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SCIENCE MEDICINES HEALTH

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Human Medicines Division

## Paediatric Committee (PDCO)

Draft Agenda for the meeting on 21-24 June 2022

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

21 June 2022, 14:00- 19:30, room 1C / virtual meeting

22 June 2022, 08:30- 19:30, room 1C / virtual meeting

23 June 2022, 08:30- 19:30, room 1C / virtual meeting

24 June 2022, 08:30- 13:00, room 1C / virtual meeting

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## 1. Introductions

### 1.1. Welcome and declarations of interest of members, alternates and experts

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PDCO plenary session to be held 21-24 June 2022. See (current) June 2022 PDCO minutes (to be published post July 2022 PDCO meeting).

### 1.2. Adoption of agenda

PDCO agenda for 21-24 June 2022.

### 1.3. Adoption of the minutes

PDCO minutes for 17-20 May 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. Oxytocin - Orphan - EMEA-003148-PIP01-21

---

OT4B; Treatment of Prader-Willi syndrome

Day 120 opinion

**Action:** For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

#### 2.1.2. Venglustat - Orphan - EMEA-001716-PIP06-21

---

Genzyme Europe B.V.; Treatment of Fabry disease

Day 120 opinion

**Action:** For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

*Note: Withdrawal request received on 15 June 2022*

### 2.1.3. Efruxifermin - EMEA-003114-PIP01-21

---

Treatment of non-alcoholic fatty liver disease including non-alcoholic steatohepatitis

Day 120 opinion

**Action:** For adoption

Gastroenterology-Hepatology

### 2.1.4. Etrasimod L-arginine - EMEA-002713-PIP02-21

---

Treatment of Crohn's disease

Day 120 opinion

**Action:** For adoption

Gastroenterology-Hepatology

### 2.1.5. Ritlecitinib - EMEA-002451-PIP02-21

---

Treatment of ulcerative colitis

Day 120 opinion

**Action:** For adoption

Gastroenterology-Hepatology

### 2.1.6. Deucravacitinib - EMEA-002350-PIP04-21

---

Treatment of ulcerative colitis

Day 120 opinion

**Action:** For adoption

Immunology-Rheumatology-Transplantation

### 2.1.7. Gliadin protease - EMEA-003116-PIP01-21

---

Treatment of coeliac disease

Day 120 opinion

**Action:** For adoption

Immunology-Rheumatology-Transplantation / Gastroenterology-Hepatology

### 2.1.8. Remibrutinib - EMEA-002582-PIP02-21

---

Treatment of multiple sclerosis

Day 120 opinion

**Action:** For adoption

Neurology

2.1.9. (R)-tetrahydrofuran-3-yl 4-(6-(5-(4-ethoxy-1-isopropylpiperidin-4-yl) pyridin-2-yl)pyrrolo[1,2-b]pyridazin-4-yl)piperazine-1-carboxylate sesquisuccinate - Orphan - EMEA-003133-PIP01-21

---

Ipsen Pharma; Treatment of fibrodysplasia ossificans progressiva

Day 120 opinion

**Action:** For adoption

Other

2.1.10. Azelastine hydrochloride / mometasone furoate - EMEA-003122-PIP01-21

---

Treatment of seasonal allergic rhinitis

Day 120 opinion

**Action:** For adoption

Oto-rhino-laryngology

2.1.11. A 2'-O-(2'-methoxyethyl) modified antisense oligonucleotide targeting prekallikrein (PKK) mRNA - EMEA-003112-PIP01-21

---

Treatment of hereditary angioedema / Prevention of hereditary angioedema

Day 120 opinion

**Action:** For adoption

Pneumology - Allergology / Haematology-Hemostaseology

2.1.12. EMEA-003098-PIP01-21

---

Treatment of proteinuric chronic kidney disease

Day 120 opinion

**Action:** For adoption

Uro-nephrology

2.1.13. Lademirsén - Orphan - EMEA-003064-PIP01-21

---

Genzyme Europe B.V.; Treatment of Alport syndrome

Day 120 opinion

**Action:** For adoption

Uro-nephrology

#### [2.1.14. Pegcetacoplan - Orphan - EMEA-002600-PIP03-21](#)

---

Apellis Ireland Limited; Treatment of glomerulonephritis and nephrotic syndrome

Day 120 opinion

**Action:** For adoption

Uro-nephrology

#### [2.1.15. Vibegron - EMEA-001415-PIP02-21](#)

---

Treatment of myoneurogenic bladder disorders

Day 120 opinion

**Action:** For adoption

Uro-nephrology

#### [2.1.16. RSV F protein - EMEA-003094-PIP02-21](#)

---

Prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV)

Day 120 opinion

**Action:** For adoption

Vaccines / Infectious Diseases

#### [2.1.17. Acetylsalicylic acid / rosuvastatin - EMEA-003206-PIP01-22](#)

---

Prevention of cardiovascular events

Day 60 opinion

**Action:** For adoption

Cardiovascular Diseases

#### [2.1.18. Ezetimibe / atorvastatin - EMEA-003205-PIP01-22](#)

---

Treatment of hypercholesterolaemia / Prevention of cardiovascular events

Day 60 opinion

**Action:** For adoption

Cardiovascular Diseases

#### [2.1.19. EMEA-003223-PIP01-22](#)

---

Treatment of palmoplantar pustulosis

Day 60 opinion

**Action:** For adoption

Dermatology

#### 2.1.20. [Nipocalimab - Orphan - EMEA-002559-PIP05-22](#)

---

Janssen-Cilag International NV; Treatment of bullous pemphigoid

Day 60 opinion

**Action:** For adoption

Dermatology

#### 2.1.21. [Gold \(Au\) - EMEA-003211-PIP01-22](#)

---

Treatment of amyotrophic lateral sclerosis (ALS)

Day 60 opinion

**Action:** For adoption

Neurology

#### 2.1.22. [Modakafusp alfa - EMEA-003217-PIP01-22](#)

---

Treatment of multiple myeloma

Day 60 opinion

**Action:** For adoption

Oncology

#### 2.1.23. [Humanised monoclonal antibody of IgG1 subtype targeting NRP1 - EMEA-003214-PIP01-22](#)

---

Treatment of diabetic retinopathy

Day 60 opinion

**Action:** For adoption

Ophthalmology

#### 2.1.24. [Magnesium lactate dihydrate / tramadol - EMEA-003216-PIP01-22](#)

---

Management of chronic pain in adults with osteoarthritis of the hip and/or knee

Day 60 opinion

**Action:** For adoption

Other

### 2.1.25. Pregabalin - EMEA-003221-PIP01-22

---

Treatment of neuropathic pain associated with diabetic peripheral neuropathy / Treatment of postherpetic neuralgia

Day 60 opinion

**Action:** For adoption

Pain / Neurology

### 2.1.26. Amlodipine / nebivolol - EMEA-003226-PIP01-22

---

Treatment of hypertension

Day 30 opinion

**Action:** For adoption

Cardiovascular Diseases

### 2.1.27. Valsartan / nebivolol - EMEA-003227-PIP01-22

---

Treatment of hypertension

Day 30 opinion

**Action:** For adoption

Cardiovascular Diseases

## 2.2. Opinions on Compliance Check

### 2.2.1. Apixaban - EMEA-C-000183-PIP01-08-M08

---

Bristol-Myers Squibb / Pfizer EEIG; Prevention of arterial thromboembolism

Day 60 opinion

**Action:** For adoption

Cardiovascular Diseases

### 2.2.2. Pegzilarginase - EMEA-C1-001925-PIP02-19

---

Immedica Pharma AB; Treatment of hyperargininaemia

Day 60 letter

**Action:** For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

### 2.2.3. [Dulaglutide - EMEA-C-000783-PIP01-09-M06](#)

---

Eli Lilly & Company Limited; Treatment of type 2 diabetes mellitus

Day 30 opinion

**Action:** For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

### 2.2.4. [Evolocumab - EMEA-C-001268-PIP01-12-M05](#)

---

Amgen Europe B.V; Treatment of elevated cholesterol

Day 30 opinion

**Action:** For adoption

Cardiovascular Diseases

## 2.3. **Opinions on Modification of an Agreed Paediatric Investigation Plan**

### 2.3.1. [Obinutuzumab - Orphan - EMEA-001207-PIP02-19-M01](#)

---

Roche Registration GmbH; Treatment of systemic lupus erythematosus

Day 60 opinion

**Action:** For adoption

Antineoplastic and immunomodulating agents

### 2.3.2. [Chlorprocaine hydrochloride - EMEA-000639-PIP03-16-M02](#)

---

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

Day 60 opinion

**Action:** For adoption

Anaesthesiology

### 2.3.3. [Bempedoic acid - EMEA-001872-PIP01-15-M02](#)

---

Esperion Therapeutics, Inc.; Treatment of elevated cholesterol

Day 60 opinion

**Action:** For adoption

Cardiovascular Diseases

### 2.3.4. [Etripamil - EMEA-002303-PIP01-17-M03](#)

---

Milestone Pharmaceuticals, Inc.; Treatment of supraventricular tachycardia

---

Day 60 opinion

**Action:** For adoption

Cardiovascular Diseases

### 2.3.5. Omecamtiv mecarbil - EMEA-001696-PIP01-14-M02

---

Cytokinetics, Inc.; Treatment of heart failure

Day 60 opinion

**Action:** For adoption

Cardiovascular Diseases

### 2.3.6. Bimekizumab - EMEA-002189-PIP01-17-M03

---

UCB Biopharma SRL; Treatment of psoriasis

Day 60 opinion

**Action:** For adoption

Dermatology

### 2.3.7. Deucravacitinib - EMEA-002350-PIP01-18-M02

---

Bristol-Myers Squibb International Corporation; Treatment of psoriasis

Day 60 opinion

**Action:** For adoption

Dermatology

### 2.3.8. Fluciclovine (18F) - Orphan - EMEA-001644-PIP02-14-M03

---

Blue Earth Diagnostics Ireland Ltd; Diagnosis of amino acid metabolism in solid malignant tumours

Day 60 opinion

**Action:** For adoption

Diagnostic / Oncology

### 2.3.9. Pegunigalsidase alfa - Orphan - EMEA-001828-PIP01-15-M03

---

Chiesi Farmaceutici S.p.A; Treatment of Fabry disease

Day 60 opinion

**Action:** For adoption

Endocrinology-Gynaecology-Fertility-Metabolism



### 2.3.10. Cilofexor - Orphan - EMEA-002554-PIP02-19-M01

---

Gilead Sciences International Ltd.; Treatment of primary sclerosing cholangitis (DB96.2)

Day 60 opinion

**Action:** For adoption

Gastroenterology-Hepatology

*Note: Withdrawal request received on 10 June 2022*

### 2.3.11. Maralixibat chloride - Orphan - EMEA-001475-PIP02-13-M02

---

Mirum Pharmaceuticals; Treatment of Alagille syndrome

Day 60 opinion

**Action:** For adoption

Gastroenterology-Hepatology

### 2.3.12. Fidanacogene elaparvovec - Orphan - EMEA-002362-PIP02-19-M02

---

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

Day 60 opinion

**Action:** For adoption

Haematology-Hemostaseology

### 2.3.13. Rilzabrutinib - Orphan - EMEA-002438-PIP02-19-M02

---

Principia Biopharma, Inc.; Treatment of immune thrombocytopenia

Day 60 opinion

**Action:** For adoption

Immunology-Rheumatology-Transplantation

### 2.3.14. Avibactam / ceftazidime - EMEA-001313-PIP01-12-M12

---

Pfizer Europe MA EEIG; Treatment of pneumonia / Treatment of infections due to aerobic gram-negative organisms / Treatment of urinary tract infections / Treatment of intra-abdominal infections

Day 60 opinion

**Action:** For adoption

Infectious Diseases

### 2.3.15. Bulevirtide - Orphan - EMEA-002399-PIP01-18-M01

---

Gilead Sciences International Ltd.; Treatment of chronic hepatitis D infection

Day 60 opinion

**Action:** For adoption

Infectious Diseases

### 2.3.16. Casirivimab - EMEA-002964-PIP01-21-M02

---

Roche Registration GmbH; Treatment of coronavirus disease 2019 (COVID-19) / Prevention of coronavirus disease 2019 (COVID-19) / Treatment of coronavirus disease 2019 (COVID-19) in hospitalised patients

Day 60 opinion

**Action:** For adoption

Infectious Diseases

### 2.3.17. Enmetazobactam - EMEA-002240-PIP02-17-M01

---

Allegra Therapeutics GmbH; Treatment of urinary tract infections

Day 60 opinion

**Action:** For adoption

Infectious Diseases

### 2.3.18. Imdevimab - EMEA-002965-PIP01-21-M02

---

Roche Registration GmbH; Prevention of coronavirus disease 2019 (COVID-19) / Treatment of coronavirus disease 2019 (COVID-19)

Day 60 opinion

**Action:** For adoption

Infectious Diseases

### 2.3.19. Pretomanid - Orphan - EMEA-002115-PIP01-17-M05

---

Global Alliance for TB Drug Development; Treatment of multi-drug-resistant tuberculosis

Day 60 opinion

**Action:** For adoption

Infectious Diseases

### 2.3.20. Rezafungin acetate - Orphan - EMEA-002319-PIP01-17-M02

---

Mundipharma Corporation (Ireland) Limited; Treatment of invasive candidiasis

Day 60 opinion

**Action:** For adoption

Infectious Diseases

### 2.3.21. Ritonavir / (1R,2S,5S)-N-{(1S)-1-cyano-2-[(3S)-2-oxopyrrolidin-3-yl]ethyl}-6,6-dimethyl-3-[3-methyl-N-(trifluoroacetyl)-L-valyl]-3-azabicyclo[3.1.0]hexane-2-carboxamide - EMEA-003081-PIP01-21-M01

---

Pfizer Europe MA EEIG; Treatment of coronavirus disease 2019 (COVID-19) / Prevention of coronavirus disease 2019 (COVID-19)

Day 60 opinion

**Action:** For adoption

Infectious Diseases

### 2.3.22. Eptinezumab - EMEA-002243-PIP01-17-M03

---

H. Lundbeck A/S; Prevention of migraine headaches

Day 60 opinion

**Action:** For adoption

Neurology

### 2.3.23. Lasmiditan - EMEA-002166-PIP01-17-M06

---

Eli Lilly and Company Limited; Treatment of migraine with and without aura

Day 60 opinion

**Action:** For adoption

Neurology

### 2.3.24. Ravulizumab - EMEA-001943-PIP03-20-M01

---

Alexion Europe SAS; Treatment of myasthenia gravis

Day 60 opinion

**Action:** For adoption

Neurology

### 2.3.25. Rimegepant - EMEA-002812-PIP02-20-M01

---

Biohaven Pharmaceutical Ireland DAC; Treatment of migraine headaches

---

Day 60 opinion

**Action:** For adoption

Neurology

#### 2.3.26. Setmelanotide - Orphan - EMEA-002209-PIP01-17-M03

---

Rhythm Pharmaceuticals, Inc; Treatment of appetite and general nutrition disorders

Day 60 opinion

**Action:** For adoption

Nutrition

#### 2.3.27. Bosutinib - EMEA-000727-PIP01-09-M06

---

Pfizer Europe MA EEIG; Treatment of chronic myeloid leukaemia

Day 60 opinion

**Action:** For adoption

Oncology

#### 2.3.28. Larotrectinib - EMEA-001971-PIP03-18-M02

---

Bayer AG; Treatment of malignant neoplasms of the central nervous system

Day 60 opinion

**Action:** For adoption

Oncology

#### 2.3.29. Lenvatinib - EMEA-001119-PIP02-12-M08

---

Eisai GmbH; Treatment of osteosarcoma / Treatment of papillary thyroid carcinoma /  
Treatment of follicular carcinoma

Day 60 opinion

**Action:** For adoption

Oncology

#### 2.3.30. Andexanet alfa - EMEA-001902-PIP01-15-M06

---

AstraZeneca AB; Prevention of factor Xa inhibitor associated haemorrhage / Treatment of  
factor Xa inhibitor associated haemorrhage

Day 60 opinion

**Action:** For adoption

Other

*Note: Withdrawal request received on 17 June 2022*

### 2.3.31. Setrusumab - Orphan - EMEA-002169-PIP01-17-M01

Mereo Biopharma 3 Ltd; Treatment of osteogenesis imperfecta

Day 60 opinion

**Action:** For adoption

Other

*Note: Withdrawal request received on 10 June 2022*

### 2.3.32. Vamorolone - Orphan - EMEA-001794-PIP02-16-M05

ReveraGen BioPharma Ltd; Treatment of Duchenne muscular dystrophy

Day 60 opinion

**Action:** For adoption

Other

### 2.3.33. Ivacaftor / tezacaftor / elexacaftor - Orphan - EMEA-002324-PIP01-17-M03

Vertex Pharmaceuticals (Ireland) Limited; Treatment of cystic fibrosis

Day 60 opinion

**Action:** For adoption

Other / Pneumology - Allergology

### 2.3.34. Dermatophagoides farinae / dermatophagoides pteronyssinus - EMEA-001258-PIP01-11-M08

ALK-Abelló A/S; Treatment of asthma / Treatment of allergic rhinitis

Day 60 opinion

**Action:** For adoption

Pneumology - Allergology

### 2.3.35. Brexpiprazole - EMEA-001185-PIP01-11-M08

Otsuka Pharmaceutical Development & Commercialisation Europe GmbH; Treatment of schizophrenia

Day 60 opinion

**Action:** For adoption

Psychiatry

### 2.3.36. Vortioxetine - EMEA-000455-PIP02-10-M09

H. Lundbeck A/S; Treatment of major depressive disorder

Day 60 opinion

**Action:** For adoption

Psychiatry

### 2.3.37. COVID-19 vaccine (ChAdOx1-S [recombinant]) - EMEA-002862-PIP01-20-M03

AstraZeneca AB; Prevention of coronavirus disease 2019 (COVID-19)

Day 60 opinion

**Action:** For adoption

Vaccines

### 2.3.38. Leniolisib phosphate - Orphan - EMEA-002989-PIP01-21-M01

Pharming Technologies B.V.; Treatment of activated phosphoinositide 3-kinase delta syndrome (APDS)

Day 30 opinion

**Action:** For adoption

Immunology-Rheumatology-Transplantation

### 2.3.39. Epcoritamab - Orphan - EMEA-002907-PIP01-20-M01

AbbVie Ltd; Treatment of mature B cell lymphoma

Day 30 opinion

**Action:** For adoption

Oncology

## **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. Zilucoplan - EMEA-C1-002747-PIP01-20

---

UCB Pharma S.A; Treatment of myasthenia gravis

Day 30 letter

**Action:** For information

Other / Neurology

## 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. Ex vivo expanded autologous human keratinocytes containing epidermal stem cells genetically modified with a gamma-retroviral (RV) vector expressing the full-length LAMB3 cDNA - Orphan - EMEA-003137-PIP01-21

---

Holostem Therapie Avanzate s.r.l.; Treatment of junctional epidermolysis bullosa (JEB)

Day 90 discussion

**Action:** For discussion

Dermatology

#### 3.1.2. Tezepelumab - EMEA-001613-PIP04-21

---

Treatment of chronic spontaneous urticaria

Day 90 discussion

**Action:** For discussion

Dermatology

#### 3.1.3. EMEA-003143-PIP01-21

---

Treatment of ulcerative colitis

Day 90 discussion

**Action:** For discussion

#### 3.1.4. Clazakizumab - EMEA-001371-PIP02-21

---

Treatment of chronic active antibody mediated rejection (AMR) in kidney transplantation

Day 90 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation

#### 3.1.5. Tocilizumab - EMEA-000309-PIP09-21

---

Treatment of systemic sclerosis

Day 90 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation

#### 3.1.6. Ibrexafungerp citrate - EMEA-002535-PIP04-21

---

Treatment of invasive candidiasis

Day 90 discussion

**Action:** For discussion

Infectious Diseases

#### 3.1.7. Corticotropin - EMEA-003097-PIP01-21

---

Treatment of infantile spasms

Day 90 discussion

**Action:** For discussion

Neurology

#### 3.1.8. Cannabidiol - EMEA-003176-PIP01-21

---

Treatment of fragile X syndrome (FXS)

Day 90 discussion

**Action:** For discussion

Psychiatry

#### 3.1.9. Troriluzole - EMEA-003084-PIP02-21

---

Treatment of obsessive-compulsive disorder

---



Day 90 discussion

**Action:** For discussion

Psychiatry

### 3.1.10. Zuranolone - EMEA-003119-PIP01-21

---

Treatment of postpartum depression

Day 90 discussion

**Action:** For discussion

Psychiatry

### 3.1.11. Recombinant COVID-19 subunit nanoparticle - EMEA-003115-PIP01-21

---

Prevention of coronavirus disease 2019 (COVID-19)

Day 90 discussion

**Action:** For discussion

Vaccines

### 3.1.12. Milvexian - EMEA-003220-PIP01-22

---

Prevention of thromboembolism

Day 60 discussion

**Action:** For discussion

Cardiovascular Diseases

### 3.1.13. Zilebesiran - EMEA-003218-PIP01-22

---

Treatment of hypertension

Day 60 discussion

**Action:** For discussion

Cardiovascular Diseases

### 3.1.14. Perflubutane - EMEA-003037-PIP02-22

---

Diagnostic evaluation of focal hepatic lesions

Day 60 discussion

**Action:** For discussion

Diagnostic / Oncology

### 3.1.15. Danuglipron - EMEA-002944-PIP02-22

---

Treatment of chronic weight management/obesity / Treatment of obesity

Day 60 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.1.16. Doxribtimine / doxecitine - Orphan - EMEA-003210-PIP01-22

---

Zogenix ROI Limited; Treatment of thymidine kinase 2 deficiency

Day 60 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.1.17. Insulin human (RDNA) - EMEA-003194-PIP02-22

---

Treatment of type 2 diabetes mellitus

Day 60 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.1.18. Synthetic peptide of 20 amino acids comprising a T cell epitope from pro-insulin - EMEA-002379-PIP01-22

---

Treatment of type 1 diabetes mellitus

Day 60 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation / Endocrinology-Gynaecology-Fertility-Metabolism / Vaccines

### 3.1.19. EMEA-003222-PIP01-22

---

Treatment of SCN8A developmental and epileptic encephalopathy

Day 60 discussion

**Action:** For discussion

Neurology

### 3.1.20. Satralizumab - Orphan - EMEA-001625-PIP04-22

---

Roche Registration GmbH; Treatment of autoimmune encephalitis

Day 60 discussion

**Action:** For discussion

Neurology

3.1.21. Autologous CD4+ and CD8+ T cells transduced with lentiviral vector encoding a chimeric antigen receptor (CAR) directed against CD19 and preserving the T cell phenotype of the leukapheresis starting material - EMEA-003212-PIP01-22

---

Treatment of mature B cell neoplasms

Day 60 discussion

**Action:** For discussion

Oncology

3.1.22. Fianlimab - EMEA-003207-PIP01-22

---

Treatment of melanoma

Day 60 discussion

**Action:** For discussion

Oncology

3.1.23. Humanised IgG2 monoclonal antibody against interleukin-6 - EMEA-003215-PIP01-22

---

Treatment of macular oedema

Day 60 discussion

**Action:** For discussion

Ophthalmology

3.1.24. Benzylamine derivative of benzofuran - EMEA-002974-PIP02-22

---

Treatment of C3 glomerulopathy

Day 60 discussion

**Action:** For discussion

Uro-nephrology

3.1.25. Hydrochlorothiazide / amlodipine / telmisartan - EMEA-003229-PIP01-22

---

Treatment of hypertension / I10 essential primary hypertension

Day 30 discussion

**Action:** For discussion

Cardiovascular Diseases

### 3.1.26. Perindopril tert-butylamin / rosuvastatin - EMEA-003228-PIP01-22

Prevention of cardiovascular events / Treatment of hypertension / Treatment of dyslipidaemia

Day 30 discussion

**Action:** For discussion

Cardiovascular Diseases

### 3.1.27. Valsartan / rosuvastatin - EMEA-003240-PIP01-22

Treatment of hypertension / Treatment of dyslipidaemia / Prevention of cardiovascular events

Day 30 discussion

**Action:** For discussion

Cardiovascular Diseases

### 3.1.28. Amlitelimab - EMEA-003233-PIP01-22

Treatment of atopic dermatitis

Day 30 discussion

**Action:** For discussion

Dermatology

### 3.1.29. CRN04777 - Orphan - EMEA-003242-PIP01-22

Crinetics Pharmaceuticals, Inc.; Treatment of congenital hyperinsulinism

Day 30 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.1.30. EMEA-003241-PIP01-22

Treatment of sickle cell disease

Day 30 discussion

**Action:** For discussion

Haematology-Hemostaseology

### 3.1.31. Inclacumab - EMEA-003219-PIP01-22

---

Treatment of sickle cell disease

Day 30 discussion

**Action:** For discussion

Haematology-Hemostaseology

### 3.1.32. Itolizumab - Orphan - EMEA-003208-PIP02-22

---

Biocon Pharma Malta-I Limited; Treatment of acute graft versus host disease

Day 30 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation

### 3.1.33. Cilgavimab / tixagevimab - EMEA-003079-PIP01-22

---

Treatment of coronavirus disease 2019 (COVID-19) / Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

**Action:** For discussion

Infectious Diseases

### 3.1.34. Opelconazole - EMEA-003249-PIP01-22

---

Treatment of bronchopulmonary aspergillosis

Day 30 discussion

**Action:** For discussion

Infectious Diseases

### 3.1.35. Tetracycline / metronidazole / bismuth - EMEA-003224-PIP01-22

---

Treatment of helicobacter pylori infection

Day 30 discussion

**Action:** For discussion

Infectious Diseases / Gastroenterology-Hepatology

### 3.1.36. Enibarcimab - EMEA-003244-PIP01-22

---

Treatment of sepsis

Day 30 discussion

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**Action:** For discussion

Neonatology - Paediatric Intensive Care / Cardiovascular Diseases

### 3.1.37. [Cemdisiran sodium - Orphan - EMEA-003237-PIP01-22](#)

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Regeneron Ireland DAC; Treatment of generalized myasthenia gravis (gMG)

Day 30 discussion

**Action:** For discussion

Neurology

### 3.1.38. [Pegcetacoplan - EMEA-002600-PIP04-22](#)

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Treatment of amyotrophic lateral sclerosis

Day 30 discussion

**Action:** For discussion

Neurology

### 3.1.39. [Pozelimab - EMEA-003238-PIP01-22](#)

---

Treatment of generalized myasthenia gravis (gMG)

Day 30 discussion

**Action:** For discussion

Neurology

### 3.1.40. [Suvecaltamide - EMEA-003248-PIP01-22](#)

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Treatment of essential tremor

Day 30 discussion

**Action:** For discussion

Neurology

### 3.1.41. [Autologous CD4+ and CD8+ T cells transduced with lentiviral vector encoding a chimeric antigen receptor \(CAR\) directed against human B cell maturation antigen \(BCMA\) and preserving the T cell phenotype of the leukapheresis starting material - EMEA-003231-PIP01-22](#)

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Treatment of multiple myeloma

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.42. Gallium 68-labelled prostate-specific membrane antigen-11 (68Ga-PSMA-11) - EMEA-003236-PIP01-22

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Visualisation of prostate specific membrane antigen in prostate cancer

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.43. Golidocitinib - EMEA-003246-PIP01-22

---

Treatment of relapsed or refractory peripheral T cell lymphoma

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.44. Lutetium (177Lu) edotreotide - Orphan - EMEA-003245-PIP01-22

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ITM Solucin GmbH; Treatment of somatostatin receptor (SSTR)-positive tumours

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.45. Monalizumab - EMEA-002751-PIP02-22

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Treatment of lung cancer

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.46. Obinutuzumab - Orphan - EMEA-001207-PIP04-22

---

Roche Registration GmbH; Prevention of cytokine release syndrome

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.47. Oleclumab - EMEA-003234-PIP01-22

---

Treatment of lung cancer / Treatment of pancreatic cancer

Day 30 discussion

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**Action:** For discussion

Oncology

### 3.1.48. [Toripalimab - EMEA-003243-PIP01-22](#)

---

Treatment of all conditions in the category of malignant neoplasms (except CNS, haematopoietic and lymphoid tissue)

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.49. [Vepsitamab - EMEA-003230-PIP01-22](#)

---

Treatment of gastrointestinal solid tumours malignant and unspecified expressing MUC17

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.50. [Xevinapant - Orphan - EMEA-003235-PIP01-22](#)

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Merck Healthcare KGaA; Treatment of squamous cell carcinoma of the head and neck

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.51. [Dimeric protein comprised of two disulfide-linked monomers, each being a fully human fusion protein consisting of a modified extracellular domain \(ECD\) of the human activin receptor type IIA \(ActRIIA\) fused to the fragment crystallizable \(Fc\) domain of human IgG1 Fc including the hinge region, CH2 and CH3 domains - EMEA-003239-PIP01-22](#)

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Treatment of myelodysplastic syndrome (MDS) and myelofibrosis (MF)

Day 30 discussion

**Action:** For discussion

Oncology / Haematology-Hemostaseology

### 3.1.52. [Tinlarebant - Orphan - EMEA-003225-PIP01-22](#)

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Belite Bio, Inc; Treatment of Stargardt disease

Day 30 discussion

**Action:** For discussion

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### 3.3.13. Belimumab - EMEA-000520-PIP02-13-M04

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Glaxo Group Limited; Treatment of systemic lupus erythematosus

Day 30 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation

### 3.3.14. Griselimab setaritox / dafsolimab setaritox - Orphan - EMEA-002087-PIP01-16-M01

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Xenikos B.V.; Treatment of acute graft versus host disease

Day 30 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation

### 3.3.15. Upadacitinib - EMEA-001741-PIP04-17-M03

---

AbbVie Ltd; Treatment of atopic dermatitis

Day 30 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation / Dermatology

### 3.3.16. Baloxavir marboxil - EMEA-002440-PIP01-18-M03

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Roche Registration GmbH; Prevention of influenza / Treatment of influenza

Day 30 discussion

**Action:** For discussion

Infectious Diseases

### 3.3.17. BNT162b2 / tozinameran - EMEA-002861-PIP02-20-M04

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BioNTech Manufacturing GmbH; Treatment of coronavirus disease 2019 (COVID-19) /  
Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

**Action:** For discussion

Infectious Diseases

### 3.3.18. Cabotegravir - EMEA-001418-PIP01-13-M05

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

Day 30 discussion

**Action:** For discussion

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Infectious Diseases

### 3.3.19. Cobicistat - EMEA-000969-PIP01-10-M06

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

Day 30 discussion

**Action:** For discussion

Infectious Diseases

### 3.3.20. Emtricitabine / tenofovir alafenamide - EMEA-001577-PIP02-14-M05

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

Day 30 discussion

**Action:** For discussion

Infectious Diseases

### 3.3.21. Lamivudine / dolutegravir - EMEA-001940-PIP01-16-M04

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

Day 30 discussion

**Action:** For discussion

Infectious Diseases

### 3.3.22. Rilpivirine - EMEA-000317-PIP02-18-M01

Janssen-Cilag International NV; Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

**Action:** For discussion

Infectious Diseases

### 3.3.23. Tenofovir alafenamide / rilpivirine / emtricitabine - EMEA-001679-PIP01-14-M02

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

Day 30 discussion

**Action:** For discussion

Infectious Diseases

### 3.3.24. Zoliflodacin - EMEA-002599-PIP01-19-M01

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Entasis Therapeutic Inc.; Treatment of gonococcal infection

Day 30 discussion

**Action:** For discussion

Infectious Diseases

### 3.3.25. Fenfluramine hydrochloride - Orphan - EMEA-001990-PIP01-16-M05

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Zogenix International Ltd; Treatment of Dravet syndrome

Day 30 discussion

**Action:** For discussion

Neurology

### 3.3.26. Ozanimod (hydrochloride) - EMEA-001710-PIP02-14-M07

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Bristol-Myers Squibb Pharma EEIG; Treatment of multiple sclerosis

Day 30 discussion

**Action:** For discussion

Neurology

### 3.3.27. Peginterferon beta-1a - EMEA-001129-PIP01-11-M05

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Biogen Idec Ltd; Treatment of multiple sclerosis

Day 30 discussion

**Action:** For discussion

Neurology

### 3.3.28. Cabozantinib - Orphan - EMEA-001143-PIP01-11-M05

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Ipsen Pharma; Treatment of malignant solid tumours

Day 30 discussion

**Action:** For discussion

Oncology

### 3.3.29. Copanlisib - Orphan - EMEA-001757-PIP02-15-M03

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Bayer AG; Treatment of mature B cell neoplasms / Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue)

Day 30 discussion

**Action:** For discussion

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Oncology

### 3.3.30. Durvalumab - EMEA-002028-PIP01-16-M03

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AstraZeneca AB; Treatment of malignant neoplasms of lymphoid tissue / Treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lymphoid tissue)

Day 30 discussion

**Action:** For discussion

Oncology

### 3.3.31. Inotuzumab ozogamicin - Orphan - EMEA-001429-PIP01-13-M06

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Pfizer Europe MA EEIG; Treatment of acute lymphoblastic leukaemia

Day 30 discussion

**Action:** For discussion

Oncology / Haematology-Hemostaseology

### 3.3.32. Lomitapide (as lomitapide mesylate) - EMEA-001124-PIP01-10-M05

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Amryt Pharmaceuticals DAC; Treatment of heterozygous and homozygous familial hypercholesterolaemia

Day 30 discussion

**Action:** For discussion

Other

### 3.3.33. Cannabidiol / delta-9-tetrahydrocannabinol - EMEA-000181-PIP02-13-M01

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GW Pharma (International) B.V; Treatment of pain

Day 30 discussion

**Action:** For discussion

Pain

### 3.3.34. Adrenaline (epinephrine) - EMEA-002749-PIP01-19-M02

---

ARS Pharmaceuticals IRL, Limited; Treatment of allergic reactions

Day 30 discussion

**Action:** For discussion

Pneumology - Allergology



### 3.3.35. Cholera vaccine, recombinant, live, oral (strain CVD 103-HgR) - EMEA-001490-PIP01-13-M03

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Emergent Netherlands B.V.; Treatment of cholera disease caused by *Vibrio cholerae* serogroup O1

Day 30 discussion

**Action:** For discussion

Vaccines

### 3.3.36. Tremelimumab - Orphan - EMEA-002029-PIP01-16-M03

---

AstraZeneca AB; Treatment of malignant neoplasms of haematologic and lymphoid tissue / Treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lymphoid tissue)

Day 30 discussion

**Action:** For discussion

Oncology

### 3.3.37. For single-stranded, 5'-capped messenger RNA (mRNA) produced using a cell-free in vitro transcription from the corresponding DNA templates, encoding the viral spike (S) protein of SARS-CoV-2 - EMEA-002893-PIP01-20-M02

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Moderna Biotech Spain, S.L.; Prevention of coronavirus disease 2019 (COVID-19)

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 11 July 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

#### 6.1.1. AZD9833 (selective estrogen receptor degrader) - EMEA-01-2022

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AstraZeneca AB; The classes of oestrogen receptor modulator medicinal products for treatment of breast malignant neoplasms / Treatment of estrogen receptor positive, locally advanced or metastatic breast cancer / Treatment of hormone receptor positive breast cancer

**Action:** For adoption

#### 6.1.2. Donanemab - EMEA-03-2022

---

Eli Lilly and Company Limited; All classes of medicinal products for treatment of Alzheimer's disease / Slowing disease progression in patients with early symptomatic Alzheimer's disease

**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 item

## 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

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**Action:** For information

#### 9.1.2. Vote by Proxy

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**Action:** For information

#### 9.1.3. Mandate of PDCO Chairperson - call for nominations

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**Action:** For information

### 9.2. Coordination with EMA Scientific Committees or CMDh-v

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

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**Action:** For information

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

#### 9.3.1. Non-clinical Working Party: D30 Products identified

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PDCO member: Karen van Malderen

**Action:** For information

#### 9.3.2. Formulation Working Group

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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)

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**Action:** For information

## 9.5. Cooperation with International Regulators

No item

## 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

### 9.8.1. EMA Business Pipeline activity and Horizon scanning

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Q2/2022 Update of the Business Pipeline report for the human scientific committees

**Action:** For information

## 10. Any other business

### 10.1. COVID-19 update

**Action:** For information

### 10.2. Exparel liposomal - EMEA/H/C/004586/II/0005 PDCO consultation from CHMP

**Action:** For discussion

### 10.3. EU Survey Testing

**Action:** For information

### 10.4. Revision of the guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus

PDCO members: Carine de Beaufort, Agnes Gyurasics

**Action:** For adoption

## **11. Breakout sessions**

### **11.1. Neonatology**

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

### **11.2. Vaccines**

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

### **11.3. Paediatric oncology**

**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/](http://www.ema.europa.eu/)