.1.40. Fasinumab - EMEA-002059-PIP02-19

Chronic pain /Chronic musculoskeletal pain /Chronic non-musculoskeletal pain / Treatment of chronic cancer pain in a palliative care setting / Treatment of moderate to severe chronic pain associated with osteoarthritis (OA) of the knee or hip in patients who achieve an inadequate response to or are intolerant to currently available analgesics (Adults only)

Day 30 discussion

Action: For discussion

Pain

3.1.41. Sodium alginate oligosaccharide - Orphan - EMEA-002321-PIP01-17

AlgiPharma AS; Symptomatic treatment of cystic fibrosis

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.42. Levocetirizine / montelukast - EMEA-002646-PIP01-19

Allergic rhinitis

Day 30 discussion

Action: For discussion

Pneumology - Allergology / Oto-rhino-laryngology

3.1.43. EMEA-002653-PIP01-19

Treatment of schizophrenia / Treatment of cognitive impairment associated with schizophrenia in patients 13 to <18 years of age

Day 30 discussion

Action: For discussion

Psychiatry

3.1.44. Canakinumab - EMEA-000060-PIP08-19

Treatment of lung carcinoma

Day 30 discussion

Action: For discussion

Oncology

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. Tralokinumab - EMEA-C1-001900-PIP02-17-M02

LEO Pharma A/S; Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.2.2. Nonacog beta pegol (glycopegylated recombinant coagulation factor IX) - EMEA-C-000731-PIP01-09-M03

Novo Nordisk A/S; Treatment of factor IX deficiency

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.2.3. Fostemsavir - EMEA-C1-001687-PIP01-14-M03

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.4. Lacosamide - EMEA-C1-000402-PIP03-17-M03

UCB Pharma S.A.; Treatment of generalised epilepsy and epileptic syndromes

Day 30 discussion

Action: For discussion

Neurology

3.2.5. Selumetinib - EMEA-C1-001585-PIP01-13-M03

AstraZeneca AB; Treatment of neurofibromatosis type 1

Day 30 discussion

Action: For discussion

Oncology

3.2.6. Vosoritide - EMEA-C2-002033-PIP01-16

BioMarin International Limited; Treatment of achondroplasia

Day 30 discussion

Action: For discussion

Other

3.2.7. Outer membrane vesicles (OMV) from neisseria meningitidis serogroup B strain NZ98/254 measured as amount of total protein containing the PorA P1.4 / Recombinant neisseria meningitidis serogroup B NadA protein / Recombinant neisseria meningitidis serogroup B fHBP fusion protein / Recombinant neisseria meningitidis serogroup B NHBA fusion protein - EMEA-C-000139-PIP01-07-M03

GSK Vaccines S.r.l.; Prevention of meningococcal meningitis

Day 30 discussion

Action: For discussion

Vaccines

3.2.8. Ad26.ZEBOV (recombinant, replication-incompetent) - EMEA-C1-002307-PIP01-17

Janssen-Cilag International NV; Prevention of Ebola virus disease / Active immunization for prevention of disease caused by Ebola virus (Zaire ebolavirus species) in individuals ⩾1 year of age

Day 30 discussion

Action: For discussion

Vaccines

3.2.9. MVA-BN-Filo (recombinant, non-replicating) - EMEA-C1-002308-PIP01-17

Janssen-Cilag International NV; Prevention of Ebola virus disease / Active immunization for prevention of disease caused by Ebola virus (Zaire ebolavirus species) in individuals ⩾1 year of age

Day 30 discussion

Action: For discussion

Vaccines – Infectious disease

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Zoledronic acid - EMEA-000057-PIP01-07-M07

Novartis Europharm Limited; Osteoporosis / Glucocorticoid-induced osteoporosis

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.2. Albutrepenonacog alfa - Orphan - EMEA-001107-PIP01-10-M04

CSL Behring GmbH; Haemophilia B / Treatment of hereditary factor IX deficiency

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.3. Alemtuzumab - EMEA-001072-PIP01-10-M03

Genzyme Europe B.V.; Multiple sclerosis / For paediatric patients with relapsing remitting multiple sclerosis (RRMS) with active disease on prior disease modifying treatment (DMT) defined by clinical or imaging features

Day 30 discussion

Action: For discussion

Neurology

3.3.4. Cannabidiol - Orphan - EMEA-001964-PIP01-16-M01

GW Pharma (International) B.V.; Lennox Gastaut Syndrome / Dravet syndrome / Tuberous Sclerosis Complex / Infantile Spasms / Treatment of seizures

Day 30 discussion

Action: For discussion

Neurology

3.3.5. Lenvatinib - EMEA-001119-PIP02-12-M06

Eisai GmbH; 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

3.3.6. Lipegfilgrastim - EMEA-001019-PIP01-10-M05

UAB ”Sicor Biotech“; Treatment of chemotherapy-induced neutropenia / Prevention of chemotherapy-induced febrile neutropenia

Day 30 discussion

Action: For discussion

Oncology

3.3.7. Nivolumab - EMEA-001407-PIP01-12-M02

Bristol-Myers Squibb Pharma EEIG; Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoietic and lymphoid tissue) / Treatment of patients with unresectable or metastatic melanoma in the age group from 12 to less than 18 years old / Treatment of a paediatric malignant solid tumour in paediatric patients from 6 months to less than 18 years old.

Day 30 discussion

Action: For discussion

Oncology

3.3.8. Nivolumab - EMEA-001407-PIP02-15-M03

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

Day 30 discussion

Action: For discussion

Oncology

3.3.9. Palonosetron / fosnetupitant - EMEA-001198-PIP03-17-M03

Helsinn Birex Pharmaceuticals Limited; Prevention of chemotherapy-induced nausea and vomiting

Day 30 discussion

Action: For discussion

Other

3.3.10. Vamorolone - Orphan - EMEA-001794-PIP02-16-M02

ReveraGen BioPharma Ltd.; Treatment of Duchenne muscular dystrophy

Day 30 discussion

Action: For discussion

Other

3.3.11. Vosoritide - Orphan - EMEA-002033-PIP01-16-M01

BioMarin International Limited; Treatment of achondroplasia

Day 30 discussion

Action: For discussion

Other

3.3.12. Bupivacaine - EMEA-000877-PIP03-17-M01

Pacira Ltd; Postsurgical analgesia

Day 30 discussion

Action: For discussion

Pain

3.3.13. Benralizumab - EMEA-001214-PIP01-11-M09

AstraZeneca AB; Asthma / Treatment of asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.14. Vilanterol trifenatate / Umeclidinium bromide / Fluticasone furoate - EMEA-002153-PIP01-17-M01

GlaxoSmithKline Trading Services Limited; ICD-10 J45.5x severe persistent asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.15. 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-M03

Seqirus Netherlands B.V.; Influenza / Prevention of influenza

Day 30 discussion

Action: For discussion

Vaccines

3.3.16. (RS)-baclofen/ natrexone HCI /D-sorbitol - EMEA-002164-PIP01-17-M02

Pharnext S.A.; Treatment of Charcot-Marie-Tooth type 1A in symptomatic paediatric patients / Treatment of Charcot-Marie-Tooth disease type 1A in adults and paediatric patients

Day 30 discussion

Action: For discussion

Neurology

3.3.17. Lumasiran sodium - Orphan - EMEA-002079-PIP01-16-M01

Alnylam UK Limited; Treatment of primary hyperoxaluria Type 1

Day 60 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 6 January 2020 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. New Scientific Advice

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

5.2. Ongoing Scientific Advice

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

5.3. Final Scientific Advice (Reports and Scientific Advice letters)

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. Brimonidine - EMEA-15-2019

Allergan Pharmaceuticals International Limited; All classes of medicinal products for treatment of age-related macular degeneration and diabetic macular oedema/ treatment of geographic atrophy secondary to age-related macular degeneration

Action: For adoption

6.1.2. Acetylcysteine - EMEA-17-2019

Zambon S.p.A.; All classes of medicinal products for treatment of chronic obstructive pulmonary disease (COPD) (excluding chronic lung diseases associated with long-term airflow limitation, such as asthma, bronchopulmonary dysplasia, primary cilia dyskinesia, obstructive lung disease related to graft-versus-host disease after [bone-marrow] transplantation/ maintenance treatment in moderate COPD in adult patients

Action: For adoption

7. Discussion on the inclusion of an indication within a condition in an agreed PIP/waiver

No items

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

9.2.2. Committee for Advanced Therapies

Action: For information

9.2.3. Pharmacovigilance Risk Assessment Committee (PRAC) – PRAC recommendation - signal of serious exacerbation of infections with ibuprofen – List of Questions to PDCO

Action: For discussion

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. Extrapolation: extrapolation guidance template

Action: For adoption

9.3.4. Meeting summary of the Healthcare Professionals Working Party (HCPWP) and Patients and Consumers Working Party (PCWP) – Joint Meeting - 25 September 2019

Action: For information

9.3.5. Draft Agenda for the Annual Healthcare Professionals Working Party (HCPWP) and Patients and Consumers Working Party (PCWP) meeting with all eligible organisations - 20 November 2019

Action: For information

9.3.6. Meeting Summary of Patients and Consumers Working Party (PCWP) 24 September 2019

Action: For information

9.3.7. Meeting Summary of Healthcare Professionals Working Party (HCPWP) 24 September 2019

Action: For information

9.4. Cooperation within the EU regulatory network

9.4.1. Draft recommendations from the joint EMA-HMA Big Data Taskforce

Action: For information

9.5. Cooperation with International Regulators

9.5.1. Report from the Paediatric Cluster Teleconference

Action: For information

9.5.2. ICH E11A – Clinical Trials in Paediatric Population - Briefing ahead of face-to-face to meeting in Singapore

Action: For information

9.5.3. Report from the pan-European Paediatric Formulary (PaedForm) project - EDQM

Action: For information

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

9.7.1. PDCO Work Plan 2020

PDCO Chair: Koenraad Norga;

Action: For discussion

9.8. Planning and reporting

No items

10. Any other business

10.1.1. Future-proofing EMA

Action: For information

10.1.2. Procedural improvement of PIP compliance checks

Action: For adoption

11. Breakout sessions

11.1.1. Paediatric oncology

Action: For discussion on Tuesday, 18:00 - 19:00, room 0-F

11.1.2. Neonatology

Action: For discussion on Wednesday, 07:30 - 08:30, room 0-E

11.1.3. Inventory

Action: For discussion on Tuesday, 18:00 - 19:00, room 0-E

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/