



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Human Medicines Division

Paediatric Committee (PDCO)

Agenda for the meeting on 19-22 April 2022

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

19 April 2022, 14:00 - 19:00, Virtual meeting

20 April 2022, 08:30 - 19:00, Virtual meeting

21 April 2022, 08:30 - 19:00, Virtual meeting

22 April 2022, 08:30 - 13:00, Virtual 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 19-22 April 2022. See April 2022 PDCO minutes (to be published post May 2022 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 19-22 April 2022.

1.3. Adoption of the minutes

PDCO minutes for 22-25 March 2022.

2. Opinions

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

2.1. Opinions on Products

2.1.1. Dersimelagon - EMEA-002850-PIP02-21

Treatment of erythropoietic protoporphyria / Treatment of X-linked protoporphyria

Day 120 opinion

Action: For adoption

Dermatology

2.1.2. Humanised KLB/FGFR1c monoclonal antibody - EMEA-003058-PIP01-21

Treatment of non-alcoholic steatohepatitis

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.3. Apraglutide - Orphan - EMEA-003016-PIP01-21

VectivBio AG; Treatment of short bowel syndrome

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.4. Recombinant adeno-associated viral (rAAV) vector expressing the human ornithine transcarbamylase (hOTC) gene - EMEA-002983-PIP01-21

Treatment of ornithine transcarbamylase deficiency

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.5. Sirolimus - EMEA-002982-PIP01-21

Treatment of ornithine transcarbamylase deficiency

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.6. Haematopoietic stem cells and blood progenitors umbilical cord-derived expanded with (1R,4R)-N1-(2-benzyl-7-(2-methyl-2H-tetrazol-5-yl)-9H-pyrimido[4,5-b]indol-4-yl)cyclohexane-1,4-diamine dihydrobromide dihydrate (ECT-001-CB) - Orphan - EMEA-003025-PIP02-21

ExCellThera; Allogeneic haematopoietic stem cell transplantation

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Oncology / Haematology-Hemostaseology

Note: Withdrawal request received on 2 April 2022

2.1.7. Reparixin - Orphan - EMEA-001693-PIP03-21

Dompé farmaceutici S.p.A.; Treatment of coronavirus disease 2019 (COVID-19)

Day 120 opinion

Action: For adoption

Infectious Diseases

2.1.8. Omaveloxolone - Orphan - EMEA-002487-PIP01-18

Reata Ireland Limited; Treatment of Friedrich's ataxia

Day 120 opinion

Action: For adoption

Neurology

2.1.9. [Cedazuridine: \(4R\)-1-\[\(2R,4R,5R\)-3,3-difluoro-4-hydroxy-5-\(hydroxymethyl\)oxolan-2-yl\]-4-hydroxy-1,3-diazinan-2-one / decitabine: 4-amino-1-\[\(2R,4S,5R\)-4-hydroxy-5-\(hydroxymethyl\)oxolan-2-yl\]-1,3,5-triazin-2\(1H\)-one - Orphan - EMEA-003071-PIP01-21](#)

Otsuka Pharmaceutical Netherlands B.V.; Treatment of acute myeloid leukaemia

Day 120 opinion

Action: For adoption

Oncology / Haematology-Hemostaseology

2.1.10. [Whole-cell heat-inactivated bacterial strains of *Escherichia coli*, *klebsiella pneumoniae*, *proteus vulgaris* and *enterococcus faecalis* - EMEA-003026-PIP02-21](#)

Prevention of urinary tract infections

Day 120 opinion

Action: For adoption

Vaccines / Infectious Diseases / Uro-nephrology

2.1.11. [Indapamide / perindopril arginine - EMEA-003186-PIP01-22](#)

Treatment of (essential) primary hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.12. [Flortaucipir F18 - EMEA-003187-PIP01-22](#)

Diagnosis of Alzheimer's disease

Day 60 opinion

Action: For adoption

Neurology

2.1.13. [Anti-TGFbeta fully human monoclonal antibody - EMEA-003178-PIP01-21](#)

Metastatic pancreatic ductal adenocarcinoma

Day 60 opinion

Action: For adoption

Oncology

2.1.14. Sugemalimab - EMEA-003179-PIP01-22

Treatment of lung cancer

Day 60 opinion

Action: For adoption

Oncology

2.2. Opinions on Compliance Check

2.2.1. Alirocumab - EMEA-C1-001169-PIP01-11-M05

sanofi-aventis recherche & développement; Treatment of elevated cholesterol

Day 60 letter

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.2.2. Elosulfase alfa - EMEA-C2-000973-PIP01-10-M03

BioMarin International Limited; Treatment of mucopolysaccharidosis, type IVA (Morquio A syndrome)

Day 60 letter

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.2.3. Lumacaftor / ivacaftor - EMEA-C6-001582-PIP01-13-M10

Vertex Pharmaceuticals (Ireland) Limited; Treatment of cystic fibrosis

Day 60 letter

Action: For adoption

Other

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Nemolizumab - EMEA-001624-PIP01-14-M05

Galderma International S.A.S; Treatment of atopic dermatitis

Day 60 opinion

Action: For adoption

Dermatology

2.3.2. [Canagliflozin \(1s\)-1,5-anhydro-1-\[3-\[\[5-\(4-fluorophenyl\)-2-thienyl\]methyl\]-4-methylphenyl\]-D-glucitol hemihydrate - EMEA-001030-PIP01-10-M10](#)

Janssen-Cilag International NV; Treatment of type 2 diabetes mellitus

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.3. [Aztreonam / avibactam - EMEA-002283-PIP01-17-M03](#)

Pfizer Europe MA EEIG; Treatment of infections caused by aerobic gram-negative bacteria

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.4. [Posaconazole - EMEA-000468-PIP02-12-M07](#)

Merck Sharp & Dohme (Europe), Inc.; Treatment of invasive fungal infections / Prevention of invasive fungal infections

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.5. [Efinaconazole - EMEA-001627-PIP01-14-M02](#)

Almirall, S.A.; Treatment of onychomycosis (tinea unguium)

Day 60 opinion

Action: For adoption

Infectious Diseases / Dermatology

2.3.6. [Dopamine hydrochloride - EMEA-001105-PIP01-10-M06](#)

BrepcO Biopharma Limited; Treatment of vascular hypotensive disorders

Day 60 opinion

Action: For adoption

2.3.7. Inebilizumab - Orphan - EMEA-001911-PIP01-15-M04

Horizon Therapeutics Ireland DAC; Treatment of neuromyelitis optica spectrum disorders

Day 60 opinion

Action: For adoption

Neurology

2.3.8. Erdafitinib - EMEA-002042-PIP02-20-M01

Janssen-Cilag International N.V.; Treatment of all conditions included in the category of malignant neoplasms (except urothelial carcinoma, haematopoietic and lymphoid tissue neoplasms)

Day 60 opinion

Action: For adoption

Oncology

2.3.9. Tisagenlecleucel - Orphan - EMEA-001654-PIP01-14-M04

Novartis Europharm Limited; Treatment of B cell acute lymphoblastic leukaemia/lymphoblastic lymphoma

Day 60 opinion

Action: For adoption

Oncology

2.3.10. Zanubrutinib - EMEA-002354-PIP02-18-M01

BeiGene Ireland Ltd.; Treatment of lymphoplasmacytic lymphoma / Treatment of mature B cell neoplasms (excluding lymphoplasmacytic lymphoma)

Day 60 opinion

Action: For adoption

Oncology

2.3.11. Lanadelumab - Orphan - EMEA-001864-PIP01-15-M07

Takeda Pharmaceuticals International AG Ireland Branch; Treatment of hereditary angioedema

Day 60 opinion

Action: For adoption

Other

2.3.12. Sodium chloride solution 4.2% (w/v) / 3,5-diamino-6-chloro-N-(N-(4-(4-(2-(hexyl((2S,3R,4R,5R)-2,3,4,5,6-pentahydroxyhexyl)amino)ethoxy)phenyl)butyl)-carbamimidoyl)pyrazine-2-carboxamide - Orphan - EMEA-002935-PIP01-20-M01

Parion Sciences, Inc.; Treatment of primary ciliary dyskinesia (PCD)

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.13. Loxapine - EMEA-001115-PIP01-10-M08

Ferrer Internacional, S.A.; Bipolar disorder / schizophrenia

Day 60 opinion

Action: For adoption

Psychiatry

2.3.14. Mirabegron - EMEA-000597-PIP03-15-M05

Astellas Pharma Europe B.V.; Treatment of neurogenic detrusor overactivity

Day 60 opinion

Action: For adoption

Uro-nephrology

2.3.15. Ravulizumab (ALXN1210) - Orphan - EMEA-001943-PIP01-16-M07

Alexion Europe SAS; Treatment of atypical haemolytic uremic syndrome

Day 60 opinion

Action: For adoption

Uro-nephrology

2.3.16. Ravulizumab (ALXN1210) - Orphan - EMEA-002077-PIP01-16-M05

Alexion Europe SAS; Treatment of paroxysmal nocturnal haemoglobinuria

Day 60 opinion

Action: For adoption

Uro-nephrology

2.3.17. Ravulizumab (ALXN1210) - EMEA-001943-PIP02-20-M01

Alexion Europe SAS; Treatment of patients with haematopoietic stem cell transplant associated thrombotic microangiopathy (HSCT-TMA)

Day 60 opinion

Action: For adoption

Uro-nephrology / Haematology-Hemostaseology

2.4. Opinions on Re-examinations

No item

2.5. Opinions on Review of Granted Waivers

No item

2.6. Finalisation and adoption of Opinions

No item

2.7. Partial Compliance Checks completed by EMA

The following partial compliance checks have been identified by the PME coordinator and PDCO rapporteur as not needing to be referred to the PDCO for discussion. The PDCO has been informed in writing.

2.7.1. Sparsentan - EMEA-C2-001984-PIP02-20

Travere Therapeutics Ireland Limited; Treatment of focal segmental glomerular sclerosis (fsgs)

Day 30 letter

Action: For information

Uro-nephrology

2.7.2. Avacopan - EMEA-C3-002023-PIP01-16-M05

ChemoCentryx Ireland Ltd.; Treatment of ANCA-associated vasculitis

Day 30 letter

Action: For information

Immunology-Rheumatology-Transplantation

2.7.3. Sparsentan - EMEA-C1-001984-PIP03-20

Traverse Therapeutics Ireland Limited; Treatment of IgA nephropathy (IgAN)

Day 30 letter

Action: For information

Uro-nephrology

3. Discussion of applications

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

3.1. Discussions on Products D90-D60-D30

3.1.1. Semaglutide / cagrilintide - EMEA-003059-PIP01-21

Treatment of obesity

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.2. EMEA-003090-PIP01-21

Treatment of hereditary angioedema

Day 90 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.3. Bepirovirsen - EMEA-003082-PIP01-21

Treatment of chronic hepatitis B infection

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.4. Lonafarnib - Orphan - EMEA-002516-PIP02-21

EigerBio Europe Limited; Treatment of hepatitis D virus infection

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.5. [Mixture of 2 synthetic double-stranded N-Acetyl-galactosamine conjugated siRNA oligonucleotides that are directed against hepatitis B virus - EMEA-002694-PIP02-21](#)

Treatment of chronic hepatitis D infection

Day 90 discussion

Action: For discussion

Infectious Diseases

3.1.6. [Alprazolam - EMEA-003043-PIP01-21](#)

Treatment of epileptic seizures

Day 90 discussion

Action: For discussion

Neurology

3.1.7. [Cannabidiol - EMEA-001964-PIP03-21](#)

Treatment of epilepsy with myoclonic atonic seizures

Day 90 discussion

Action: For discussion

Neurology

3.1.8. [Autologous tumour-infiltrating lymphocytes \(TILs\) isolated from a patient's cancer tissue and expanded ex vivo - EMEA-003072-PIP01-21](#)

Treatment of advanced melanoma

Day 90 discussion

Action: For discussion

Oncology

3.1.9. [Rituximab / CD3+CD4+CD25+CD127-FoxP3+ regulatory T cells - EMEA-002737-PIP01-19](#)

Treatment of type 1 diabetes mellitus (T1DM)

Day 90 discussion

Action: For discussion

Other / Endocrinology-Gynaecology-Fertility-Metabolism

3.1.10. Benralizumab - EMEA-001214-PIP09-21

Treatment of eosinophilic granulomatosis with polyangiitis (EGPA)

Day 90 discussion

Action: For discussion

Pneumology - Allergology

3.1.11. Sibeprenlimab - Orphan - EMEA-003085-PIP01-21

Otsuka Pharmaceutical Netherlands B.V.; Treatment of primary IgA nephropathy

Day 90 discussion

Action: For discussion

Uro-nephrology

3.1.12. Respiratory syncytial virus stabilised prefusion F subunit vaccine (RSVpreF) - EMEA-002795-PIP02-21

Prevention of lower respiratory tract disease caused by respiratory syncytial virus /
Prevention of RSV-associated lower respiratory tract illness

Day 90 discussion

Action: For discussion

Vaccines

3.1.13. A 2'-MOE antisense oligonucleotide targeting apoC-III - EMEA-003177-PIP01-21

Treatment of familial chylomicronaemia syndrome / Treatment of severe and extreme hypertriglyceridaemia

Day 60 discussion

Action: For discussion

Cardiovascular Diseases

3.1.14. Treprostinil - EMEA-003182-PIP01-22

Treatment of pulmonary arterial hypertension

Day 60 discussion

Action: For discussion

Cardiovascular Diseases

3.1.15. Beremagene geperpavec - Orphan - EMEA-002472-PIP03-22

Krystal Biotech, Inc.; Treatment of dystrophic epidermolysis bullosa

Day 60 discussion

Action: For discussion

Dermatology

3.1.16. Lenzilumab - EMEA-003188-PIP01-22

Treatment of coronavirus disease 2019 (COVID-19)

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.17. Methylphenidate hydrochloride - EMEA-003189-PIP01-22

Treatment of attention-deficit hyperactivity disorder

Day 60 discussion

Action: For discussion

Neurology

3.1.18. Tolebrutinib - EMEA-002566-PIP02-22

Treatment of myasthenia gravis

Day 60 discussion

Action: For discussion

Neurology

3.1.19. Enzastaurin hydrochloride - EMEA-003096-PIP02-22

Treatment of vascular Ehlers-Danlos syndrome

Day 60 discussion

Action: For discussion

Other

3.1.20. Stiripentol - Orphan - EMEA-003200-PIP01-22

Biocodex SA; Primary hyperoxaluria

Day 30 discussion

Action: For discussion

Uro-nephrology

3.1.21. [Autologous bone marrow-derived mononuclear cell enriched white blood cells - EMEA-003193-PIP01-22](#)

Chronic limb-threatening ischemia

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.22. [Botulinum toxin type E - EMEA-003190-PIP01-22](#)

Muscle-induced wrinkles

Day 30 discussion

Action: For discussion

Dermatology

3.1.23. [EMEA-003196-PIP01-22](#)

Treatment of ulcerative colitis / Treatment of Crohn's disease

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.24. [Derivative of 6-\[2-\(pyridin-2-yl\)phenoxy\]methyl}-1,2,3,4-tetrahydroisoquinoline - EMEA-003002-PIP02-22](#)

Treatment of clinically significant portal hypertension (CSPH)

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.25. [6-\[\(3S,4S\)-4-methyl-1-\(pyrimidin-2-ylmethyl\)pyrrolidin-3-yl\]-3-tetrahydropyran-4-yl-7H-imidazo\[1,5-a\]pyrazin-8-one - Orphan - EMEA-003201-PIP01-22](#)

Imara Inc.; Sickle cell disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.26. Depemokimab - EMEA-003051-PIP05-22

Treatment of hypereosinophilic syndrome (HES)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.27. Vidofludimus - EMEA-003195-PIP01-22

Treatment of multiple sclerosis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Neurology

3.1.28. Clonidine - EMEA-003198-PIP01-22

Treatment of attention deficit hyperactivity disorder

Day 30 discussion

Action: For discussion

Neurology

3.1.29. Exenatide acetate - Orphan - EMEA-003183-PIP02-22

Invex Therapeutics Ltd; Idiopathic intracranial hypertension (ICD-11 8D60)

Day 30 discussion

Action: For discussion

Neurology

3.1.30. Troriluzole - Orphan - EMEA-003084-PIP03-22

Biohaven Pharmaceutical Ireland DAC; Treatment of hereditary spinocerebellar ataxia

Day 30 discussion

Action: For discussion

Neurology

3.1.31. Infigratinib - Orphan - EMEA-002594-PIP04-22

Helsinn Birex Pharmaceuticals Ltd.; Treatment of paediatric low-grade gliomas (LGG)

Day 30 discussion

Action: For discussion

Oncology

3.1.32. Lurbinectedin - Orphan - EMEA-002846-PIP02-22

Pharma Mar, S.A.; Treatment of mesothelioma

Day 30 discussion

Action: For discussion

Oncology

3.1.33. Parsaclisib (as hydrochloride) - Orphan - EMEA-002696-PIP03-22

Incyte Biosciences Distribution B.V.; Treatment of primary myelofibrosis

Day 30 discussion

Action: For discussion

Oncology

3.1.34. Peptide KLBPVQLWV / Peptide SMPPPGTRV / Peptide YLQLVFGIEV / Peptide RLLQETELV / Peptide YLSGADLNL / Peptide LLTFWNPPV / Peptide IMIGHLVGV / Peptide KVAEIVHFL / Peptide KVFGSLAFV / Pan HLA DR-binding epitope D-Ala-Lys-Cha-Val-Ala-Ala-Trp-Thr-Leu-Lys-Ala-Ala-D-Ala - EMEA-003181-PIP01-22

Treatment of lung cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.35. Radium-224 adsorbed in calcium carbonate microparticles - EMEA-003199-PIP01-22

Treatment of peritoneal carcinomatosis

Day 30 discussion

Action: For discussion

Oncology

3.1.36. Trabectedin - Orphan - EMEA-000610-PIP02-22

Pharma Mar, S.A.; Treatment of leiomyosarcoma

Day 30 discussion

Action: For discussion

Oncology

3.1.37. Botulinum toxin type A - EMEA-003202-PIP01-22

Treatment of upper facial wrinkles

Day 30 discussion

Action: For discussion

Other

3.1.38. Efavaleukin alfa - EMEA-003156-PIP02-22

Ulcerative colitis

Day 30 discussion

Action: For discussion

Other

3.1.39. Depemokimab - EMEA-003051-PIP04-22

Treatment of eosinophilic granulomatosis with polyangiitis (EGPA)

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.40. Treprostinil palmitil - EMEA-003204-PIP01-22

Treatment of pulmonary hypertension associated with interstitial lung diseases (ILD-PH)

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.41. COVID-19 vaccine (recombinant, adjuvanted) - EMEA-003191-PIP01-22

Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.2. Discussions on Compliance Check

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

3.2.1. Ritlecitinib - EMEA-C1-002451-PIP01-18

Pfizer Europe MA EEIG; Treatment of alopecia areata

Day 30 discussion

Action: For discussion

Dermatology

3.2.2. Pitolisant - EMEA-C-001176-PIP01-11-M06

BIOPROJET PHARMA; Treatment of narcolepsy

Day 30 discussion

Action: For discussion

Neurology

3.2.3. Crisantapase - EMEA-C1-002934-PIP01-20

Jazz Pharmaceuticals Ireland Limited; Treatment of acute lymphoblastic leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Lebrikizumab - EMEA-002536-PIP01-18-M02

Eli Lilly and Company Limited; Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.3.2. Garadacimab - Orphan - EMEA-002726-PIP01-19-M02

CSL Behring GmbH; Hereditary angioedema attacks (HAE)

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.3. Vadadustat - EMEA-001944-PIP01-16-M04

Otsuka Pharmaceutical Development & Commercialisation Europe GmbH; Treatment of anaemia due to chronic disorders

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.4. Avacopan - Orphan - EMEA-002023-PIP01-16-M06

ChemoCentryx Ireland Ltd.; Treatment of anti-neutrophil cytoplasmic auto-antibody (ANCA)-associated vasculitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.5. Liposomal ciclosporin A (L-CsA) - Orphan - EMEA-002344-PIP02-18-M01

Zambon S.p.A.; Treatment of bronchiolitis obliterans syndrome (BOS)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.6. Oritavancin (diphosphate) - EMEA-001270-PIP01-12-M05

Menarini International Operations Luxembourg S.A.; Treatment of acute bacterial skin and skin structure infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.7. Remdesivir - EMEA-002826-PIP01-20-M03

Gilead Sciences International Ltd.; Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.8. Cannabidiol - Orphan - EMEA-001964-PIP01-16-M04

GW Pharma (International) B.V.; Dravet syndrome / Tuberous sclerosis complex / Infantile

spasms / Lennox gastaut syndrome

Day 30 discussion

Action: For discussion

Neurology

3.3.9. Delandistrogene moxeparvovec - Orphan - EMEA-002677-PIP01-19-M02

Roche Registration GmbH; Duchenne muscular dystrophy

Day 30 discussion

Action: For discussion

Neurology

3.3.10. Lacosamide - EMEA-000402-PIP03-17-M06

UCB Pharma S.A.; Treatment of generalized epilepsy and epilepsy syndromes

Day 30 discussion

Action: For discussion

Neurology

3.3.11. Daratumumab - Orphan - EMEA-002152-PIP01-17-M03

Janssen-Cilag International NV; Treatment of lymphoid malignancies (except mature B cell neoplasms)

Day 30 discussion

Action: For discussion

Oncology

3.3.12. Ixazomib - Orphan - EMEA-001410-PIP02-17-M04

Takeda Pharma A/S; Treatment of multiple myeloma / Treatment of lymphoid malignancies (excluding multiple myeloma)

Day 30 discussion

Action: For discussion

Oncology

3.3.13. Mometasone (furoate) / Indacaterol (acetate) - EMEA-001217-PIP01-11-M08

Novartis Europharm Limited; Treatment of asthma

Day 30 discussion

Action: For discussion

3.3.14. Dexmedetomidine (hydrochloride) - EMEA-002758-PIP01-19-M02

BioXcel Therapeutics, Inc.; Treatment of schizophrenia / Treatment of bipolar disorder

Day 30 discussion

Action: For discussion

Psychiatry

3.3.15. Daprodustat - EMEA-001452-PIP01-13-M04

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

Day 30 discussion

Action: For discussion

Uro-nephrology / Haematology-Hemostaseology

3.3.16. Pneumococcal polysaccharide conjugate vaccine (20-valent, adsorbed) EMEA-002330-PIP01-18-M02

Pfizer Europe MA EEIG; Prevention of disease caused by *Streptococcus pneumoniae*

Day 30 discussion

Action: For discussion

Vaccines

3.3.17. Hepatitis B (rDNA) surface antigen adjuvanted - EMEA-001127-PIP02-11-M02

Dynavax GmbH; Prevention of hepatitis B virus infection

Day 30 discussion

Action: For discussion

Vaccines

3.3.18. *Neisseria meningitidis* serogroup W polysaccharide conjugated to tetanus toxoid / *Neisseria meningitidis* serogroup Y polysaccharide conjugated to tetanus toxoid / *Neisseria meningitidis* serogroup C polysaccharide conjugated to tetanus toxoid / *Neisseria meningitidis* serogroup A polysaccharide conjugated to tetanus toxoid - EMEA-001930-PIP01-16-M04

Sanofi Pasteur; Prevention of invasive meningococcal disease

Day 30 discussion

Action: For discussion

Vaccines

3.3.19. Nirsevimab - EMEA-001784-PIP01-15-M04

AstraZeneca AB; Prevention of respiratory syncytial viral infections

Day 30 discussion

Action: For discussion

Vaccines

3.3.20. NVX-CoV2373 - EMEA-002941-PIP01-20-M02

Novavax CZ, a.s.; Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Vaccines

3.3.21. Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Yamagata lineage) / split influenza virus, inactivated containing antigens equivalent to the B-like strain (Victoria lineage) / split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain / split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain - EMEA-002359-PIP01-18-M05

Sanofi Pasteur; Prevention of influenza infection

Day 30 discussion

Action: For discussion

Vaccines

4. Nominations

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

4.1. List of submissions of applications with start of procedure 25 April 2022 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

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

6. Discussion on the applicability of class waivers

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

6.1. Discussions on the applicability of class waiver for products

No item

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. Mavacamten (SAR439152/MYK-461) - EMEA-002231-PIP01-17

Bristol-Myers Squibb Pharma EEIG; Treatment of hypertrophic cardiomyopathy

Proposed PIP indication: nonobstructive hypertrophic cardiomyopathy

Action: For adoption

8. Annual reports on deferrals

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

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. PDCO membership

Action: For information

9.1.2. Vote by Proxy

Action: For information

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

Action: For information

9.3. 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

9.4. 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

9.5.1. Paediatric cluster conference

Action: For information

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

No item

9.7. PDCO work plan

No item

9.8. Planning and reporting

No item

10. Any other business

10.1. ALADDIN - Educational program on regulatory science in paediatric oncology

Action: For information

10.2. COVID-19 update

Action: For information

10.3. Innovation Task Force (ITF) annual report 2021

Action: For information

10.4. Marketing Authorisation Applications (MAAs) 3-year forecast report

Action: For information

10.5. Paediatric addendum for antibacterial agents

PDCO member: Maria Fernandez Cortizo

Action: For adoption

10.6. Complex clinical trials (CCT) Questions & Answers document

Action: For discussion

10.7. Reflection of extrapolation in PIP opinions

Action: For information

11. Breakout sessions

11.1. Neonatology

Action: For discussion on Tuesday, 13:00 - 14:00

11.2. Paediatric oncology

Action: For discussion on Wednesday, 13:00 - 14:00

11.3. Vaccines

Action: For discussion on Thursday, 13:00 - 14:00

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/