



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

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Human Medicines Division

## Paediatric Committee (PDCO)

### Draft Agenda for the meeting on 20-23 July 2021

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

20 July 2021, 11:00 - 19:00

21 July 2021, 08:30 - 19:00

22 July 2021, 08:30 - 19:00

23 July 2021, 08:30 - 13:00

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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 ongoing 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 20-23 July 2021. See July 2021 PDCO minutes (to be published post September 2021 PDCO meeting).

### 1.2. Adoption of agenda

PDCO agenda for 20-23 July 2021

### 1.3. Adoption of the minutes

PDCO minutes for 22-25 June 2021

## 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. EMEA-002870-PIP01-20

---

General anesthesia

Day 120 opinion

**Action:** For adoption

Anaesthesiology

#### 2.1.2. Benralizumab - EMEA-001214-PIP05-19

---

Treatment of eosinophilic esophagitis (EoE)

Day 120 opinion

**Action:** For adoption

Gastroenterology-Hepatology

#### 2.1.3. Cendakimab - EMEA-002640-PIP01-19

---

Eosinophilic esophagitis

---

Day 120 opinion

**Action:** For adoption

Gastroenterology-Hepatology

2.1.4. [\(S\)-1-\(5-\(\(2,3-dihydro-\[1,4\]dioxino\[2,3-b\]pyridin-7-yl\)sulfonyl\)-3,4,5,6-tetrahydropyrrolo\[3,4-c\]pyrrol-2\(1H\)-yl\)-3-hydroxy-2-phenylpropan-1-one - Orphan - EMEA-002924-PIP01-20](#)

---

Forma Therapeutics, Inc.; Treatment of sickle cell disease

Day 120 opinion

**Action:** For adoption, Oral explanation to be held on Wednesday, 21 July 2021 at 14:00

Haematology-Hemostaseology

2.1.5. [Concizumab - Orphan - EMEA-002326-PIP04-20](#)

---

Novo Nordisk A/S; Treatment of congenital haemophilia A / Treatment of congenital haemophilia B

Day 120 opinion

**Action:** For adoption

Haematology-Hemostaseology

2.1.6. [Baricitinib - EMEA-001220-PIP08-20](#)

---

Treatment of alopecia areata

Day 120 opinion

**Action:** For adoption

Immunology-Rheumatology-Transplantation

2.1.7. [Casirivimab - EMEA-002964-PIP01-21](#)

---

Prophylaxis of SARS-CoV-2 infection / Treatment of coronavirus disease 2019 (COVID-19) / Treatment and decreased transmission of coronavirus disease 2019 (COVID-19)

Day 120 opinion

**Action:** For adoption

Infectious Diseases

2.1.8. [Imdevimab - EMEA-002965-PIP01-21](#)

---

Prophylaxis of SARS-CoV-2 infection / Treatment of coronavirus disease 2019 (COVID-19) / Treatment and decreased transmission of coronavirus disease 2019 (COVID-19)

Day 120 opinion

**Action:** For adoption

Infectious Diseases

---

#### 2.1.9. Potassium Bitartrate / Citric Acid / L-Lactic Acid - EMEA-002917-PIP01-20

---

Prevention of urogenital *Chlamydia trachomatis* (CT) infection and *Neisseria gonorrhoeae* (GC) infections in females

Day 120 opinion

**Action:** For adoption

Infectious Diseases

---

#### 2.1.10. Epcoritamab - EMEA-002907-PIP01-20

---

Treatment of mature B-cell malignancies

Day 120 opinion

**Action:** For adoption

Oncology

---

#### 2.1.11. Ribitol - Orphan - EMEA-002887-PIP01-20

---

Premier Research Group S.L.; Treatment of Limb-Girdle muscular dystrophy

Day 120 opinion

**Action:** For adoption

Other

---

#### 2.1.12. Ligelizumab - EMEA-001811-PIP03-20

---

Treatment of food allergy

Day 120 opinion

**Action:** For adoption

Pneumology - Allergology

---

#### 2.1.13. Single chain urokinase plasminogen activator (scuPA) - Orphan - EMEA-002896-PIP01-20

---

Lung Therapeutics, Inc.; Treatment of infectious pleural effusion

Day 120 opinion

**Action:** For adoption

Pneumology - Allergology

2.1.14. [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](#)

---

Parion Sciences, Inc.; Primary Ciliary Dyskinesia (PCD)

Day 120 opinion

**Action:** For adoption

Pneumology - Allergology

2.1.15. [Multivalent pneumococcal polysaccharide conjugate to carrier protein - EMEA-002780-PIP02-20](#)

---

Prevention of disease caused by *Streptococcus pneumoniae*

Day 120 opinion

**Action:** For adoption

Vaccines

2.1.16. [Florbetaben \(18F\) - Orphan - EMEA-001090-PIP02-21](#)

---

Life Molecular Imaging GmbH; Diagnosis of cardiac amyloidosis

Day 60 opinion

**Action:** For adoption

2.1.17. [Bisoprolol / amlodipine / indapamide / perindopril \(arginine\) - EMEA-003015-PIP01-21](#)

---

Treatment of (essential) primary hypertension

Day 60 opinion

**Action:** For adoption

Cardiovascular Diseases

2.1.18. [Prasterone / levonorgestrel / ethinylestradiol - EMEA-002960-PIP02-21](#)

---

Treatment of hypoactive sexual desire disorder secondary to combined oral contraception use in women requiring contraception

Day 60 opinion

**Action:** For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

#### 2.1.19. Atezolizumab - EMEA-001638-PIP02-21

---

Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumors, hematopoietic and lymphoid tissue neoplasms)

Day 60 opinion

**Action:** For adoption

Oncology

#### 2.1.20. Ociperlimab - EMEA-003028-PIP01-21

---

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

Day 60 opinion

**Action:** For adoption

Oncology

#### 2.1.21. Prednisolone - EMEA-003004-PIP01-21

---

Treatment of prostate cancer

Day 60 opinion

**Action:** For adoption

Oncology

#### 2.1.22. Selinexor - EMEA-002387-PIP02-21

---

Recurrent or advanced endometrial cancer

Day 60 opinion

**Action:** For adoption

Oncology

#### 2.1.23. Tocilizumab - EMEA-000309-PIP07-21

---

Treatment of coronavirus disease 2019 (COVID-19)

Day 60 opinion

**Action:** For adoption

Immunology-Rheumatology-Transplantation

#### 2.1.24. Ligelizumab - EMEA-001811-PIP04-21

---

Treatment of chronic inducible urticaria

Day 60 opinion

**Action:** For adoption

Dermatology

#### 2.1.25. Molnupiravir - EMEA-002940-PIP01-20

---

Treatment of coronavirus disease 2019 (COVID-19)

Day 90 opinion

**Action:** For adoption

Infectious Diseases

## **2.2. Opinions 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.

#### 2.2.1. Octocog alfa - EMEA-C-001064-PIP01-10-M03

---

Bayer AG; Treatment of hereditary Factor VIII deficiency

Day 60 opinion

**Action:** For adoption

Haematology-Hemostaseology

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

#### 2.3.1. Entrectinib - EMEA-002096-PIP01-16-M03

---

Roche Registration GmbH; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms)

Day 60 opinion

**Action:** For adoption

#### 2.3.2. Rezafungin acetate - Orphan - EMEA-002319-PIP01-17-M01

---

Mundipharma Corporation (Ireland) Limited; Treatment of invasive candidiasis

Day 60 opinion

**Action:** For adoption

#### 2.3.3. Brodalumab - EMEA-001089-PIP02-13-M02

---

LEO Pharma A/S; Treatment of psoriasis

---



Day 60 opinion

**Action:** For adoption

Dermatology

#### 2.3.4. Rubidium Rb-82 Chloride - EMEA-000882-PIP03-11-M05

Jubilant DraxImage Inc., dba Jubilant Radiopharma; Visualisation of myocardial perfusion for diagnostic purposes

Day 60 opinion

**Action:** For adoption

Diagnostic

#### 2.3.5. Avalglucosidase alfa - Orphan - EMEA-001945-PIP01-16-M03

Genzyme Europe B.V.; Glycogen storage disease (Pompe disease)

Day 60 opinion

**Action:** For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

#### 2.3.6. Dasiglucagon - Orphan - EMEA-002233-PIP01-17-M01

Zealand Pharma A/S; Treatment of hypoglycaemia

Day 60 opinion

**Action:** For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

#### 2.3.7. Metreleptin - Orphan - EMEA-001701-PIP01-14-M02

Amryt Pharmaceuticals DAC; Treatment of lipodystrophy

Day 60 opinion

**Action:** For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

#### 2.3.8. Recombinant parathyroid hormone: rhPTH (1-84) - Orphan - EMEA-001526-PIP01-13-M05

Shire Pharmaceuticals Ireland Limited; Hypoparathyroidism

Day 60 opinion

**Action:** For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

### 2.3.9. Tolvaptan - EMEA-001231-PIP02-13-M08

Otsuka Pharmaceutical Netherlands B.V.; Polycystic kidney disease (PKD)

Day 60 opinion

**Action:** For adoption

Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology

### 2.3.10. Dupilumab - EMEA-001501-PIP04-19-M01

Regeneron Ireland DAC; Eosinophilic esophagitis

Day 60 opinion

**Action:** For adoption

Gastroenterology-Hepatology

### 2.3.11. Naldemedine - EMEA-001893-PIP01-15-M02

Shionogi B.V.; Opioid-induced constipation (OIC)

Day 60 opinion

**Action:** For adoption

Gastroenterology-Hepatology

### 2.3.12. Pegylated-fibroblast growth factor 21 (BMS-986036) - EMEA-002448-PIP01-18-M02

Bristol-Myers Squibb International Corporation; Treatment of non-alcoholic steatohepatitis (NASH)

Day 60 opinion

**Action:** For adoption

Gastroenterology-Hepatology

### 2.3.13. Fidanacogene elaparvovec - Orphan - EMEA-002362-PIP02-19-M01

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

Day 60 opinion

**Action:** For adoption

Haematology-Hemostaseology

#### 2.3.14. Narsoplimab - Orphan - EMEA-002479-PIP01-18-M01

---

Omeros Ireland Limited; Treatment in haematopoietic stem cell transplantation

Day 60 opinion

**Action:** For adoption

Haematology-Hemostaseology

#### 2.3.15. Aztreonam / Avibactam - EMEA-002283-PIP01-17-M02

---

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

Day 60 opinion

**Action:** For adoption

Infectious Diseases

#### 2.3.16. Cabotegravir - EMEA-001418-PIP01-13-M03

---

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

Day 60 opinion

**Action:** For adoption

Infectious Diseases

#### 2.3.17. Cabotegravir - EMEA-001418-PIP02-15-M02

---

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

Day 60 opinion

**Action:** For adoption

Infectious Diseases

#### 2.3.18. Remdesivir - EMEA-002826-PIP01-20-M02

---

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

Day 60 opinion

**Action:** For adoption

Infectious Diseases

#### 2.3.19. (R)-2-amino-3-phenylpropylcarbamate hydrochloride - EMEA-002184-PIP01-17-M01

---

Jazz Pharmaceuticals Ireland Limited; Treatment of narcolepsy / Treatment of obstructive sleep apnoea

Day 60 opinion

**Action:** For adoption

Neurology

#### 2.3.20. Bumetanide - EMEA-001303-PIP01-12-M04

---

Les Laboratoires Servier; Autism spectrum disorder

Day 60 opinion

**Action:** For adoption

Neurology

#### 2.3.21. Lacosamide - EMEA-000402-PIP03-17-M05

---

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

Day 60 opinion

**Action:** For adoption

Neurology

#### 2.3.22. Autologous tumor-infiltrating lymphocytes (LN-144/LN-145) - EMEA-002776-PIP01-20-M01

---

Iovance Biotherapeutics, Inc.; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms)

Day 60 opinion

**Action:** For adoption

Oncology

#### 2.3.23. Bintrafusp alfa - Orphan - EMEA-002586-PIP01-19-M02

---

Merck Europe B.V.; Treatment of all conditions included in the category of malignant neoplasms (except central nervous system neoplasms, haematopoietic and lymphoid tissue neoplasms)

Day 60 opinion

**Action:** For adoption

Oncology

#### 2.3.24. Bosutinib - EMEA-000727-PIP01-09-M05

---

Pfizer Europe MA EEIG; Treatment of chronic myeloid leukemia

Day 60 opinion

**Action:** For adoption

Oncology

#### **2.3.25. Pevonedistat - Orphan - EMEA-002117-PIP01-17-M02**

---

Takeda Pharma A/S; Treatment of acute myeloid leukaemia / Treatment of myelodysplastic syndromes

Day 60 opinion

**Action:** For adoption

Oncology

#### **2.3.26. Selumetinib - Orphan - EMEA-001585-PIP01-13-M05**

---

AstraZeneca AB; Treatment of thyroid cancer / Treatment of melanoma / Treatment of neurofibromatosis type 1

Day 60 opinion

**Action:** For adoption

Oncology

#### **2.3.27. Bupropion HCl / Naltrexone HCl - EMEA-001373-PIP01-12-M04**

---

Orexigen Therapeutics Ireland Limited; Treatment of obesity

Day 60 opinion

**Action:** For adoption

Other

#### **2.3.28. Eliglustat - Orphan - EMEA-000461-PIP02-11-M04**

---

Genzyme Europe B.V.; Treatment of Gaucher disease Type 1 and Type 3; Treatment of Gaucher disease Type 2

Day 60 opinion

**Action:** For adoption

Other

#### **2.3.29. Human Thrombin / Human Fibrinogen - EMEA-001149-PIP01-11-M07**

---

Omrix Biopharmaceuticals N.V.; Treatment of cerebrospinal fluid leakage resulting from a surgical procedure / Treatment of haemorrhage resulting from a surgical procedure

Day 60 opinion

**Action:** For adoption

Other

### 2.3.30. Mexiletine hydrochloride - Orphan - EMEA-002012-PIP01-16-M03

Lupin Europe GmbH; Treatment of myotonic disorders

Day 60 opinion

**Action:** For adoption

Other

### 2.3.31. Patiromer calcium - EMEA-001720-PIP01-14-M02

Vifor Fresenius Medical Care Renal Pharma France; Treatment of hyperkalaemia

Day 60 opinion

**Action:** For adoption

Other

### 2.3.32. Bupivacaine - EMEA-000877-PIP03-17-M03

Pacira Ltd; Postsurgical analgesia

Day 60 opinion

**Action:** For adoption

Pain

### 2.3.33. Amikacin sulfate - Orphan - EMEA-000525-PIP01-08-M07

Insmed Netherlands B.V.; Treatment of nontuberculous mycobacterial (NTM) lung infection / Treatment of Pseudomonas aeruginosa lung infection/colonisation in cystic fibrosis patients

Day 60 opinion

**Action:** For adoption

Pneumology - Allergology

### 2.3.34. Bertralstat - EMEA-002449-PIP02-18-M01

BioCryst Ireland Limited; Treatment of hereditary angioedema

Day 60 opinion

**Action:** For adoption

Pneumology - Allergology

2.3.35. Mometasone (furoate) / Glycopyrronium bromide / Indacaterol - EMEA-001812-PIP01-15-M01

---

Novartis Europharm Limited; Treatment of asthma

Day 60 opinion

**Action:** For adoption

Pneumology - Allergology

2.3.36. Pneumococcal Polysaccharide Serotype 33F - Diphtheria CRM197 Conjugate /  
Pneumococcal Polysaccharide Serotype 23F - Diphtheria CRM197 Conjugate /  
Pneumococcal Polysaccharide Serotype 22F - Diphtheria CRM197 Conjugate /  
Pneumococcal Polysaccharide Serotype 19F - Diphtheria CRM197 Conjugate /  
Pneumococcal Polysaccharide Serotype 19A - Diphtheria CRM197 Conjugate /  
Pneumococcal Polysaccharide Serotype 18C - Diphtheria CRM197 Conjugate /  
Pneumococcal Polysaccharide Serotype 14 - Diphtheria CRM197 Conjugate /  
Pneumococcal Polysaccharide Serotype 9V - Diphtheria CRM197 Conjugate /  
Pneumococcal Polysaccharide Serotype 7F - Diphtheria CRM197 Conjugate /  
Pneumococcal Polysaccharide Serotype 6B - Diphtheria CRM197 Conjugate /  
Pneumococcal Polysaccharide Serotype 6A - Diphtheria CRM197 Conjugate /  
Pneumococcal Polysaccharide Serotype 5 - Diphtheria CRM197 Conjugate /  
Pneumococcal Polysaccharide Serotype 4 - Diphtheria CRM197 Conjugate /  
Pneumococcal Polysaccharide Serotype 3 - Diphtheria CRM197 Conjugate /  
Pneumococcal Polysaccharide Serotype 1 - Diphtheria CRM197 Conjugate - EMEA-002215-PIP01-17-M03

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Merck Sharp & Dohme (Europe), Inc.; Prevention of disease caused by Streptococcus pneumoniae

Day 60 opinion

**Action:** For adoption

Vaccines

2.3.37. Pneumococcal polysaccharide serotype 33F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 23F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate /  
Pneumococcal polysaccharide serotype 22F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 19F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate /  
Pneumococcal polysaccharide serotype 19A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 18C conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate /  
Pneumococcal polysaccharide serotype 15B conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 14 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate /  
Pneumococcal polysaccharide serotype 12F conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 11A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate /  
Pneumococcal polysaccharide serotype 10A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 9V conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate /  
Pneumococcal polysaccharide serotype 8 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 7F

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conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 6B conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 6A conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 5 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polyssacharide serotype 4 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 3 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate / Pneumococcal polysaccharide serotype 1 conjugated to CRM197 carrier protein and adsorbed on aluminium phosphate - EMEA-002330-PIP01-18-M01

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Pfizer Europe MA EEIG; Disease caused by *Streptococcus pneumoniae*

Day 60 opinion

**Action:** For adoption

Vaccines

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### 2.3.38. Recombinant *Clostridioides difficile* Toxoids A and B - EMEA-002112-PIP01-16-M01

---

Pfizer Europe MA EEIG; Prevention of *Clostridioides difficile* infection

Day 60 opinion

**Action:** For adoption

Vaccines

### 2.3.39. 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-M03

---

Sanofi Pasteur; Prevention of influenza infection

Day 60 opinion

**Action:** For adoption

Vaccines

## 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. Tabelecleucel - EMEA-C1-002025-PIP04-19

---

Atara Biotherapeutics Inc; Treatment of Epstein-Barr virus associated post-transplant lymphoproliferative disorder

Day 30 letter

**Action:** For information

Immunology-Rheumatology-Transplantation / Oncology

### 2.7.2. Remdesivir - EMEA-C2-002826-PIP01-20-M01

---

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

Day 30 letter

**Action:** For information

Infectious Diseases

### 2.7.3. Gadopiclenol - EMEA-C1-001949-PIP01-16-M04

---

Guerbet; Detection and visualisation of areas with disruption of the blood brain barrier and/or abnormal vascularity for diagnostic purposes

Day 30 letter

**Action:** For information

Diagnostic

### 2.7.4. Gadopiclenol - EMEA-C1-001949-PIP02-18-M01

---

Guerbet; Detection and visualization of disorders or lesions with suspected abnormal vascularity in various body regions for diagnostic purposes

Day 30 letter

**Action:** For information

Diagnostic

### 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. PCSK9-targeted, antisense oligonucleotide (ASO) - EMEA-002962-PIP01-21

---

Treatment of elevated cholesterol / Treatment of mixed dyslipidaemia

Day 90 discussion

**Action:** For discussion

Cardiovascular Diseases

##### 3.1.2. EMEA-002944-PIP01-20

---

Treatment of Type 2 Diabetes Mellitus

Day 90 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

##### 3.1.3. Drospirenone - EMEA-001495-PIP02-21

---

Treatment of endometriosis

Day 90 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

##### 3.1.4. Glepaglutide - EMEA-002926-PIP01-20

---

Treatment of short bowel syndrome

Day 90 discussion

**Action:** For discussion

Gastroenterology-Hepatology

##### 3.1.5. Semaglutide - EMEA-001441-PIP05-20

---

Treatment of non-alcoholic steatohepatitis / Treatment of non-alcoholic steatohepatitis (NASH)

Day 90 discussion

**Action:** For discussion

Gastroenterology-Hepatology

### 3.1.6. EMEA-002927-PIP01-20

---

Treatment of chronic idiopathic arthritis / Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis)

Day 90 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation

### 3.1.7. Islatravir - EMEA-002938-PIP01-20

---

Prevention of human immunodeficiency virus (HIV-1) infection

Day 90 discussion

**Action:** For discussion

Infectious Diseases

### 3.1.8. Pritelivir - EMEA-002180-PIP02-19

---

Treatment of herpes simplex virus disease

Day 90 discussion

**Action:** For discussion

Infectious Diseases

### 3.1.9. EMEA-002984-PIP01-21

---

Treatment of onychomycosis

Day 90 discussion

**Action:** For discussion

Infectious Diseases

### 3.1.10. Crisantaspace - EMEA-002934-PIP01-20

---

Acute lymphoblastic leukaemia / lymphoma / Treatment of acute lymphoblastic leukaemia / lymphoma

Day 90 discussion

**Action:** For discussion

Oncology

### 3.1.11. Loncastuximab tesirine - EMEA-002665-PIP02-20

---

Treatment of B-cell non-Hodgkin Lymphoma / Treatment of mature B-cell neoplasms

Day 90 discussion

**Action:** For discussion

Oncology

### 3.1.12. Brensocatib - EMEA-002905-PIP01-20

---

Non-cystic fibrosis bronchiectasis (NCFBE)

Day 90 discussion

**Action:** For discussion

Pneumology - Allergology

### 3.1.13. Thienopyrimidine Derivative - EMEA-002901-PIP01-20

---

Treatment of fibrosing interstitial lung disease

Day 90 discussion

**Action:** For discussion

Pneumology - Allergology

### 3.1.14. Ravulizumab - EMEA-001943-PIP02-20

---

Treatment in haematopoietic stem cell transplantation / Treatment in haematopoietic stem cell transplantation

Day 90 discussion

**Action:** For discussion

Uro-nephrology / Haematology-Hemostaseology

### 3.1.15. EMEA-002873-PIP01-20

---

Active immunisation for the prevention of disease caused by chikungunya virus

Day 90 discussion

**Action:** For discussion

Vaccines

### 3.1.16. Respiratory Syncytial Virus (RSV) PreF3 recombinant Fusion protein - EMEA-002904-PIP01-20

---

Prevention of lower respiratory tract disease caused by respiratory syncytial virus

Day 90 discussion

**Action:** For discussion

Vaccines

### [3.1.17. Abelacimab - EMEA-003017-PIP01-21](#)

---

Prevention of venous thromboembolism associated with cancer

Day 60 discussion

**Action:** For discussion

Cardiovascular Diseases

### [3.1.18. Dersimelagon - EMEA-002850-PIP02-21](#)

---

Treatment of erythropoietic protoporphyria / Treatment of X-linked protoporphyria

Day 60 discussion

**Action:** For discussion

Dermatology

### [3.1.19. EMEA-003027-PIP01-21](#)

---

Treatment of Hyperphenylalaninaemia

Day 60 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### [3.1.20. EMEA-002992-PIP01-21](#)

---

Treatment of Fibrodysplasia Ossificans Progressiva (FOP).

Day 60 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### [3.1.21. EMEA-003019-PIP01-21](#)

---

Treatment of inborn errors of amino acid metabolism

Day 60 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.1.22. Apraglutide - Orphan - EMEA-003016-PIP01-21

---

VectivBio AG; Treatment of short bowel syndrome

Day 60 discussion

**Action:** For discussion

Gastroenterology-Hepatology

### 3.1.23. Benralizumab - EMEA-001214-PIP07-21

---

Treatment of eosinophilic gastritis/eosinophilic gastroenteritis

Day 60 discussion

**Action:** For discussion

Gastroenterology-Hepatology

### 3.1.24. Izencitinib - EMEA-002757-PIP02-21

---

Treatment of Crohn's disease

Day 60 discussion

**Action:** For discussion

Gastroenterology-Hepatology

### 3.1.25. Autologous CD34+ cells transduced ex vivo with a lentiviral vector containing a modified gamma-globin gene - Orphan - EMEA-003029-PIP01-21

---

Aruvant Sciences GmbH; Treatment of sickle cell disease

Day 60 discussion

**Action:** For discussion

Haematology-Hemostaseology

### 3.1.26. Recombinant humanized anti-blood dendritic cell antigen 2 (BDCA2) monoclonal antibody - EMEA-002555-PIP02-21

---

Lupus erythematosus

Day 60 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation

### 3.1.27. 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 60 discussion

**Action:** For discussion

Infectious Diseases

---

### 3.1.28. Azithromycin - EMEA-003021-PIP01-21

---

Prevention of bronchopulmonary dysplasia

Day 60 discussion

**Action:** For discussion

Neonatology - Paediatric Intensive Care

---

### 3.1.29. Adeno-associated viral vector serotype rh.10 expressing beta-galactosidase - Orphan - EMEA-003020-PIP01-21

---

Lysogene; Treatment of GM1 gangliosidosis

Day 60 discussion

**Action:** For discussion

Neurology

---

### 3.1.30. Efgartigimod alfa - Orphan - EMEA-002597-PIP05-21

---

argenx BV; Treatment of myasthenia gravis

Day 60 discussion

**Action:** For discussion

Neurology

---

### 3.1.31. 2'-O-(2-methoxyethyl) modified antisense oligonucleotide targeting fused in sarcoma (FUS) pre-mRNA - EMEA-003024-PIP01-21

---

Amyotrophic lateral sclerosis (ALS) patients with fused in sarcoma (FUS) mutations (FUS-ALS)  $\geq 12$  years of age

Day 60 discussion

**Action:** For discussion

Neurology

---

### 3.1.32. Recombinant fusion protein linking human frataxin to TAT cell-penetrant peptide - Orphan - EMEA-003022-PIP01-21

---

Larimar Therapeutics Inc.; Friedreich's ataxia

Day 60 discussion

**Action:** For discussion

Neurology

### 3.1.33. Lorlatinib - EMEA-002669-PIP03-21

---

ALK-aberrant neuroblastoma

Day 60 discussion

**Action:** For discussion

Oncology

### 3.1.34. Pemigatinib - Orphan - EMEA-002370-PIP02-21

---

Incyte Biosciences Distribution B.V.; Treatment of myeloid/lymphoid neoplasms with eosinophilia and FGFR1 rearrangement

Day 60 discussion

**Action:** For discussion

Oncology

### 3.1.35. Vodobatinib - EMEA-003014-PIP01-21

---

Chronic myeloid leukemia

Day 60 discussion

**Action:** For discussion

Oncology

### 3.1.36. Vorasidenib - EMEA-002932-PIP02-21

---

Treatment of glioma

Day 60 discussion

**Action:** For discussion

Oncology

### 3.1.37. A recombinant SARS-CoV-2 Spike (S)-trimer fusion protein - EMEA-002987-PIP01-21

---

Prevention of COVID-19 disease

Day 60 discussion

**Action:** For discussion

Vaccines / Infectious Diseases



### 3.1.38. Amlodipine / zofenopril - EMEA-003036-PIP01-21

---

Treatment of essential hypertension

Day 30 discussion

**Action:** For discussion

Cardiovascular Diseases

### 3.1.39. Ezetimibe / rosuvastatin - EMEA-001447-PIP02-21

---

Prevention of cardiovascular events

Day 30 discussion

**Action:** For discussion

Cardiovascular Diseases

### 3.1.40. Ezetimibe / Rosuvastatin - EMEA-003018-PIP01-21

---

Treatment of hypercholesterolemia / Prevention of cardiovascular events

Day 30 discussion

**Action:** For discussion

Cardiovascular Diseases

### 3.1.41. Ezetimibe / Rosuvastatin - EMEA-003039-PIP01-21

---

Treatment of hypercholesterolemia / Prevention of cardiovascular events

Day 30 discussion

**Action:** For discussion

Cardiovascular Diseases

### 3.1.42. Dupilumab - EMEA-001501-PIP09-21

---

Chronic inducible cold urticaria

Day 30 discussion

**Action:** For discussion

Dermatology

### 3.1.43. Phospholipid esters from herring roe - EMEA-003053-PIP01-21

---

Treatment of psoriasis

Day 30 discussion

**Action:** For discussion

Dermatology

#### 3.1.44. [Bilastine - EMEA-000347-PIP06-21](#)

---

Treatment of acute type I hypersensitivity reactions either alone, or in severe cases as an adjunctive agent

Day 30 discussion

**Action:** For discussion

Dermatology / Pneumology - Allergology / Oto-rhino-laryngology

#### 3.1.45. [Manganese chloride - EMEA-003035-PIP01-21](#)

---

Diagnostic evaluation of liver lesions by magnetic resonance imaging (MRI)

Day 30 discussion

**Action:** For discussion

Diagnostic / Oncology

#### 3.1.46. [Perflubutane - EMEA-003037-PIP01-21](#)

---

Imaging of focal liver lesions

Day 30 discussion

**Action:** For discussion

Diagnostic / Oncology

#### 3.1.47. [Ibutamoren mesilate - Orphan - EMEA-003032-PIP01-21](#)

---

Lumos Pharma, Inc.; Treatment of growth hormone deficiency

Day 30 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

#### 3.1.48. [Pyridoxine / doxylamine - EMEA-001608-PIP02-21](#)

---

Treatment of nausea and vomiting of pregnancy / Treatment of nausea and vomiting of pregnancy

Day 30 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.1.49. Zinc Gluconate / Alisitol / Retinyl Palmitate - Orphan - EMEA-002198-PIP01-21

Vanessa Research Magyarorszag Kft/Vanessa Research Hungary Ltd; Diarrhea neonatal

Day 30 discussion

**Action:** For discussion

Gastroenterology-Hepatology

### 3.1.50. Mitapivat - Orphan - EMEA-002684-PIP02-21

Agios Netherlands B.V.; Treatment of thalassaemia

Day 30 discussion

**Action:** For discussion

Haematology-Hemostaseology

### 3.1.51. Rozanolixizumab - Orphan - EMEA-002681-PIP02-21

UCB Pharma S.A; Treatment of immune thrombocytopenia

Day 30 discussion

**Action:** For discussion

Haematology-Hemostaseology

### 3.1.52. Rusfertide - Orphan - EMEA-003045-PIP01-21

Protagonist Therapeutics, Inc.; Treatment of polycythaemia vera

Day 30 discussion

**Action:** For discussion

Haematology-Hemostaseology

### 3.1.53. Autologous bone marrow derived CD34+cells transduced with the lentiviral vector CL20-4i-EF1 $\alpha$ -hyc-OPT - Orphan - EMEA-003050-PIP01-21

Mustang Bio, Inc.; Treatment of X-linked severe combined immunodeficiency (XSCID)

Day 30 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation

### 3.1.54. Otilimab - EMEA-001882-PIP04-21

Treatment of COVID-19

Day 30 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation

### 3.1.55. Tocilizumab - EMEA-000309-PIP06-21

---

Scleroderma and associated disorders

Day 30 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation

### 3.1.56. Anti-C1s Humanized IgG4 Monoclonal Antibody - EMEA-002903-PIP03-21

---

Treatment of chronic inflammatory demyelinating Polyradiculoneuropathy

Day 30 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology / Neurology

### 3.1.57. ECT-001-CB (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) - Orphan - EMEA-003025-PIP02-21

---

ExCellThera; 2020-ICD-10-CM Diagnosis code: Z94.84T (allogeneic haematopoietic stem cell transplantation)

Day 30 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation / Oncology / Haematology-Hemostaseology

### 3.1.58. Reparixin - Orphan - EMEA-001693-PIP03-21

---

Dompé farmaceutici S.p.A.; Treatment of COVID-2019 complications

Day 30 discussion

**Action:** For discussion

Infectious Diseases

### 3.1.59. ALPRAZOLAM - EMEA-003043-PIP01-21

---

Treatment of prolonged epileptic seizures

Day 30 discussion

**Action:** For discussion

Neurology

### 3.1.60. Anti-neonatal Fc receptor human monoclonal antibody - EMEA-002559-PIP04-21

Treatment of chronic inflammatory demyelinating polyradiculoneuropathy

Day 30 discussion

**Action:** For discussion

Neurology

### 3.1.61. Efgartigimod alfa - EMEA-002597-PIP06-21

Chronic inflammatory demyelinating polyneuropathy

Day 30 discussion

**Action:** For discussion

Neurology

### 3.1.62. Invimestrocel - EMEA-002317-PIP02-21

Treatment of acute ischaemic stroke / Acute ischaemic stroke

Day 30 discussion

**Action:** For discussion

Neurology

### 3.1.63. Izaflortaucipir (18F) - Orphan - EMEA-003040-PIP01-21

Life Molecular Imaging GmbH; Diagnosis of corticobasal degeneration / Diagnosis of progressive supranuclear palsy

Day 30 discussion

**Action:** For discussion

Neurology

### 3.1.64. Ocrelizumab - EMEA-000310-PIP04-21

Treatment of multiple sclerosis

Day 30 discussion

**Action:** For discussion

Neurology

### 3.1.65. Ravulizumab - EMEA-001943-PIP05-21

---

Amyotrophic lateral sclerosis

Day 30 discussion

**Action:** For discussion

Neurology

### 3.1.66. Rozanolixizumab - EMEA-002681-PIP03-21

---

Myelin oligodendrocyte glycoprotein antibody-associated disease

Day 30 discussion

**Action:** For discussion

Neurology

### 3.1.67. 1-[(4-[(4-fluoro-2-methyl-1H-indol-5-yl)oxy]-6-methoxyquinolin-7-yl)oxy)methyl]cyclopropan-1-amine bishydrochloride - Orphan - EMEA-002486-PIP04-21

---

Advenchen Laboratories, LLC.; Treatment of soft tissue sarcomas

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.68. 5'-capped mRNA encoding HPV16 oncoprotein E7 / 5'-capped mRNA encoding HPV16 oncoprotein E6 - EMEA-003023-PIP01-21

---

First-line treatment in combination with pembrolizumab for adult patients with metastatic or recurrent unresectable head and neck squamous cell carcinoma (excluding nasopharyngeal carcinoma) whose tumour is human papilloma virus 16 positive (HPV16+) and expresses programmed death-ligand 1 (PD L1) with a combined positive score  $\geq 1$

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.69. Alnuctamab - EMEA-003046-PIP01-21

---

Treatment of mature B cell neoplasms

Day 30 discussion

**Action:** For discussion

Oncology

3.1.70. Anti-CD123 IgG1 humanised monoclonal antibody conjugated to N1-(2-(2,5-dioxo-2,5-dihydro-1H-pyrrol-1-yl)ethyl)-N6-((S)-1-(((S)-1-(3-(((S)-8-methoxy-6-oxo-11,12,12a,13-tetrahydro-6H-benzo[5,6][1,4]diazepino[1,2-a]indol-9-yl)oxy)methyl)-5-(((S)-8-methoxy-6-oxo-12a,13-dihydro-6Hbenzo[5,6][1,4]diazepino[1,2-a]indol-9-yl)oxy)methyl)phenyl)amino)-1-oxopropan-2-yl)amino)-1-oxopropan-2-yl)adipamide - Orphan - EMEA-003044-PIP01-21

---

Immunogen BioPharma (Ireland) Limited; Treatment of blastic plasmacytoid dendritic cell neoplasm

Day 30 discussion

**Action:** For discussion

Oncology

3.1.71. B cell maturation antigen antibody-drug conjugate comprised of an immunoglobulin G1 humanized antibody conjugated covalently to the dibenzocyclooctyne noncleavable linker maytansinoid warhead - EMEA-003047-PIP01-21

---

Treatment of mature B cell neoplasms

Day 30 discussion

**Action:** For discussion

Oncology

3.1.72. Batiraxcept - EMEA-003042-PIP01-21

---

Treatment of ovarian cancer / Ovarian Cancer

Day 30 discussion

**Action:** For discussion

Oncology

3.1.73. Plinabulin - EMEA-003054-PIP01-21

---

Chemotherapy-induced neutropenia

Day 30 discussion

**Action:** For discussion

Oncology

3.1.74. Pralsetinib - EMEA-002575-PIP03-21

---

Treatment of all conditions included in the category of malignant neoplasms (except thyroid neoplasms)

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.75. [Senaparib - EMEA-003034-PIP01-21](#)

---

Metastatic castrate-resistant prostate cancer

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.76. [Tazemetostat - Orphan - EMEA-003055-PIP01-21](#)

---

Epizyme, Inc.; Soft tissue sarcomas / Treatment of soft tissue sarcomas / Treatment of mature B-Cell neoplasms / Mature B-Cell neoplasms

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.77. [Humanized monoclonal antibody of IgG1 sub-type targeting the human SEMA3A polypeptide - EMEA-002957-PIP02-21](#)

---

Treatment of diabetic retinopathy

Day 30 discussion

**Action:** For discussion

Ophthalmology

### 3.1.78. [EMEA-003048-PIP01-21](#)

---

Treatment of dry eye disease

Day 30 discussion

**Action:** For discussion

Ophthalmology

### 3.1.79. [Ofloxacin / Dexamethasone - EMEA-003031-PIP01-21](#)

---

Pre and post-operative eye surgeries where infection and inflammation may coexist / Bacterial infections of the eye showing a severe inflammatory reaction

Day 30 discussion

**Action:** For discussion

Ophthalmology



### 3.1.80. Lutetium (<sup>177</sup>Lu) - EMEA-003038-PIP01-21

---

Radiolabelling agent

Day 30 discussion

**Action:** For discussion

Other

### 3.1.81. Pabinafusp alfa - Orphan - EMEA-003033-PIP01-21

---

JCR Pharmaceuticals Co., Ltd.; Mucopolysaccharidosis Type II

Day 30 discussion

**Action:** For discussion

Other

### 3.1.82. Depemokimab - EMEA-003051-PIP01-21

---

Treatment of nasal polyps

Day 30 discussion

**Action:** For discussion

Pneumology - Allergology

### 3.1.83. EMEA-003052-PIP01-21

---

Treatment of cystic fibrosis

Day 30 discussion

**Action:** For discussion

Pneumology - Allergology

### 3.1.84. L-Carnitine/Glucose/Calcium Chloride Dihydrate/Magnesium Chloride Hexahydrate/Sodium Lactate/Sodium Chloride - EMEA-003049-PIP01-21

---

Treatment of patients in need of peritoneal dialysis

Day 30 discussion

**Action:** For discussion

Uro-nephrology

### 3.1.85. Neisseria meningitidis serogroup B fHbp subfamily B / Neisseria meningitidis serogroup B fHbp subfamily A / Neisseria meningitidis group Y polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis group W-135 polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria meningitidis group C polysaccharide conjugated to tetanus toxoid carrier protein / Neisseria

### meningitidis group A polysaccharide conjugated to tetanus toxoid carrier protein - EMEA-002814-PIP02-21

---

Invasive disease caused by *Neisseria meningitidis* group A, B, C, W and Y from 2 months of age

Day 30 discussion

**Action:** For discussion

Vaccines

### 3.1.86. SARS-CoV-2, produced in Vero cells, Inactivated - EMEA-003057-PIP01-21

---

Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

**Action:** For discussion

Vaccines

### 3.1.87. Yellow fever virus - EMEA-003030-PIP01-21

---

Prevention of yellow fever disease

Day 30 discussion

**Action:** For discussion

Vaccines

## 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. Tadalafil - EMEA-C-000452-PIP02-10-M06

---

Eli Lilly and Company Limited; Treatment of pulmonary arterial hypertension

Day 30 discussion

**Action:** For discussion

Cardiovascular Diseases

### 3.2.2. Cipaglucosidase alfa - EMEA-C2-002447-PIP01-18-M01

---

Amicus Therapeutics Europe Limited; Treatment of glycogen storage disease Type II (Pompe's disease)

Day 30 discussion

**Action:** For discussion

### 3.2.3. [Turoctocog alfa pegol - EMEA-C-001174-PIP02-12-M02](#)

---

Novo Nordisk A/S; Treatment of hereditary Factor VIII deficiency

Day 30 discussion

**Action:** For discussion

Haematology-Hemostaseology

### 3.2.4. [Relebactam / cilastatin sodium / imipenem monohydrate - EMEA-C3-001809-PIP01-15-M02](#)

---

Merck Sharp & Dohme (Europe), Inc.; Treatment of infections caused by Gram-negative organisms

Day 30 discussion

**Action:** For discussion

Infectious Diseases

### 3.2.5. [Cannabidiol - EMEA-C3-001964-PIP01-16-M03](#)

---

GW Pharma (International) B.V.; Treatment of seizures associated with infantile spasms

Day 30 discussion

**Action:** For discussion

Neurology

### 3.2.6. [Ganaxolone - EMEA-C1-002341-PIP01-18-M01](#)

---

Marinus Pharmaceuticals Inc.; Treatment of cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder

Day 30 discussion

**Action:** For discussion

Neurology

### 3.2.7. [Dexmedetomidine hydrochloride - EMEA-C1-002758-PIP01-19](#)

---

BioXcel Therapeutics, Inc.; Treatment of bipolar disorder

Day 30 discussion

**Action:** For discussion

Psychiatry

### 3.2.8. Mirabegron - EMEA-C3-000597-PIP03-15-M03

---

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

Day 30 discussion

**Action:** For discussion

Uro-nephrology

## 3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

### 3.3.1. Remimazolam - EMEA-001880-PIP02-19-M03

---

PAION Deutschland GmbH; Sedation / General anesthesia

Day 30 discussion

**Action:** For discussion

Anaesthesiology

### 3.3.2. Edoxaban tosylate - EMEA-000788-PIP02-11-M11

---

Daiichi Sankyo Europe GmbH; Prevention of venous thromboembolism / Treatment of venous thromboembolism / Prevention of arterial thromboembolism

Day 30 discussion

**Action:** For discussion

Cardiovascular Diseases / Haematology-Hemostaseology

### 3.3.3. Dulaglutide - EMEA-000783-PIP01-09-M06

---

Eli Lilly and Company; Treatment of type 2 diabetes mellitus

Day 30 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.3.4. Empagliflozin - EMEA-000828-PIP01-09-M09

---

Boehringer Ingelheim International GmbH; Treatment of type 2 diabetes mellitus

Day 30 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.3.5. Linagliptin - EMEA-000498-PIP01-08-M10

---

Boehringer Ingelheim International GmbH; Treatment of type 2 diabetes mellitus

Day 30 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.3.6. Recombinant human glutamic acid dexarboxylase (rhGAD65) - EMEA-000609-PIP01-09-M03

---

Diamyd Medical AB; Treatment of type 1 diabetes

Day 30 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.3.7. Semaglutide - EMEA-001441-PIP03-17-M02

---

Novo Nordisk A/S; Treatment of obesity

Day 30 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.3.8. Oxalobacter formigenes Strain HC-1 - Orphan - EMEA-000370-PIP02-18-M01

---

OxThera AB; Treatment of hyperoxaluria

Day 30 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology

### 3.3.9. Recombinant Human A Disintegrin and Metalloprotease with Thrombospondin Type-1 Motifs 13 (rADAMTS13) - Orphan - EMEA-001160-PIP01-11-M02

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Baxalta Innovations GmbH own by Takeda Pharmaceutical International AG; Treatment of thrombotic thrombocytopenic purpura

Day 30 discussion

**Action:** For discussion

Haematology-Hemostaseology

### 3.3.10. Fostemsavir (tromethamine) - EMEA-001687-PIP01-14-M05

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

Day 30 discussion

**Action:** For discussion

Infectious Diseases

### 3.3.11. [Oteficonazole - EMEA-002392-PIP01-18-M02](#)

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Gedeon Richter Plc.; Treatment of vulvovaginal candidiasis

Day 30 discussion

**Action:** For discussion

Infectious Diseases

### 3.3.12. [5-\[\[4-\[2-\[5-\(1-Hydroxyethyl\)-2-pyridinyl\]ethoxy\]phenyl\]methyl\]-2,4-thiazolidinedione hydrochloride - Orphan - EMEA-002106-PIP01-16-M01](#)

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Minoryx Therapeutics S.L.; Adrenoleukodystrophy (ALD)

Day 30 discussion

**Action:** For discussion

Neurology

### 3.3.13. [Galcanzumab - EMEA-001860-PIP03-16-M06](#)

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Eli Lilly and Company Limited; Prevention of migraine headaches

Day 30 discussion

**Action:** For discussion

Neurology

### 3.3.14. [Ganaxolone - Orphan - EMEA-002341-PIP01-18-M02](#)

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Marinus Pharmaceuticals Inc.; Cyclin-dependent kinase-like 5 (CDKL5) deficiency disorder

Day 30 discussion

**Action:** For discussion

Neurology

### 3.3.15. [Ozanimod hydrochloride - EMEA-001710-PIP02-14-M06](#)

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Celgene Europe B.V.; Treatment of multiple sclerosis

Day 30 discussion

**Action:** For discussion

Neurology

### 3.3.16. Abemaciclib - EMEA-002342-PIP01-18-M02

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Eli Lilly and Company Limited; Ewing's sarcoma (ES)

Day 30 discussion

**Action:** For discussion

Oncology

### 3.3.17. Abemaciclib - EMEA-002342-PIP02-18-M01

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Eli Lilly and Company Limited; High grade glioma

Day 30 discussion

**Action:** For discussion

Oncology

### 3.3.18. Brigatinib - EMEA-002296-PIP01-17-M03

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Takeda Pharm A/S; Anaplastic large cell lymphoma (ALCL) / Non-small cell lung cancer (NSCLC) / Inflammatory myofibroblastic tumors (IMT)

Day 30 discussion

**Action:** For discussion

Oncology

### 3.3.19. Imatinib (as imatinib mesylate) - EMEA-002643-PIP01-19-M01

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Accord Healthcare S.L.U.; Treatment of Ph+ acute lymphoblastic leukaemia / Treatment of Ph+ chronic myeloid leukemia

Day 30 discussion

**Action:** For discussion

Oncology

### 3.3.20. Palbociclib - EMEA-002146-PIP01-17-M03

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Pfizer Europe MA EEIG; Treatment of Ewing sarcoma

Day 30 discussion

**Action:** For discussion

Oncology

### 3.3.21. Temozolomide - EMEA-002634-PIP01-19-M01

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Accord Healthcare S.L.U.; Treatment of malignant glioma

Day 30 discussion

**Action:** For discussion

Oncology

### 3.3.22. Fluocinolone acetonide - EMEA-000801-PIP03-16-M01

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Alimera Sciences Limited; Recurrent non-infectious uveitis affecting the posterior segment of the eye

Day 30 discussion

**Action:** For discussion

Ophthalmology

### 3.3.23. Ivacaftor / tezacaftor - Orphan - EMEA-001640-PIP01-14-M07

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Vertex Pharmaceuticals (Ireland) Limited; Cystic fibrosis

Day 30 discussion

**Action:** For discussion

Other / Pneumology - Allergology

### 3.3.24. Ivacaftor / Tezacaftor / Elexacaftor - Orphan - EMEA-002324-PIP01-17-M02

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Vertex Pharmaceuticals (Ireland) Limited; Cystic fibrosis

Day 30 discussion

**Action:** For discussion

Other / Pneumology - Allergology

### 3.3.25. Nintedanib - EMEA-001006-PIP05-18-M01

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Boehringer Ingelheim International GmbH; Treatment of fibrosing interstitial lung diseases (ILD)

Day 30 discussion

**Action:** For discussion

Pneumology - Allergology / Oncology

### 3.3.26. Mirabegron - EMEA-000597-PIP03-15-M04

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

Day 30 discussion

**Action:** For discussion

Uro-nephrology



### 3.3.27. Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, live) - EMEA-001786-PIP01-15-M02

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Merck Sharp & Dohme (Europe), Inc.; Prevention of Ebola disease

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 17 August 2021 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. Icenticaftor - EMEA-06-2021

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All classes of medicinal products for treatment of chronic obstructive pulmonary disease (COPD) (excluding chronic lung diseases associated with long-term airflow limitation, such as asthma, bronchopulmonary dysplasia, primary cilia dyskinesia, obstructive lung disease

related to graft-versus-host disease after [bone-marrow] transplantation) / Treatment of chronic obstructive pulmonary disease

**Action:** For discussion

#### 6.1.2. EMEA-07-2021

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The class of pyrimidine - and pyrimidine analogue - containing medicinal products for treatment of lung malignant neoplasms / As monotherapy for the first-line treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating epidermal growth factor receptor (EGFR) mutations / As monotherapy for the treatment of adult patients with locally advanced or metastatic EGFR T790M mutation-positive NSCLC

**Action:** For discussion

## 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

No item

### 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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No item

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

#### 9.3.1. Non-clinical Working Group: 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

#### 9.3.3. CHMP List of Questions to the SWP and NcWG of the PDCO

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PDCO member: Karen van Malderen

**Action:** For adoption

#### 9.3.4. Patients and Consumers Working Party (PCWP)/ Healthcare Professionals Working Party (HCPWP) on 1-2 June 2021

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Minutes of meeting on 1-2 June 2021

**Action:** For information

#### 9.3.5. Call for interest for nomination of PDCO members to join temporary ad-hoc group on complex trials Q&A – call for experts

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The European Commission (DG Santé B4) has initiated the development of a question and answer document on 'complex clinical trials' in collaboration with EMA and the clinical trials facilitation group (CTFG). A first draft is now available, spanning a large scope of topics (master protocols, Bayesian methodology, use of external control, biomarkers, safety, transparency and study integrity). As the next important step, the EC/EMA/CTFG drafting group is now looking for volunteers from the network to contribute to this first draft and subsequent activities expected to span over the rest of 2021, and possibly beyond.

**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

#### 9.4.2. Study supporting the Impact Assessment of the revision of the EU legislation on medicines for children and rare diseases | Follow-up interview

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Public consultation for the revision of the Paediatric Regulation

**Action:** For discussion

## **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**

No item

# **10. Any other business**

## **10.1. COVID -19 update**

No item

# **11. Breakout sessions**

## **11.1. Internal PDCO Operations**

**Action:** For discussion on Tuesday, 10:00 - 11:00

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