



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 October 2019
EMA/PDCO/523933/2019
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft agenda for the meeting on 15-18 October 2019

Chair: Koenraad Norga – Vice-Chair: to be elected

15 October 2019, 14:00- 17:00, room 2D

16 October 2019, 08:30- 19:00, room 2D

17 October 2019, 08:30- 19:00, room 2D

18 October 2019, 08:30- 13:00, room 2D

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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 15-18 October 2019. See 15-18 October 2019 PDCO minutes (to be published post 12-15 November 2019 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 15-18 October 2019

1.3. Adoption of the minutes

PDCO minutes for 17-20 September 2019

2. Opinions

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. Remimazolam - EMEA-001880-PIP02-19

Sedation during medical procedures / General anaesthesia and post-operative sedation up to 24h / Sedation in the intensive care unit (ICU) / Sedation for short procedures

Day 120 Opinion

Action: For discussion

Anaesthesiology

2.1.2. Ralinepag - Orphan - EMEA-002432-PIP01-18

United Therapeutics Corporation; Treatment of pulmonary arterial hypertension / Treatment of pulmonary arterial hypertension WHO Group I to improve exercise capacity and to delay clinical worsening

Day 120 Opinion

Action: For adoption

Cardiovascular Diseases

2.1.3. Narsoplimab - Orphan - EMEA-002479-PIP01-18

Omeros London Limited; Treatment in haematopoietic stem cell transplantation / Treatment of haematopoietic stem cell transplant associated thrombotic microangiopathy (HSCT-TMA)

Day 120 Opinion

Action: For adoption

Haematology-Hemostaseology

2.1.4. Artesunate - Orphan - EMEA-002402-PIP02-18

ACE Pharmaceuticals BV; Plasmodia infections / Treatment of severe malaria caused by plasmodium falciparum in children aged 1 month to 18 years

Day 120 Opinion

Action: For adoption

Infectious Diseases

2.1.5. Iclaprim - EMEA-002391-PIP02-19

Infection with gram-positive bacteria

Day 120 Opinion

Action: For adoption

Infectious Diseases

2.1.6. Hydrocortisone - EMEA-002305-PIP01-17

Prevention of bronchopulmonary dysplasia

Day 120 Opinion

Action: For adoption

Neonatology - Paediatric Intensive Care

2.1.7. Ganaxolone - EMEA-002341-PIP01-18

Cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder / Adjunctive treatment of seizures in paediatric patients aged 6 months to < 18 years old with cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder

Day 120 Opinion

Action: For adoption

Neurology

2.1.8. Padsevonil - EMEA-002466-PIP01-18

Treatment of focal-onset seizures (FOS) in patients with epilepsy / Treatment of FOS in adults and paediatric patients (≥ 1 month to < 18 years of age) with epilepsy

Day 120 Opinion

Action: For adoption

Neurology

2.1.9. Phenobarbital - EMEA-002532-PIP01-18

Epilepsy

Day 120 Opinion

Action: For adoption

Neurology

2.1.10. Recombinant human arylsulfatase A (rhASA) - Orphan - EMEA-002050-PIP01-16

Shire Pharmaceuticals Ireland Limited; Treatment of metachromatic leukodystrophy (MLD)

Day 120 Opinion

Action: For adoption

Neurology

2.1.11. 6-(2-hydroxy-2-methylpropoxy)-4-(6-(6-((6-methoxypyridin-3-yl)methyl)-3,6-diazabicyclo[3.1.1]heptan-3-yl)pyridin-3-yl)pyrazolo[1,5-a]pyridine-3-carbonitrile - Orphan - EMEA-002544-PIP01-18

Eli Lilly and Company Limited; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms) / Treatment of paediatric patients from ≥ 6 months to < 18 years of age with rearranged during transfection (RET)-altered, locally advanced or metastatic, solid tumours or primary central nervous system (CNS) tumours

Day 120 Opinion

Action: For adoption

Oncology

2.1.12. Crizotinib - EMEA-001493-PIP03-18

Anaplastic lymphoma kinase (ALK)-positive inflammatory myofibroblastic tumour (IMT) / ALK-positive anaplastic large cell lymphoma (ALCL) / Treatment of paediatric patients with relapsed/refractory systemic ALK-positive ALCL, Treatment of paediatric patients with unresectable or relapsed/refractory ALK-positive IMT

Day 120 Opinion

Action: For adoption

Oncology

2.1.13. Iodine (¹³¹I) murine IgG1 monoclonal antibody against B7-H3 - Orphan - EMEA-002101-PIP02-18

Y-mAbs Therapeutics A/S; Treatment of paediatric neuroblastoma patients with central nervous system (CNS) relapse as evidenced by CNS/ leptomeningeal (LM) metastases

Day 120 Opinion

Action: For adoption

Oncology

2.1.14. Ivosidenib - Orphan - EMEA-002247-PIP02-17

Agios Pharmaceuticals, Inc.; Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours, haematopoietic and lymphoid tissue neoplasms), Treatment of malignant neoplasms of the central nervous system / Treatment of paediatric patients (2 to less than 18 years of age) with recurrent or progressive (R/P) malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms), including central nervous system tumours, with an isocitrate dehydrogenase-1 (IDH1) mutation

Day 120 Opinion

Action: For adoption

Oncology

2.1.15. Larotrectinib - EMEA-001971-PIP03-18

Treatment of malignant neoplasms of the central nervous system / Treatment of paediatric patients with a primary CNS tumour with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion

Day 120 Opinion

Action: For adoption

Oncology

2.1.16. Marizomib - EMEA-002452-PIP01-18

Treatment of malignant glial tumors / Treatment of patients (paediatric) with diffuse intrinsic pontine glioma (DIPG) who have received radiation therapy.

Day 120 Opinion

Action: For adoption

Oncology

2.1.17. Zanubrutinib - EMEA-002354-PIP02-18

Treatment of mature B-cell neoplasms excluding lymphoplasmacytic lymphoma (Waldenström's macroglobulinaemia) / Treatment of lymphoplasmacytic lymphoma (Waldenström's macroglobulinaemia) / Treatment of primary mediastinal B-cell lymphoma, Treatment of Burkitt lymphoma / Treatment of diffuse large B-cell lymphoma

Day 120 Opinion

Action: For adoption

Oncology

2.1.18. Atropine - EMEA-002538-PIP01-18

Treatment of myopia

Day 120 Opinion

Action: For adoption

Ophthalmology

2.1.19. Ketamine / sufentanil - EMEA-001739-PIP02-16

ICD10:R52 Treatment of pain

Day 120 Opinion

Action: For adoption

Pain

2.1.20. EMEA-001976-PIP02-18

Asthma / Treatment to control persistent asthma

Day 120 Opinion

Action: For adoption

Pneumology - Allergology

2.1.21. Synthetic double-stranded siRNA oligonucleotide directed against lactate dehydrogenase A mRNA and containing four modified nucleosides which form a ligand cluster of four N-acetylgalactosamine residues - Orphan - EMEA-002493-PIP01-18

Dicerna EU Limited; The treatment of primary hyperoxaluria

Day 120 Opinion

Action: For adoption

Uro-nephrology

2.1.22. Ezetimibe / atorvastatin - EMEA-002649-PIP01-19

Treatment of hypercholesterolemia / The combination of atorvastatin and ezetimibe is indicated for the treatment of hypercholesterolemia as substitution therapy in adult patients adequately controlled with the individual substances given concurrently at the same dose level as in the fixed dose combination, but as separate products.

Day 60 Opinion

Action: For adoption

Cardiovascular Diseases

2.1.23. ⁶⁸Ga-satoreotide trizoxetan - Orphan - EMEA-002632-PIP01-19

Ipsen Pharma; Small cell lung cancer / Neuroendocrine tumours / Breast cancer

Day 60 Opinion

Action: For adoption

Diagnostic / Oncology

2.1.24. EMEA-002622-PIP01-19

Diagnosis of biochemical recurrence of prostate cancer

Day 60 Opinion

Action: For adoption

Diagnostic / Uro-nephrology

2.1.25. Ambrisentan - EMEA-002613-PIP01-19

Portal Hypertension secondary to decompensated cirrhosis

Day 60 Opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.26. ¹⁷⁷Lu-satoreotide tetraxetan - Orphan - EMEA-002629-PIP01-19

Ipsen Pharma; Small cell lung cancer / Neuroendocrine tumours / Breast cancer

Day 60 Opinion

Action: For adoption

Oncology

2.1.27. EMEA-002615-PIP01-19

Multiple myeloma

Day 60 Opinion

Action: For adoption

Oncology

2.1.28. Duvelisib - Orphan - EMEA-002587-PIP01-19

Verastem, Inc.; Treatment of chronic lymphocytic leukaemia /small lymphocytic lymphoma /
Treatment of follicular lymphoma

Day 60 Opinion

Action: For adoption

Oncology

2.1.29. Savolitinib - EMEA-002627-PIP01-19

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

Day 60 Opinion

Action: For adoption

Oncology

2.1.30. Sitravatinib malate - EMEA-002633-PIP01-19

Treatment of non-small cell lung cancer

Day 60 Opinion

Action: For adoption

Oncology

2.1.31. Loxoprofen - EMEA-002626-PIP01-19

Local treatment of pain

Day 60 Opinion

Action: For adoption

Pain

2.1.32. Thiocolchicoside / diclofenac - EMEA-002580-PIP01-19

Acute low back pain / Treatment of acute low back pain in adults

Day 60 Opinion

Action: For adoption

Pain

2.1.33. Gefapixant - EMEA-002267-PIP02-19

R05 - Treatment of cough

Day 60 Opinion

Action: For adoption

Pneumology Allergology

2.1.34. Canakinumab - EMEA-000060-PIP07-19

Gout

Day 1 Opinion

Action: For adoption

Immunology – Rheumatology – Transplantation

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. Asfotase alfa - EMEA-C-000987-PIP01-10-M04

Alexion Europe S.A.S.; Treatment of hypophosphatasia

Day 30 letter

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.2.2. Decitabine - EMEA-C-000555-PIP01-09-M06

Janssen-Cilag International NV; Treatment of acute myeloid leukaemia

Day 60 letter

Action: For adoption

Oncology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Rubidium (⁸²Rb) chloride - EMEA-000882-PIP03-11-M04

Jubilant DraxImage Inc.; Visualization of myocardial perfusion for diagnostic purposes / rubidium chloride (⁸²Rb) injection is a radiopharmaceutical to be used in in positron-emission tomography (PET) imaging for the assessment of myocardial perfusion abnormalities

Day 60 Opinion

Action: For adoption

2.3.2. Chloroprocaine hydrochloride - EMEA-000639-PIP03-16-M01

Sintetica GmbH; Peripheral nerve block (local anesthesia by perineural injection)

Day 60 Opinion

Action: For adoption

Anaesthesiology

2.3.3. Ambrisentan - Orphan - EMEA-000434-PIP01-08-M06

Glaxo Group Limited; Treatment of pulmonary arterial hypertension

Day 60 Opinion

Action: For adoption

Cardiovascular Diseases

2.3.4. Aciclovir - EMEA-001066-PIP02-11-M03

VECTANS PHARMA; Herpes simplex labialis

Day 60 Opinion

Action: For adoption

Dermatology

2.3.5. Bimekizumab - EMEA-002189-PIP01-17-M01

UCB Biopharma SPRL; Treatment of psoriasis / Treatment of moderate to severe chronic plaque psoriasis in children from the age of 6 years and older

Day 60 Opinion

Action: For adoption

Dermatology

2.3.6. Dupilumab - EMEA-001501-PIP01-13-M06

Regeneron Pharmaceuticals, Inc; Atopic dermatitis

Day 60 Opinion

Action: For adoption

Dermatology

2.3.7. Volanesorsen - A phosphorothioate oligonucleotide targeted to apolipoprotein C-III - Orphan - EMEA-001915-PIP01-15-M01

Akcea Therapeutics; Familial chylomicronemia syndrome

Day 60 Opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.8. Liraglutide - EMEA-000128-PIP02-09-M03

Novo Nordisk A/S; E66 Obesity / Treatment of obesity

Day 60 Opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.9. Lubiprostone - EMEA-000245-PIP01-08-M06

Sucampo AG; Chronic idiopathic constipation

Day 60 Opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.10. Maralixibat chloride - Orphan - EMEA-001475-PIP03-17-M01

SFL Regulatory Services GmbH; Treatment of progressive familial intrahepatic cholestasis (PFIC)

Day 60 Opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.11. Naloxegol - EMEA-001146-PIP01-11-M05

Kyowa Kirin Pharmaceutical Development Limited; Treatment of opioid-induced constipation
Day 60 Opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.12. Teduglutide - Orphan - EMEA-000482-PIP01-08-M05

Shire Pharmaceuticals Ireland Limited; ICD-9-CM Diagnosis 579.3 - Other and unspecified post surgical non absorption - short bowel syndrome / Treatment of short bowel syndrome

Day 60 Opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.13. Avatrombopag - EMEA-001136-PIP01-11-M01

Dova Pharmaceuticals Ireland Limited; Chronic immune thrombocytopenia / Treatment of thrombocytopenia in patients with chronic immune thrombocytopenia

Day 60 Opinion

Action: For adoption

Haematology-Hemostaseology

2.3.14. Crizanlizumab - Orphan - EMEA-002141-PIP01-17-M02

Novartis Europharm Limited; Treatment of sickle cell disease / Prevention of vaso-occlusive crises in patients with sickle cell disease

Day 60 Opinion

Action: For adoption

Haematology-Hemostaseology

2.3.15. Synthetic double-stranded siRNA oligonucleotide directed against antithrombin mRNA and covalently linked to a ligand containing three N-acetylgalactosamine residues - Orphan - EMEA-001855-PIP01-15-M01

Genzyme Europe B.V.; Treatment of Haemophilia B, Treatment of Haemophilia A / Indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in children aged ≥ 1 year with severe Haemophilia B, including patients who express neutralizing antibodies to exogenous factor IX substitution / Indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in children aged ≥ 1 year with severe Haemophilia A, including patients who express neutralizing antibodies to exogenous factor VIII substitution

Day 60 Opinion

Action: For adoption

Haematology-Hemostaseology

2.3.16. Vonicog alfa - EMEA-001164-PIP01-11-M03

Baxalta Innovations GmbH; Von Willebrand disease / Prevention and treatment of bleeding episodes and for surgical and invasive procedures in paediatric patients (less than 18 years of age) with von Willebrand disease

Day 60 Opinion

Action: For adoption

Haematology-Hemostaseology

2.3.17. Apremilast - EMEA-000715-PIP02-11-M04

Celgene Europe B.V.; Treatment of juvenile idiopathic arthritis (JIA) / Treatment of juvenile psoriatic arthritis (JPsA)

Day 60 Opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.18. Apremilast - EMEA-000715-PIP05-13-M04

Celgene Europe B.V.; Treatment of Behçet's disease / Treatment of oral ulcers associated with Behçet's disease

Day 60 Opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.19. Avacopan - Orphan - EMEA-002023-PIP01-16-M03

ChemoCentryx Ireland Ltd.; Treatment of antineutrophil cytoplasmic antibody (ANCA) -associated vasculitis

Day 60 Opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.20. Ibrutinib - Orphan - EMEA-001397-PIP04-17-M01

Janssen-Cilag International N.V.; Treatment of chronic graft versus host disease (cGVHD) / Treatment of cGVHD in children 1 year of age and older

Day 60 Opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.21. Itacitinib - Orphan - EMEA-002178-PIP01-17-M01

Incyte Biosciences Distribution B.V; Treatment of acute graft versus host disease (D89.810, ICD-10-CM) / Treatment of steroid naïve paediatric population with acute graft versus host disease after allogeneic hematopoietic stem cell transplantation

Day 60 Opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.22. Rimiducid - Orphan - EMEA-001870-PIP01-15-M02

Bellicum Pharma Ltd; Treatment of graft versus host disease / Treatment of graft versus host disease in paediatric patients who have received a mismatched, related, allogeneic haematopoietic stem cell transplantation together with rivogenlecleucel

Day 60 Opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.23. Rivogenlecleucel - Orphan - EMEA-001869-PIP01-15-M02

Bellicum Pharma Ltd; Adjunctive 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 60 Opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.24. Tofacitinib citrate - EMEA-000576-PIP01-09-M11

Pfizer Europe MA EEIG; Juvenile idiopathic arthritis / Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis)

Day 60 Opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.25. [Daclatasvir - EMEA-001191-PIP01-11-M03](#)

Bristol-Myers Squibb Pharma EEIG; Treatment of chronic viral hepatitis C

Day 60 Opinion

Action: For adoption

Infectious Diseases

2.3.26. [Dalbavancin - EMEA-000016-PIP01-07-M07](#)

Allergan Pharmaceuticals International Limited; Treatment of acute bacterial skin and skin structure infections (ABSSSI)

Day 60 Opinion

Action: For adoption

Infectious Diseases

2.3.27. [Letemovir - Orphan - EMEA-001631-PIP01-14-M04](#)

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

Day 60 Opinion

Action: For adoption

Infectious Diseases

2.3.28. [Zanamivir - EMEA-001318-PIP01-12-M03](#)

GlaxoSmithKline Trading Services Limited; Treatment of influenza / Prevention of influenza / Treatment of influenza A and B virus infection / Prevention of influenza A and B virus infection

Day 60 Opinion

Action: For adoption

Infectious Diseases

2.3.29. [Fremanezumab - EMEA-001877-PIP01-15-M02](#)

Teva GmbH; Prevention of migraine headaches

Day 60 Opinion

Action: For adoption

Neurology

2.3.30. Peginterferon beta-1a - EMEA-001129-PIP01-11-M04

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

Day 60 Opinion

Action: For adoption

Neurology

2.3.31. Abemaciclib - EMEA-002342-PIP01-18-M01

Eli Lilly and Company Limited; Ewing's Sarcoma (ES) / Treatment of relapsed/refractory Ewing sarcoma in children and young adults, in combination with irinotecan and temozolomide

Day 60 Opinion

Action: For adoption

Oncology

2.3.32. Autologous T lymphocyte-enriched population of cells transduced with a lentiviral vector encoding a chimeric antigen receptor targeting human B cell maturation antigen with 4-1BB and CD3-zeta intracellular signaling domains - Orphan - EMEA-002369-PIP01-18-M01

Celgene Europe B.V.; Treatment of mature B-cell neoplasms / Treatment of paediatric patients with relapsed or refractory BCMA+ B-cell non-Hodgkin lymphoma

Day 60 Opinion

Action: For adoption

Oncology

2.3.33. Pevonedistat - Orphan - EMEA-002117-PIP01-17-M01

Takeda Pharma A/S; Treatment of acute myeloid leukaemia (AML) / Treatment of myelodysplastic syndromes (MDS) / Treatment of paediatric patients with newly diagnosed high risk AML or relapsed or refractory (R/R) AML / Treatment of relapsed/refractory (R/R) myelodysplastic syndromes (MDS)

Day 60 Opinion

Action: For adoption

Oncology

2.3.34. Ruxolitinib phosphate - EMEA-000901-PIP04-17-M01

Novartis Europharm Limited; Chronic graft versus host disease / Treatment of chronic graft versus host disease (GvHD) after allogeneic hematopoietic stem cell transplantation (alloSCT) in paediatric patients aged 28 days and above

Day 60 Opinion

Action: For adoption

Oncology

2.3.35. [Inotuzumab ozogamicin - Orphan - EMEA-001429-PIP01-13-M03](#)

Pfizer Europe MA EEIG; Treatment of acute lymphoblastic leukaemia / Treatment of relapsed or refractory B cell precursor acute lymphoblastic leukaemia

Day 60 Opinion

Action: For adoption

Oncology / Haematology-Hemostaseology

2.3.36. [Bilastine - EMEA-000347-PIP02-16-M01](#)

Faes Farma S.A.; Treatment of allergic conjunctivitis

Day 60 Opinion

Ophthalmology

2.3.37. [Mexiletine hydrochloride - Orphan - EMEA-002012-PIP01-16-M02](#)

Lupin Europe GmbH; Treatment of myotonic disorders

Day 60 Opinion

Action: For adoption

Other

2.3.38. [Rolapitant - EMEA-001768-PIP02-15-M02](#)

Tesaro Bio Netherlands B.V.; Chemotherapy-induced nausea and vomiting (CINV) in subjects receiving highly emetogenic chemotherapy (HEC)

Day 60 Opinion

Action: For adoption

Other

2.3.39. [Loxapine - EMEA-001115-PIP01-10-M07](#)

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

Day 60 Opinion

Action: For adoption

Psychiatry

2.3.40. Lurasidone hydrochloride - EMEA-001230-PIP01-11-M05

AZIENDE CHIMICHE RIUNITE ANGELINI FRANCESCO - A.C.R.A.F. S.p.A.; Schizophrenia

Day 60 Opinion

Action: For adoption

Psychiatry

2.3.41. Influenza virus surface antigens (Haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (Haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (Haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (Haemagglutinin and neuraminidase) of strain A (H1N1) - EMEA-001894-PIP01-15-M01

Seqirus GmbH; For the prevention of influenza caused by Influenza virus types A and B contained in the vaccine

Day 60 Opinion

Vaccines

2.3.42. Beclometasone dipropionate/ formoterol fumarate dihydrate/ glycopyrronium bromide - EMEA-001875-PIP02-18-M01

Chiesi Farmaceutici S.p.A.; Treatment of asthma / Regular treatment of asthma in patients not controlled with medium-high doses of inhaled corticosteroids and long-acting beta2-agonists

Day 0 Opinion

Action: For adoption

Pneumology-Allergology

2.3.43. Sodium thiosulfate - EMEA-002147-PIP02-17-M01

Fennec Pharmaceuticals, Inc.; Prevention of platinum-induced ototoxic hearing loss / Prevention of platinum-induced ototoxic hearing loss for standard risk hepatoblastoma (SR-HB) / Prevention of ototoxicity induced by cisplatin (CIS) chemotherapy in patients 1 month and <18 years of age with localized, non-metastatic, solid tumors

Day 1 Opinion

Action: For adoption

Oncology – Oto-rhino-laryngology

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. Vosoritide - EMEA-C1-002033-PIP01-16

BioMarin International Limited; Treatment of achondroplasia

Day 1 letter

Action: For information

Other

2.7.2. Durvalumab - EMEA-C1-002028-PIP01-16-M01

AstraZeneca AB; Treatment of malignant neoplasms of haematopoietic and lymphoid tissue

Day 1 letter

Action: For information

Oncology

2.7.3. Tremelimumab - EMEA-C1-002029-PIP01-16-M01

AstraZeneca AB; Treatment of malignant neoplasms of haematopoietic and lymphoid tissue

Day 1 letter

Action: For information

Oncology

2.7.4. Finerenone - EMEA-C1-001623-PIP01-14-M02

Bayer AG; Treatment of chronic kidney disease

Day 1 letter

Action: For information

Uro-nephrology

2.7.5. Ivacaftor / tezacaftor /
N-(1,3-dimethyl-1H-pyrazole-4-sulfonyl)-6-[3-(3,3,3-trifluoro-2,2-dimethylpropoxy)-1H-pyrazol-1-yl]-2-[(4S)-2,2,4-trimethylpyrrolidin-1-yl]pyridine-3-carboxamide -
EMA-C1-002324-PIP01-17

Vertex Pharmaceuticals (Ireland) Limited; Treatment of cystic fibrosis

Day 1 letter

Action: For information

Other

2.7.6. Burosumab - Recombinant Human IgG1 monoclonal antibody targeting fibroblast growth factor 23 (FGF23) - EMA-C3-001659-PIP01-15-M03

Kyowa Kirin Holdings B.V.; Treatment of X-linked hypophosphataemia; Indicated for the treatment of X-linked hypophosphataemia with radiographic evidence of bone disease in children 1 year of age and older and adolescents with growing skeletons

Day 1 letter

Action: For information

Other

2.7.7. Delamanid - EMA-C1-001113-PIP01-10-M06

Otsuka Pharmaceutical Development & Commercialisation Europe GmbH; Treatment of multi drug resistant tuberculosis

Day 1 letter

Action: For information

Infectious Diseases

2.8. Revision of PDCO Opinions

No items

3. Discussion of applications

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. Abemaciclib - EMA-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 90 discussion

Action: For discussion

Oncology

3.1.2. EMEA-002616-PIP01-19

Treatment of atopic dermatitis

Day 60 discussion

Action: For discussion

Dermatology

3.1.3. EMEA-002582-PIP01-19

Treatment of chronic spontaneous urticaria

Day 60 discussion

Action: For discussion

Dermatology

3.1.4. Ruxolitinib - EMEA-002618-PIP01-19

Vitiligo

Day 60 discussion

Action: For discussion

Dermatology

3.1.5. Ladarixin - EMEA-002642-PIP01-19

Treatment of type 1 diabetes / Treatment of new-onset type 1 diabetes mellitus

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.6. Pegzilarginase - Orphan - EMEA-001925-PIP02-19

Aeglea BioTherapeutics, Inc.; Arginase 1 deficiency

Day 60 discussion

Action: For discussion

3.1.7. Benralizumab - EMEA-001214-PIP05-19

Treatment of eosinophilic esophagitis (EoE)

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.8. Guselkumab - EMEA-001523-PIP04-19

Ulcerative colitis: ICD K51 / Treatment of ulcerative colitis

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.9. Guselkumab - EMEA-001523-PIP05-19

Crohn's disease: ICD K50 / Treatment of Crohn's disease

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.10. EMEA-002640-PIP01-19

Eosinophilic esophagitis / Treatment of eosinophilic esophagitis

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.11. Relamorelin - EMEA-002323-PIP02-19

Gastroparesis

Day 60 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.12. Benralizumab - EMEA-001214-PIP04-19

Treatment of hypereosinophilic syndrome (HES)

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.13. EMEA-001312-PIP02-19

Prevention of acute graft-versus-host disease (GVHD)

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.14. Ravagalimab - EMEA-002617-PIP01-19

Ulcerative colitis

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.15. Ritonavir / atazanavir - EMEA-002588-PIP01-19

Treatment of human immunodeficiency virus (HIV-1) infection

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.16. The whole range of unmanipulated autologous mononuclear cells derived from human umbilical cord blood (Hau-UCB-mnc) - Orphan - EMEA-001799-PIP03-19

BrainRepair UG (haftungsbeschränkt); Periventricular leukomalacia (PVL) ICD-10-CM P91.2

Day 60 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.1.17. Cenobamate - EMEA-002563-PIP02-19

Treatment of epilepsy

Day 60 discussion

Action: For discussion

Neurology

3.1.18. Gaboxadol - Orphan - EMEA-002620-PIP01-19

Ovid Therapeutics; Angelman syndrome

Day 60 discussion

Action: For discussion

Neurology

3.1.19. Chimeric 2'-O-(2-methoxyethyl) modified antisense oligonucleotide - Orphan - EMEA-002546-PIP01-19

Roche Registration GmbH; Huntington's disease

Day 60 discussion

Action: For discussion

Neurology

3.1.20. EMEA-002631-PIP01-19

Treatment of acute myeloid leukaemia

Day 60 discussion

Action: For discussion

Oncology

3.1.21. Autologous inactivated glioma cells - Orphan - EMEA-002661-PIP01-19

ERC Belgium; Recurrent high grade glioma / Treatment of recurrent high grade glioma

Day 60 discussion

Action: For discussion

Oncology

3.1.22. Autologous inactivated glioma cells - Orphan - EMEA-002662-PIP01-19

ERC Belgium; Recurrent high grade glioma / Treatment of recurrent high grade glioma

Day 60 discussion

Action: For discussion

Oncology

3.1.23. Autologous inactivated glioma cells - Orphan - EMEA-002663-PIP01-19

ERC Belgium; Recurrent high grade glioma / Treatment of recurrent high grade glioma

Day 60 discussion

Action: For discussion

Oncology

3.1.24. Autologous inactivated glioma cells - Orphan - EMEA-002664-PIP01-19

ERC Belgium; Recurrent high grade glioma / Treatment of recurrent high grade glioma

Day 60 discussion

Action: For discussion

Oncology

3.1.25. Sulindac / eflornithine hydrochloride monohydrate - Orphan - EMEA-001518-PIP03-19

CANCER PREVENTION PHARMA (IRELAND) LIMITED; Treatment of familial adenomatous polyposis

Day 60 discussion

Action: For discussion

Oncology

3.1.26. Temozolomide - EMEA-002634-PIP01-19

Treatment of malignant glioma / Children from the age of three years and adolescent patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy, who have difficulty swallowing

Day 60 discussion

Action: For discussion

Oncology

3.1.27. Atropine - EMEA-002545-PIP01-19

Myopia

Day 60 discussion

Action: For discussion

Ophthalmology

3.1.28. Propranolol - EMEA-002625-PIP01-19

Retinopathy of prematurity

Day 60 discussion

Action: For discussion

Ophthalmology

3.1.29. Ondansetron - EMEA-002623-PIP01-19

Treatment of alcohol use disorder (AUD)

Day 60 discussion

Action: For discussion

Other / Neurology

3.1.30. EMEA-002639-PIP01-19

Cystic fibrosis / Treatment of cystic fibrosis in children from birth to <18 years

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.31. EMEA-002638-PIP01-19

Cystic fibrosis / Treatment of cystic fibrosis in children from birth to <18 years

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.32. EMEA-002641-PIP01-19

Prevention of pneumococcal disease caused by *S. pneumoniae* / For the active immunisation for the prevention of invasive pneumococcal diseases (IPD) caused by *S. pneumoniae* in infants, children and adolescents from 6 weeks to < 18 years of age

Day 60 discussion

Action: For discussion

Vaccines

3.1.33. Chloroprocaine - EMEA-000639-PIP04-19

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

Day 30 discussion

Action: For discussion

Anaesthesiology

3.1.34. Chloroprocaine - EMEA-000639-PIP05-19

Ocular surface anesthesia

Day 30 discussion

Action: For discussion

Anaesthesiology

3.1.35. Ethanol - EMEA-002672-PIP01-19

Treatment of primary hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

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

Alexion Europe S.A.S.; Wilson disease

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.37. 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 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.38. 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 30 discussion

Action: For discussion

Infectious Diseases

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

AB Science; Treatment of amyotrophic lateral sclerosis

Day 30 discussion

Action: For discussion

Neurology

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

UCB Pharma S.A.; Treatment of myasthenia gravis

Day 30 discussion

Action: For discussion

Neurology

3.1.41. EMEA-002635-PIP01-19

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

Day 30 discussion

Action: For discussion

Oncology

3.1.42. EMEA-001862-PIP02-19

Treatment of mantle cell lymphoma

Day 30 discussion

Action: For discussion

Oncology

3.1.43. 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 30 discussion

Action: For discussion

Oncology

3.1.44. Iberdomide - EMEA-002636-PIP01-19

Treatment of mature B-cell neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.1.45. 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 30 discussion

Action: For discussion

Oncology

3.1.46. Lenvatinib - EMEA-001119-PIP03-19

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

Day 30 discussion

Action: For discussion

Oncology

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

Refractory/relapsed triple-negative breast cancer (TNBC)

Day 30 discussion

Action: For discussion

Oncology

3.1.48. EMEA-002606-PIP02-19

Treatment of multiple myeloma

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.1.49. EMEA-002656-PIP01-19

Chikungunya disease

Day 30 discussion

Action: For discussion

Vaccines

3.1.50. Aztreonam / avibactam sodium - 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 90 discussion

Action: For discussion

Infectious Diseases

3.2. Discussions on Compliance Check

The following compliance checks have been put up for discussion and the members of the PDCO have been invited to comment on issues of possible non-compliance

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

BioMarin International Ltd.; Treatment of congenital haemophilia A

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

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

Roche Registration GmbH; Treatment of influenza

Day 30 discussion

Action: For discussion

Infectious Diseases

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

Eli Lilly and Company Limited; Treatment of migraine headache

Day 30 discussion

Action: For discussion

Neurology

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

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

Day 30 discussion

Action: For discussion

Pneumology - Allergology

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

ADVICENNE; Treatment of renal tubular acidosis

Day 30 discussion

Action: For discussion

Uro-nephrology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Edoxaban - 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 30 discussion

Action: For discussion

Cardiovascular Diseases / Haematology-Hemostaseology

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

Pfizer Europe MA EEIG; moderate to severe atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.3.3. 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 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. 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 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology

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

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

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.6. 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 β --thalassaemia major and severe intermedia

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.7. 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 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.8. 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 30 discussion

Action: For discussion

Haematology-Hemostaseology

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

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

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.10. 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 30 discussion

Action: For discussion

Infectious Diseases

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

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

Day 30 discussion

Action: For discussion

Neurology

3.3.12. 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 30 discussion

Action: For discussion

Oncology

3.3.13. 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 30 discussion

Action: For discussion

Oncology

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

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

Day 30 discussion

Action: For discussion

Other

3.3.15. Selexipag - EMEA-000997-PIP01-10-M03

Janssen Cilag International NV; Pulmonary arterial hypertension / Treatment of pulmonary arterial hypertension

Day 30 discussion

Action: For discussion

Other

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

sanofi-aventis recherche & développement; Treatment of asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.17. 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 30 discussion

Action: For discussion

Pneumology - Allergology

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

Les Laboratoires Servier; Major Depressive Episodes

Day 30 discussion

Action: For discussion

Psychiatry

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

Alnylam UK Limited; Treatment of primary hyperoxaluria Type 1

Day 30 discussion

Action: For discussion

Uro-nephrology

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

Alexandra West; Treatment of anaemia associated with chronic renal disease

Day 30 discussion

Action: For discussion

Uro-nephrology / Haematology-Hemostaseology

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 for Nomination of Rapporteur and Peer reviewer

No items

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. EMEA-14-2019

The classes of oestrogen receptor modulator, of growth and sex hormone as well as their releasing or inhibiting factors, and of sex hormone-metabolism modulator medicinal products

for treatment of breast malignant neoplasms / Treatment of advanced/metastatic oestrogen receptor (ER)+ breast cancer

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

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

9.1.1. PDCO Vice-Chairperson - election

Action: For adoption

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. Extrapolation: case studies under assessment

MSWP Chair: Kristin Karlsson

Action: For information

9.3.4. Extrapolation: Adoption of draft extrapolation guidance template

Action: For adoption

9.3.5. Scientific advice working party (SAWP) – nomination of a PDCO representative

Action: For adoption

9.4. Cooperation within the EU regulatory network

9.4.1. European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA): Report on face-to-face meeting

PDCO member: Marek Migdal, Angeliki Siapkara

Action: For information

9.5. Cooperation with International Regulators

9.5.1. Report from the Paediatric Cluster Teleconference

Action: For information

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

9.6.1. Fifth Accelerate Paediatric Strategy Forum for Medicinal Product Development of Epigenetic Modifiers in Children

Action: For information

9.7. PDCO work plan

9.7.1. PDCO Work Plan 2020 proposal

PDCO member: Koenraad Norga

Action: For discussion

9.8. Planning and reporting

No items

10. Any other business

10.1.1. Update on EMA relocation

EMA: Irene Zanetti

Action: For information

11. Breakout sessions

11.1.1. Paediatric oncology

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

11.1.2. Neonatology

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

11.1.3. Inventory

Action: For discussion on Tuesday, 18:00 - 19:00, room 2-D

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/