



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

18 February 2022  
EMA/PDCO/65222/2022  
Human Medicines Division

## Paediatric Committee (PDCO)

### Draft Agenda for the meeting on 22-25 February 2022

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

22 February 2022, 11:00 - 19:00, Virtual meeting

23 February 2022, 08:30 - 19:00, Virtual meeting

24 February 2022, 08:30 - 19:00, Virtual meeting

25 February 2022, 08:30 - 13:00, 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 22-25 February 2022. See February 2022 PDCO minutes (to be published post March 2022 PDCO meeting).

### 1.2. Adoption of agenda

PDCO agenda for 22-25 February 2022

### 1.3. Adoption of the minutes

PDCO minutes for 18-21 January 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. Abelacimab - EMEA-003017-PIP01-21

Prevention of venous thromboembolism associated with cancer

Day 120 opinion

**Action:** For adoption

Cardiovascular Diseases

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

Treatment of chronic inducible cold urticaria

Day 120 opinion

**Action:** For adoption

Dermatology

### 2.1.3. EMEA-003027-PIP01-21

---

Treatment of hyperphenylalaninaemia

Day 120 opinion

**Action:** For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

### 2.1.4. Benzylamine derivative of benzofuran - EMEA-002974-PIP01-21

---

Treatment of paroxysmal nocturnal haemoglobinuria

Day 120 opinion

**Action:** For adoption

Haematology-Hemostaseology

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

---

UCB Pharma S.A; Treatment of immune thrombocytopenia

Day 120 opinion

**Action:** For adoption

Haematology-Hemostaseology

### 2.1.6. Censavudine - EMEA-003075-PIP01-21

---

Treatment of Aicardi-Goutières syndrome

Day 120 opinion

**Action:** For adoption

Neurology

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

---

Treatment of acute ischaemic stroke

Day 120 opinion

**Action:** For adoption

Neurology

### 2.1.8. 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 / Treatment of Ewing sarcoma

---

Day 120 opinion

**Action:** For adoption

Oncology

2.1.9. Autologous CD34+ hematopoietic stem and progenitor cells (HSPCs) genetically modified with the lentiviral vector IDUA LV, encoding for the human  $\alpha$ -L-iduronidase (IDUA) cDNA - Orphan - EMEA-003001-PIP01-21

---

Orchard Therapeutics (Netherlands) B.V.; Treatment of mucopolysaccharidosis type I, Hurler syndrome (MPS-IH)

Day 120 opinion

**Action:** For adoption

Other

2.1.10. Pamrevlumab - Orphan - EMEA-002979-PIP01-21

---

FibroGen, Inc.; Treatment of Duchenne muscular dystrophy

Day 120 opinion

**Action:** For adoption

Other

2.1.11. Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A/H5N1 - EMEA-002869-PIP01-21

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Influenza due to identified zoonotic or pandemic influenza virus

Day 120 opinion

**Action:** For adoption

Vaccines

2.1.12. Crovalimab - EMEA-002709-PIP02-21

---

Guillain - Barré syndrome

Day 60 opinion

**Action:** For adoption

*Note: Withdrawal request received on 14 February 2022*

2.1.13. Acetylsalicylic acid / ticagrelor - EMEA-003146-PIP01-21

---

Prevention of atherothrombotic events

Day 60 opinion

**Action:** For adoption  
Cardiovascular Diseases

#### 2.1.14. Indapamide / telmisartan - EMEA-003151-PIP01-21

Treatment of hypertension  
Day 60 opinion  
**Action:** For adoption  
Cardiovascular Diseases

#### 2.1.15. EMEA-002927-PIP02-21

Treatment of polymyalgia rheumatica  
Day 60 opinion  
**Action:** For adoption  
Immunology-Rheumatology-Transplantation

#### 2.1.16. Secukinumab - EMEA-000380-PIP09-21

Treatment of lichen planus (including mucosal lichen planus)  
Day 60 opinion  
**Action:** For adoption  
Immunology-Rheumatology-Transplantation

#### 2.1.17. Cevostamab - Orphan - EMEA-003145-PIP01-21

Roche Registration GmbH; Treatment of multiple myeloma  
Day 60 opinion  
**Action:** For adoption  
Oncology

#### 2.1.18. Human IgG4 monoclonal antibody against BCMA and CD3 - EMEA-003147-PIP01-21

Treatment of multiple myeloma  
Day 60 opinion  
**Action:** For adoption  
Oncology

### 2.1.19. Retifanlimab - Orphan - EMEA-002798-PIP02-21

---

Incyte Biosciences Distribution B.V.; Endometrial carcinoma

Day 60 opinion

**Action:** For adoption

Oncology

### 2.1.20. Sintilimab - EMEA-002919-PIP02-21

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Oesophageal cancer

Day 60 opinion

**Action:** For adoption

Oncology

## 2.2. Opinions on Compliance Check

### 2.2.1. Dupilumab - EMEA-C-001501-PIP01-13-M07

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Regeneron Pharmaceuticals, Inc.; Treatment of atopic dermatitis

Day 60 opinion

**Action:** For adoption

Dermatology

### 2.2.2. Ligelizumab - EMEA-C2-001811-PIP02-15-M04

---

Novartis Europharm Limited; Treatment of chronic spontaneous urticaria

Day 60 letter

**Action:** For adoption

Dermatology

### 2.2.3. Cobicistate / atazanavir sulphate - EMEA-C2-001465-PIP01-13-M03

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Bristol-Myers Squibb Pharma EEIG; Treatment of human immunodeficiency virus (HIV-1) infection

Day 60 letter

**Action:** For adoption

Infectious Diseases

#### 2.2.4. Eribulin - EMEA-C-001261-PIP01-11-M07

---

Eisai GmbH; Treatment of soft tissue sarcoma

Day 60 opinion

**Action:** For adoption

Oncology

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

#### 2.3.1. Migalastat hydrochloride - Orphan - EMEA-001194-PIP01-11-M05

---

Amicus Therapeutics Europe Limited; Treatment of Fabry disease

Day 60 opinion

**Action:** For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

#### 2.3.2. Saxagliptin - EMEA-000200-PIP01-08-M09

---

AstraZeneca AB; Treatment of type 2 diabetes

Day 60 opinion

**Action:** For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

#### 2.3.3. Eluxadoline - EMEA-001579-PIP01-13-M05

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Allergan Pharmaceuticals International Limited; Treatment of diarrhoea-predominant irritable bowel syndrome

Day 60 opinion

**Action:** For adoption

Gastroenterology-Hepatology

#### 2.3.4. Ozanimod hydrochloride - EMEA-001710-PIP04-17-M03

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Celgene Europe B.V.; Treatment of Crohn's disease

Day 60 opinion

**Action:** For adoption

Gastroenterology-Hepatology

### 2.3.5. [Bezlotoxumab - EMEA-001645-PIP01-14-M04](#)

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Merck Sharp & Dohme (Europe), Inc.; Prevention of recurrence of *Clostridioides difficile* infection

Day 60 opinion

**Action:** For adoption

Infectious Diseases

### 2.3.6. [Brincidofovir - Orphan - EMEA-001904-PIP02-17-M01](#)

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SymBio Pharmaceuticals Limited; Treatment of adenovirus in immunocompromised patients

Day 60 opinion

**Action:** For adoption

Infectious Diseases

*Note: Withdrawal request received on 4 February 2022*

### 2.3.7. [Cabotegravir - EMEA-001418-PIP02-15-M03](#)

---

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

Day 60 opinion

**Action:** For adoption

Infectious Diseases

### 2.3.8. [Rilpivirine \(hydrochloride\) - EMEA-000317-PIP01-08-M13](#)

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

Day 60 opinion

**Action:** For adoption

Infectious Diseases

### 2.3.9. [Cannabidiol / delta-9-tetrahydrocannabinol - EMEA-000181-PIP01-08-M06](#)

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GW Pharma (International) B.V; Spasticity

Day 60 opinion

**Action:** For adoption

Neurology

### 2.3.10. Galcanezumab - EMEA-001860-PIP03-16-M07

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Eli Lilly and Company Limited; Prevention of migraine headache

Day 60 opinion

**Action:** For adoption

Neurology

### 2.3.11. Leriglitzone - Orphan - EMEA-002106-PIP01-16-M02

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Minoryx Therapeutics S.L.; Treatment of adrenoleukodystrophy

Day 60 opinion

**Action:** For adoption

Neurology

### 2.3.12. Ofatumumab - EMEA-002397-PIP01-18-M02

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Novartis Ireland Limited; Treatment of multiple sclerosis

Day 60 opinion

**Action:** For adoption

Neurology

### 2.3.13. Siponimod (hemifumarate) - EMEA-000716-PIP01-09-M04

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Novartis Europharm Ltd; Treatment of multiple sclerosis

Day 60 opinion

**Action:** For adoption

Neurology

### 2.3.14. (4S,7aR,9aR,10S,11E,14S,15R)-6'-chloro-10-methoxy-14,15-dimethyl-3',4',7a,8,9,9a,10,13,14,15-decahydro-2'H,7H-spiro[1,19-ethenocyclobuta[i][1,4]oxazepino[3,4f][1,2,7]thiadiazacyclohexadecine-4,1'-naphthalen]-18(17H)-one 16,16-dioxide - EMEA-002631-PIP01-19-M01

---

Amgen Europe BV; Treatment of acute myeloid leukaemia

Day 60 opinion

**Action:** For adoption

Oncology

### 2.3.15. Axicabtagene ciloleucel - Orphan - EMEA-002010-PIP01-16-M03

---

Kite Pharma EU B.V.; Treatment of mature B cell neoplasms

---



Day 60 opinion

**Action:** For adoption

Oncology

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#### 2.3.16. Bempegaldesleukin - EMEA-002492-PIP01-18-M02

---

Nektar Therapeutics; Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoetic, and lymphoid tissue neoplasms)

Day 60 opinion

**Action:** For adoption

Oncology

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#### 2.3.17. Palbociclib - EMEA-002146-PIP01-17-M04

---

Pfizer Europe MA EEIG; Treatment of Ewing sarcoma

Day 60 opinion

**Action:** For adoption

Oncology

---

#### 2.3.18. Ponatinib - Orphan - EMEA-001186-PIP01-11-M03

---

Incyte Biosciences Distribution B.V.; Treatment of chronic myeloid leukaemia / Treatment of Philadelphia chromosome positive acute lymphoblastic leukaemia

Day 60 opinion

**Action:** For adoption

Oncology

---

#### 2.3.19. Inotuzumab ozogamicin - Orphan - EMEA-001429-PIP01-13-M05

---

Pfizer Europe MA EEIG; Treatment of acute lymphoblastic leukaemia

Day 60 opinion

**Action:** For adoption

Oncology / Haematology-Hemostaseology

---

#### 2.3.20. Fosdenopterin - Orphan - EMEA-001491-PIP01-13-M02

---

Comharsa Life Sciences Limited; Treatment of molybdenum cofactor deficiency type A

Day 60 opinion

**Action:** For adoption

Other

### 2.3.21. Amikacin (sulfate) - Orphan - EMEA-000525-PIP01-08-M08

Insmed Netherlands B.V.; Treatment of nontuberculous mycobacterial (NTM) lung infection

Day 60 opinion

**Action:** For adoption

Pneumology - Allergology

### 2.3.22. Benralizumab - EMEA-001214-PIP01-11-M11

AstraZeneca AB; Asthma

Day 60 opinion

**Action:** For adoption

Pneumology - Allergology

### 2.3.23. (S)-(2-(5-chloro-4-methyl-1H-benzo[d]imidazol-2-yl)-2-methylpyrrolidin-1-yl)(4-methoxy-2-(2H-1,2,3-triazol-2-yl)phenyl)methanone hydrochloride - EMEA-002121-PIP03-19-M01

Idorsia Pharmaceuticals Deutschland GmbH; Treatment of insomnia

Day 60 opinion

**Action:** For adoption

Psychiatry

### 2.3.24. Esketamine hydrochloride - EMEA-001428-PIP03-15-M02

Janssen-Cilag International NV; Major depressive disorder (MDD)

Day 60 opinion

**Action:** For adoption

Psychiatry

### 2.3.25. Lisdexamfetamine dimesylate - EMEA-000553-PIP01-09-M05

Shire Pharmaceuticals Contract Limited; Treatment of attention deficit hyperactivity disorder (ADHD)

Day 60 opinion

**Action:** For adoption

Psychiatry

### 2.3.26. Etelcalcetide - EMEA-001554-PIP01-13-M03

---

Amgen Europe B.V.; Treatment of hyperparathyroidism

Day 60 opinion

**Action:** For adoption

Uro-nephrology

### 2.3.27. Ferumoxytol - EMEA-000373-PIP02-09-M05

---

Covis Pharma Europe B.V.; Treatment of iron deficiency anaemia

Day 60 opinion

**Action:** For adoption

Uro-nephrology / Haematology-Hemostaseology

### 2.3.28. Recombinant influenza hemagglutinin-strain B (Yamagata lineage) / recombinant influenza hemagglutinin-strain B (Victoria lineage) / recombinant influenza hemagglutinin-strain A (H3N2 subtype) / recombinant influenza hemagglutinin-strain A (H1N1 subtype) - EMEA-002418-PIP01-18-M02

---

Sanofi Pasteur; Prevention of influenza infection

Day 60 opinion

**Action:** For adoption

Vaccines

## 2.4. Opinions on Re-examinations

### 2.4.1. L-Carnitine / glucose / calcium chloride dihydrate / magnesium chloride hexahydrate / sodium lactate / sodium chloride - EMEA-003049-PIP01-21

---

Iperboreal Pharma Srl; Treatment of renal failure with carnitine deficiency

Final opinion

**Action:** For adoption. Oral explanation to be held on Wednesday, 23 February at 11:00

Uro-nephrology

## 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. Gadopiclenol - EMEA-C2-001949-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

### 2.7.2. Gadopiclenol - EMEA-C2-001949-PIP02-18-M01

---

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

Day 30 letter

**Action:** For information

Diagnostic

### 2.7.3. Dalbavancin hydrochloride - EMEA-C2-000016-PIP01-07-M08

---

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

Day 30 letter

**Action:** For information

Infectious Diseases

### 2.7.4. Dupilumab - EMEA-C1-001501-PIP04-19-M01

---

Regeneron Ireland DAC; Treatment of eosinophilic esophagitis

Day 30 letter

**Action:** For information

Gastroenterology-Hepatology

### 2.7.5. Sacubitril / valsartan - EMEA-C2-000316-PIP02-11-M05

---

Novartis Europharm Ltd; Treatment of heart failure

Day 30 letter

**Action:** For information

Cardiovascular Diseases

#### 2.7.6. [Recombinant human monoclonal antibody against mannan-binding lectin-associated serine protease-2 \(INN: narsoplimab\) - EMEA-C2-002479-PIP01-18-M01](#)

---

Omeros Ireland Limited; Treatment in haematopoietic stem cell transplantation

Day 30 letter

**Action:** For information

Haematology-Hemostaseology

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

---

Lumos Pharma, Inc.; Treatment of growth hormone deficiency

Day 90 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

##### 3.1.2. [Peptide derivative of glucagon-like-peptide 1 and glucagon with fatty acid side chain - EMEA-002942-PIP02-20](#)

---

Treatment of obesity

Day 90 discussion

**Action:** For discussion

Gastroenterology-Hepatology

##### 3.1.3. [Alisitol / retinyl palmitate / zinc gluconate - Orphan - EMEA-002198-PIP01-21](#)

---

Vanessa Research Magyarorszag Kft/Vanessa Research Hungary Ltd; Treatment of microvillus inclusion disease

Day 90 discussion

**Action:** For discussion

Gastroenterology-Hepatology

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

---

Agios Netherlands B.V.; Treatment of thalassaemia

Day 90 discussion

**Action:** For discussion

Haematology-Hemostaseology

#### 3.1.5. Deucravacitinib - EMEA-002350-PIP02-20

---

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

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

---

Lysogene; Treatment of GM1 gangliosidosis

Day 90 discussion

**Action:** For discussion

Neurology

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

---

ALK-aberrant neuroblastoma

Day 90 discussion

**Action:** For discussion

Oncology

#### 3.1.8. Recombinant SARS-CoV-2 spike (S)-protein virus-like particle - EMEA-003008-PIP01-21

---

Prevention of coronavirus disease 2019 (COVID-19)

Day 90 discussion

**Action:** For discussion

Vaccines

#### 3.1.9. SARS-CoV-2 virus, beta-propiolactone inactivated - EMEA-003077-PIP01-21

---

Prevention of coronavirus disease 2019 (COVID-19)

---

Day 90 discussion

**Action:** For discussion

Vaccines

### 3.1.10. [Asundexian - EMEA-003144-PIP01-21](#)

---

Prevention of arterial thromboembolism

Day 60 discussion

**Action:** For discussion

Cardiovascular Diseases

### 3.1.11. [Oxytocin - Orphan - EMEA-003148-PIP01-21](#)

---

OT4B; Treatment of Prader-Willi syndrome

Day 60 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.1.12. [Etrasimod L-arginine - EMEA-002713-PIP02-21](#)

---

Treatment of Crohn's disease

Day 60 discussion

**Action:** For discussion

Gastroenterology-Hepatology

### 3.1.13. [EMEA-003143-PIP01-21](#)

---

Treatment of ulcerative colitis

Day 60 discussion

**Action:** For discussion

Gastroenterology-Hepatology

### 3.1.14. [Ianalumab - EMEA-002338-PIP03-21](#)

---

Treatment of systemic lupus erythematosus (SLE)

Day 60 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation

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

---

Treatment of systemic sclerosis

Day 60 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation

### 3.1.16. A fully human IgG1 monoclonal antibody targeting an epitope in the receptor-binding domain of the spike glycoprotein of SARS-CoV-2 - EMEA-003118-PIP01-21

---

Treatment and prevention of coronavirus disease 2019 (COVID-19)

Day 60 discussion

**Action:** For discussion

Infectious Diseases

*Note: Withdrawal request received on 11 February 2022*

### 3.1.17. Ensovibep - EMEA-003150-PIP01-21

---

Treatment of coronavirus disease 2019 (COVID-19)

Day 60 discussion

**Action:** For discussion

Infectious Diseases

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

---

Treatment of multiple sclerosis

Day 60 discussion

**Action:** For discussion

Neurology

### 3.1.19. EMEA-003110-PIP02-21

---

Treatment of neurofibromatosis type 1

Day 60 discussion

**Action:** For discussion

Oncology

### 3.1.20. Odronextamab - EMEA-003149-PIP01-21

---

Aggressive mature B cell Non-Hodgkin lymphoma (B-NHL)

---



Day 60 discussion

**Action:** For discussion

Oncology

### 3.1.21. [EMEA-003141-PIP01-21](#)

---

Treatment of coronavirus disease 2019 (COVID-19)

Day 60 discussion

**Action:** For discussion

Other

*Note: Withdrawal request received on 10 February 2022*

### 3.1.22. [Apitegromab - Orphan - EMEA-002951-PIP02-21](#)

---

Scholar Rock, Inc.; Spinal muscular atrophy

Day 60 discussion

**Action:** For discussion

Other / Neurology

### 3.1.23. [Influenza virus A/turkey/Turkey/1/2005 \(H5N1\) NIBRG-23 strain, HA surface antigen - EMEA-002869-PIP03-21](#)

---

Influenza due to identified zoonotic or pandemic influenza virus

Day 60 discussion

**Action:** For discussion

Vaccines

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

---

Prevention of respiratory tract disease caused by respiratory syncytial virus

Day 60 discussion

**Action:** For discussion

Vaccines / Infectious Diseases

### 3.1.25. [Amlodipine / indapamide / perindopril arginine / atorvastatin - EMEA-003173-PIP01-21](#)

---

Treatment of vascular hypertensive disorders

Day 30 discussion

**Action:** For discussion  
Cardiovascular Diseases

### 3.1.26. Cediogant - EMEA-003142-PIP02-21

---

Treatment of moderate to severe psoriasis  
Day 30 discussion  
**Action:** For discussion  
Dermatology

### 3.1.27. Dupilumab - EMEA-001501-PIP11-21

---

Treatment of chronic pruritus of unknown origin  
Day 30 discussion  
**Action:** For discussion  
Dermatology

### 3.1.28. Sirolimus - Orphan - EMEA-003168-PIP01-21

---

Desitin Arzneimittel GmbH; Tuberous sclerosis  
Day 30 discussion  
**Action:** For discussion  
Dermatology

### 3.1.29. Manganese chloride tetrahydrate - EMEA-003035-PIP02-21

---

Diagnostic evaluation of liver lesions by magnetic resonance imaging (MRI)  
Day 30 discussion  
**Action:** For discussion  
Diagnostic

### 3.1.30. Avexitide acetate - Orphan - EMEA-003125-PIP02-21

---

EigerBio Europe Limited; Treatment of congenital hyperinsulinism  
Day 30 discussion  
**Action:** For discussion  
Endocrinology-Gynaecology-Fertility-Metabolism

### 3.1.31. [Glucagon analogue linked to a human immunoglobulin Fc fragment - Orphan - EMEA-003170-PIP01-21](#)

---

Hanmi Pharm. Co., Ltd.; Treatment of congenital hyperinsulinism

Day 30 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.1.32. [Insulin lispro - EMEA-003166-PIP01-21](#)

---

Treatment of diabetes mellitus type 2 / Treatment of diabetes mellitus type 1

Day 30 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.1.33. [Semaglutide - EMEA-001441-PIP07-21](#)

---

Treatment of obesity

Day 30 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.1.34. [Efavaleukin alfa - EMEA-003156-PIP01-21](#)

---

Systemic lupus erythematosus (SLE)

Day 30 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation

### 3.1.35. [Vilobelimab - EMEA-003080-PIP02-21](#)

---

SARS-Cov-2 induced severe pneumonia

Day 30 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation / Infectious Diseases / Dermatology / Oncology

*Note: Withdrawal request received on 3 February 2022*

### 3.1.36. [HIV-1 maturation inhibitor - EMEA-003153-PIP01-21](#)

---

Treatment of human immunodeficiency virus (HIV-1) infection

---

Day 30 discussion

**Action:** For discussion

Infectious Diseases

---

### 3.1.37. [HIV-1 maturation inhibitor / dolutegravir - EMEA-003152-PIP01-21](#)

---

Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

**Action:** For discussion

Infectious Diseases

---

### 3.1.38. [Interferon beta-1a - EMEA-003056-PIP01-22](#)

---

Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

**Action:** For discussion

Infectious Diseases

---

### 3.1.39. [Adeno-associated virus vector serotype 1 containing the human GRN gene - Orphan - EMEA-003167-PIP01-21](#)

---

Passage Bio, Inc.; Treatment of frontotemporal dementia

Day 30 discussion

**Action:** For discussion

Neurology

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### 3.1.40. [Anti-CD40L humanised monoclonal antibody - EMEA-002945-PIP02-21](#)

---

Multiple sclerosis

Day 30 discussion

**Action:** For discussion

Neurology

---

### 3.1.41. [Batoclimab - EMEA-003162-PIP01-21](#)

---

Generalised myasthenia gravis

Day 30 discussion

**Action:** For discussion

Neurology

### 3.1.42. Izaflortaucipir (<sup>18</sup>F) - EMEA-003040-PIP02-21

---

Diagnosis of Alzheimer's disease

Day 30 discussion

**Action:** For discussion

Neurology

### 3.1.43. Latozinemab - Orphan - EMEA-002997-PIP02-22

---

Alector, Inc.; Treatment of amyloid lateral sclerosis

Day 30 discussion

**Action:** For discussion

Neurology

### 3.1.44. Pridopidine hydrochloride - Orphan - EMEA-003174-PIP01-21

---

Prilenia Therapeutics B.V.; Treatment of Huntington disease (HD)

Day 30 discussion

**Action:** For discussion

Neurology

### 3.1.45. Satralizumab - Orphan - EMEA-001625-PIP03-21

---

Roche Registration GmbH; Treatment of myelin oligodendrocyte glycoprotein antibody-associated disease

Day 30 discussion

**Action:** For discussion

Neurology

### 3.1.46. EMEA-003161-PIP01-21

---

Treatment of mature B cell neoplasms

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.47. EMEA-003169-PIP01-21

---

Treatment of gastrointestinal stromal tumours

Day 30 discussion

---

**Action:** For discussion

Oncology

### 3.1.48. Camidanlumab tesirine - EMEA-003160-PIP01-21

---

Treatment of Hodgkin lymphoma

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.49. Emactuzumab - EMEA-003172-PIP01-21

---

Treatment of tenosynovial giant cell tumour, local and diffuse type

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.50. Human IgG4-based bispecific antibody binding to both B-cell maturation antigen (BCMA) and cluster of differentiation 3 (CD3) - EMEA-003175-PIP01-21

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Multiple myeloma

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.51. Infigratinib - Orphan - EMEA-002594-PIP03-21

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Helsinn Birex Pharmaceuticals Ltd.; Treatment of urothelial carcinoma

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.52. Obecabtagene autoleucel - EMEA-003171-PIP01-21

---

Treatment of acute lymphoblastic leukaemia

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.53. Sacituzumab govitecan - Orphan - EMEA-002645-PIP03-21

---

Gilead Sciences International Ltd.; Lung carcinoma

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.54. Zandelisib - EMEA-003158-PIP01-21

---

Mature B cell neoplasms

Day 30 discussion

**Action:** For discussion

Oncology

### 3.1.55. EMEA-003159-PIP01-21

---

Treatment of idiopathic pulmonary fibrosis (IPF)

Day 30 discussion

**Action:** For discussion

Pneumology - Allergology

### 3.1.56. Freeze-dried allergen extract of *Betula pendula* pollen - EMEA-003117-PIP02-21

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Diagnosis of IgE mediated allergy to tree pollen of the birch group

Day 30 discussion

**Action:** For discussion

Pneumology - Allergology

### 3.1.57. Pseudoephedrine / bilastine - EMEA-003164-PIP01-21

---

Allergic rhinitis

Day 30 discussion

**Action:** For discussion

Pneumology - Allergology

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

---

Treatment of fragile X syndrome (FXS)

Day 30 discussion

**Action:** For discussion

Psychiatry

### 3.1.59. [Atrasentan - Orphan - EMEA-001666-PIP02-21](#)

---

Chinook Therapeutics, Inc.; Treatment of primary IgA nephropathy

Day 30 discussion

**Action:** For discussion

Uro-nephrology

### 3.1.60. [EMEA-003165-PIP01-21](#)

---

Treatment of chronic kidney disease

Day 30 discussion

**Action:** For discussion

Uro-nephrology

### 3.1.61. [Fusion protein composed of the first 2 immunoglobulin \(Ig\)-like domains of the human ROBO2 fused to human IgG1 Fc - EMEA-003157-PIP01-21](#)

---

Treatment of focal segmental glomerulosclerosis (FSGS)

Day 30 discussion

**Action:** For discussion

Uro-nephrology

### 3.1.62. [Repagermanium - Orphan - EMEA-003154-PIP01-21](#)

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Dimerix Bioscience Pty Ltd; Treatment of focal segmental glomerulosclerosis (FSGS)

Day 30 discussion

**Action:** For discussion

Uro-nephrology

### 3.1.63. [Pneumococcal polysaccharide serotype 35B – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 31 – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 24F – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 23B – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 23A – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 16F – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 15C – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 15A – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 20 – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 17F – diphtheria CRM197 conjugate / Pneumococcal polysaccharide serotype 12F – diphtheria CRM197 conjugate /](#)

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Pneumococcal polysaccharide serotype 11A – diphtheria CRM197 conjugate /  
Pneumococcal polysaccharide serotype 10A – diphtheria CRM197 conjugate /  
Pneumococcal polysaccharide serotype 9N – diphtheria CRM197 conjugate /  
Pneumococcal polysaccharide serotype 8 – diphtheria CRM197 conjugate /  
Pneumococcal polysaccharide serotype 33F – diphtheria CRM197 conjugate /  
Pneumococcal polysaccharide serotype 22F – diphtheria CRM197 conjugate /  
Pneumococcal polysaccharide serotype 19A – diphtheria CRM197 conjugate /  
Pneumococcal polysaccharide serotype 7F – diphtheria CRM197 conjugate /  
Pneumococcal polysaccharide serotype 6A – diphtheria CRM197 conjugate /  
Pneumococcal polysaccharide serotype 3 – diphtheria CRM197 conjugate - EMEA-003155-PIP01-21

---

Prevention of disease caused by *Streptococcus pneumoniae*

Day 30 discussion

**Action:** For discussion

Vaccines

### 3.1.64. Yellow fever virus, strain vYF-247 - EMEA-003030-PIP02-21

---

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. Treosulfan - EMEA-C-000883-PIP01-10-M05

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medac Gesellschaft für klinische Spezialpräparate mbH; Conditioning treatment prior to haematopoietic progenitor cell transplantation

Day 30 discussion

**Action:** For discussion

Immunology-Rheumatology-Transplantation

### 3.2.2. Casirivimab - EMEA-C2-002964-PIP01-21

---

Regeneron Ireland DAC; Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

**Action:** For discussion

Infectious Diseases

*Note: Withdrawal request received on 3 February 2022*

### 3.2.3. [Imdevimab - EMEA-C2-002965-PIP01-21](#)

---

Regeneron Ireland DAC; Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

**Action:** For discussion

Infectious Diseases

*Note: Withdrawal request received on 3 February 2022*

### 3.2.4. [Oritavancin - EMEA-C2-001270-PIP01-12-M04](#)

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

Day 30 discussion

**Action:** For discussion

Infectious Diseases

### 3.2.5. [Dabrafenib - EMEA-C3-001147-PIP01-11-M07](#)

---

Novartis Europharm Limited; Treatment of solid malignant tumours (excluding melanoma and glioma)

Day 30 discussion

**Action:** For discussion

Oncology

### 3.2.6. [Ibrutinib - EMEA-C-001397-PIP03-14-M06](#)

---

Janssen-Cilag International NV; Treatment of mature B cell neoplasm

Day 30 discussion

**Action:** For discussion

Oncology

### 3.2.7. [Trametinib - EMEA-C2-001177-PIP01-11-M06](#)

---

Novartis Europharm Limited; Treatment of melanoma

Day 30 discussion

**Action:** For discussion

Oncology

### 3.2.8. Alpelisib - EMEA-C1-002016-PIP03-19-M01

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Novartis Europharm Limited; Treatment of PIK3CA related overgrowth spectrum

Day 30 discussion

**Action:** For discussion

Other

### 3.2.9. Dexmedetomidine hydrochloride - EMEA-C2-002758-PIP01-19-M01

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

Day 30 discussion

**Action:** For discussion

Psychiatry

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

### 3.3.1. Regdanvimab - EMEA-002961-PIP01-21-M01

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Celltrion Healthcare Hungary Kft.; Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

**Action:** For discussion

Vaccines

### 3.3.2. Human, recombinant, non-fucosylated IgG1k monoclonal antibody targeting OX-40 receptor on activated T cells - EMEA-002886-PIP01-20-M01

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Amgen Europe B.V.; Atopic dermatitis

Day 30 discussion

**Action:** For discussion

Dermatology

### 3.3.3. Remibrutinib - EMEA-002582-PIP01-19-M01

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Novartis Europharm Limited; Chronic spontaneous urticaria

Day 30 discussion

**Action:** For discussion

Dermatology

### 3.3.4. Bis-choline tetrathiomolybdate - Orphan - EMEA-002232-PIP02-19-M02

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Alexion Europe S.A.S.; Wilson disease

Day 30 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.3.5. Dapagliflozin - EMEA-000694-PIP02-14-M03

---

AstraZeneca AB; Treatment of type 1 diabetes mellitus

Day 30 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.3.6. Tirzepatide - EMEA-002360-PIP01-18-M02

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Eli Lilly and Company Ltd; Type 2 diabetes mellitus

Day 30 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

### 3.3.7. Tolvaptan - EMEA-001231-PIP02-13-M09

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

Day 30 discussion

**Action:** For discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Uro-nephrology

### 3.3.8. Odevixibat - Orphan - EMEA-002054-PIP01-16-M03

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Albireo AB; Treatment of progressive familial intrahepatic cholestasis (PFIC)

Day 30 discussion

**Action:** For discussion

Gastroenterology-Hepatology

### 3.3.9. Potassium sulphate / magnesium sulphate heptahydrate / sodium sulphate anhydrous - EMEA-000816-PIP02-10-M03

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IPSEN Consumer Healthcare; Diagnostic of organic and/or functional bowel diseases

Day 30 discussion

**Action:** For discussion

### 3.3.10. Betibeglogene autotemcel - Orphan - EMEA-001665-PIP01-14-M06

bluebird bio (Netherlands) B.V.; Treatment of beta-thalassaemia

Day 30 discussion

**Action:** For discussion

Haematology-Hemostaseology

### 3.3.11. Luspatercept - Orphan - EMEA-001521-PIP01-13-M06

Bristol-Myers Squibb Pharma EEIG; Treatment of beta-thalassaemia

Day 30 discussion

**Action:** For discussion

Haematology-Hemostaseology

### 3.3.12. Brincidofovir - Orphan - EMEA-001904-PIP03-18-M02

Chimerix IRL Limited; Treatment of smallpox

Day 30 discussion

**Action:** For discussion

Infectious Diseases

### 3.3.13. Cefiderocol - EMEA-002133-PIP01-17-M02

Shionogi B.V.; Treatment of infections due to aerobic gram-negative bacteria

Day 30 discussion

**Action:** For discussion

Infectious Diseases

### 3.3.14. Eslicarbazepine acetate - EMEA-000696-PIP02-10-M08

BIAL - Portela & Ca, SA; Treatment of epilepsy with partial onset seizures

Day 30 discussion

**Action:** For discussion

Neurology

### 3.3.15. Cemiplimab - EMEA-002007-PIP02-17-M02

Regeneron Ireland DAC; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue)

Day 30 discussion

**Action:** For discussion

Oncology

### 3.3.16. Lenvatinib - EMEA-001119-PIP03-19-M02

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Eisai GmbH; Treatment of all conditions included in the category of malignant neoplasms except haematopoietic and lymphoid tissue neoplasms, papillary thyroid cancer, follicular thyroid cancer and osteosarcoma

Day 30 discussion

**Action:** For discussion

Oncology

### 3.3.17. Venetoclax - Orphan - EMEA-002018-PIP02-16-M05

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AbbVie Ltd; Treatment of haematopoietic and lymphoid malignant neoplasms / Treatment of solid tumour malignant neoplasms

Day 30 discussion

**Action:** For discussion

Oncology / Haematology-Hemostaseology

### 3.3.18. Sonlicromanol - Orphan - EMEA-002113-PIP01-16-M01

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Khondrion BV; Treatment of mitochondrial respiratory chain/oxidative phosphorylation defects

Day 30 discussion

**Action:** For discussion

Other

### 3.3.19. Ketamine / sufentanil - EMEA-001739-PIP02-16-M01

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Cessatech A/S; Treatment of acute pain

Day 30 discussion

**Action:** For discussion

Pain

## 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 21 February 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. ANGPTL3 agonist - EMEA-16-2021

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Novartis Europharm Limited; All classes of medicinal products for treatment of primary and secondary osteoarthritis / Treatment of osteoarthritis (OA) of the knee

**Action:** For adoption

##### 6.1.2. Astegolimab - EMEA-17-2021

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Roche Registration GmbH; 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) / Long-term maintenance treatment to reduce the risk of exacerbations of COPD in patients with a history of exacerbations

**Action:** For adoption

##### 6.1.3. Plasmid expressing variant of human interleukin 10 - EMEA-18-2022

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Xalud Therapeutics, Inc; All classes of medicinal products for treatment of primary and

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secondary osteoarthritis / Treatment of moderate-to-severe pain; treatment of reduced function due to osteoarthritis; and modification of osteoarthritis 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

### **9.2. 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

#### **9.2.2. Comirnaty/Spikevax booster in adolescents – request from CHMP**

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**Action:** For adoption



### **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. Patients and Consumers Working Party (PCWP)/Healthcare Professionals Working Party (HCPWP)**

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Meeting Summary – Annual PCWP/HCPWP meeting with all eligible organisations on 24 November 2021

Draft Agenda - PCWP/HCPWP joint meeting on 2-3 March 2022

**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**

No item

## **10. Any other business**

### **10.1. Accelerating Clinical Trials in the EU (ACT EU)**

**Action:** For information

### **10.2. Multi-Stakeholder Meeting on Paediatric Atopic Dermatitis**

**Action:** For information

### **10.3. COVID-19 update**

**Action:** For information

### **10.4. Working party implementation update - call for nominations**

**Action:** For information

## **11. Breakout sessions**

### **11.1. Internal PDCO Operations**

**Action:** For discussion on Tuesday, 11:00 - 12:00

### **11.2. Neonatology**

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

### **11.3. Paediatric oncology**

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

### **11.4. 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/)