



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

6 September 2022
EMA/PDCO/696132/2022
Human Medicines Division

Paediatric Committee (PDCO)

Agenda for the meeting on 06-09 September 2022

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

06 September 2022, 14:00 - 19:30, room 2C / virtual meeting

07 September 2022, 08:30 - 19:30, room 2C / virtual meeting

08 September 2022, 08:30 - 19:30, room 2C / virtual meeting

09 September 2022, 08:30 - 13:00, room 2C / virtual meeting

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the PDCO Committee meeting reports (after the PDCO Opinion is adopted), and on the Opinions and decisions on paediatric investigation plans webpage (after the EMA Decision is issued).

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).



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1. Introductions

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PDCO plenary session to be held 06-09 September 2022. See September 2022 PDCO minutes (to be published post October 2022 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 06-09 September 2022.

1.3. Adoption of the minutes

PDCO minutes for 19-22 July 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. Treprostinil - EMEA-003182-PIP01-22

Treatment of pulmonary arterial hypertension

Day 120 opinion

Action: For adoption

Cardiovascular Diseases

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

Krystal Biotech, Inc.; Treatment of dystrophic epidermolysis bullosa

Day 120 opinion

Action: For adoption

Dermatology

2.1.3. Recombinant fusion protein linking iduronate 2-sulfatase to engineered Fc with binding site for transferrin receptor - EMEA-002845-PIP01-20

Treatment of mucopolysaccharidosis II (Hunter syndrome)

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.4. Resmetirom - EMEA-003087-PIP01-21

Treatment of non-alcoholic steatohepatitis

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.5. Cenerimod - EMEA-003108-PIP01-21

Treatment of systemic lupus erythematosus (SLE)

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.6. Efavaleukin alfa - EMEA-003156-PIP01-21

Treatment of systemic lupus erythematosus (SLE)

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.7. Ianalumab - EMEA-002338-PIP03-21

Treatment of systemic lupus erythematosus (SLE)

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.8. Branaplam - EMEA-002204-PIP02-20

Treatment of Huntington's disease

Day 120 opinion

Action: For adoption

Neurology

2.1.9. [Satralizumab - Orphan - EMEA-001625-PIP03-21](#)

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

Day 120 opinion

Action: For adoption

Neurology

2.1.10. [Odronextamab - EMEA-003149-PIP01-21](#)

Treatment of mature B cell malignancies

Day 120 opinion

Action: For adoption

Oncology

2.1.11. [Freeze-dried allergen extract of *Betula pendula* pollen - EMEA-003117-PIP02-21](#)

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

Day 120 opinion

Action: For adoption

Pneumology - Allergology

2.1.12. [Fusion protein composed of the first 2 immunoglobulin \(Ig\)-like domains of the human ROBO2 fused to human IgG1 Fc \(PF-06730512\) - Orphan - EMEA-003157-PIP01-21](#)

Pfizer Europe MA EEIG; Treatment of focal segmental glomerulosclerosis (FSGS)

Day 120 opinion

Action: For adoption

Uro-nephrology

2.1.13. [Yellow fever virus, strain vYF-247 - EMEA-003030-PIP02-21](#)

Prevention of yellow fever disease

Day 120 opinion

Action: For adoption

Vaccines

[2.1.14. Rosuvastatin / telmisartan - EMEA-003262-PIP01-22](#)

Prevention of cardiovascular events / Treatment of hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

[2.1.15. Fluorine \(18F\) PSMA-1007 - EMEA-003250-PIP01-22](#)

Visualisation of prostate specific membrane antigen in prostate cancer

Day 60 opinion

Action: For adoption

Diagnostic

[2.1.16. EMEA-003252-PIP01-22](#)

Treatment of multiple system atrophy

Day 60 opinion

Action: For adoption

Neurology

[2.1.17. Pridopidine HCl - Orphan - EMEA-003174-PIP02-22](#)

Prilenia Therapeutics B.V.; Treatment of amyotrophic lateral sclerosis (ALS)

Day 60 opinion

Action: For adoption

Neurology

[2.1.18. EMEA-003260-PIP01-22](#)

Treatment of dedifferentiated liposarcoma

Day 60 opinion

Action: For adoption

Oncology

[2.1.19. EMEA-003197-PIP02-22](#)

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

2.1.20. Trilaciclib - EMEA-002534-PIP03-22

Treatment of breast malignant neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.1.21. Valemetostat tosilate - Orphan - EMEA-003256-PIP01-22

Daiichi Sankyo Europe GmbH; Treatment of mature T cell neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.1.22. Batoclimab - EMEA-003162-PIP02-22

Treatment of thyroid eye disease (TED)

Day 60 opinion

Action: For adoption

Ophthalmology

2.1.23. Tadalafil / finasteride - EMEA-003261-PIP01-22

Treatment of patients with benign prostatic hyperplasia

Day 60 opinion

Action: For adoption

Other

2.1.24. Lidocaine - EMEA-003255-PIP01-22

Local anaesthesia

Day 60 opinion

Action: For adoption

Pain

2.1.25. Human papillomavirus type 58 L1 protein / human papillomavirus type 52 L1 protein / human papillomavirus type 45 L1 protein / human papillomavirus type 33 L1 protein / human papillomavirus type 31 L1 protein / human papillomavirus type 18 L1 protein / human papillomavirus type 16 L1 protein / human papillomavirus type 11 L1 protein / human papillomavirus type 6 L1 protein - EMEA-003209-PIP01-22

Prevention of infection by human papillomavirus (HPV)

Day 60 opinion

Action: For adoption

Vaccines / Infectious Diseases

2.2. Opinions on Compliance Check

2.2.1. Artesunate - EMEA-C-002710-PIP01-19

Amivas Ireland Limited; Treatment of malaria

Day 60 opinion

Action: For adoption

Infectious Diseases

2.2.2. Lanadelumab - EMEA-C-001864-PIP01-15-M07

Takeda Pharmaceuticals International AG Ireland Branch; Prevention of hereditary angioedema attacks

Day 60 opinion

Action: For adoption

Other

2.2.3. Influenza virus A / turkey / turkey / 1 / 2005 (H5N1) NIBRG-23 strain, HA surface antigen - EMEA-C-002869-PIP03-21

Seqirus Netherlands B.V.; Prevention of influenza due to identified zoonotic or pandemic influenza virus

Day 60 opinion

Action: For adoption

Vaccines

2.2.4. Recombinant influenza hemagglutinin-strain B (Victoria lineage) / recombinant influenza hemagglutinin-strain A (H1N1 subtype) / recombinant influenza

hemagglutinin-strain A (H3N2 subtype) / recombinant influenza hemagglutinin-strain B (Yamagata lineage) - EMEA-C3-002418-PIP01-18-M02

Sanofi Pasteur; Prevention of influenza infection

Day 60 letter

Action: For adoption

Vaccines

2.2.5. Nifurtimox - EMEA-C-003134-PIP01-21

Bayer AG; Treatment of Chagas disease

Day 30 opinion

Action: For adoption

Infectious Diseases

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Ambrisentan - Orphan - EMEA-000434-PIP01-08-M09

Glaxo Group Limited; Treatment of pulmonary arterial hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.2. Sotatercept - Orphan - EMEA-002756-PIP01-19-M01

Merck Sharp & Dohme B.V.; Treatment of pulmonary arterial hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.3. Vericiguat - EMEA-001636-PIP01-14-M03

Bayer AG; Treatment of left ventricular failure

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.4. Ritlecitinib - EMEA-002451-PIP01-18-M01

Pfizer Europe MA EEIG; Treatment of alopecia areata

Day 60 opinion

Action: For adoption

Dermatology

2.3.5. 3,6-diamino-2,5-bis{N-[(1R)-1-carboxy-2-hydroxyethyl]carbamoyl}pyrazine (designated MB-102) - EMEA-001983-PIP01-16-M01

MediBeacon Inc.; Monitoring of renal function

Day 60 opinion

Action: For adoption

Diagnostic / Uro-nephrology

2.3.6. Levonorgestrel - EMEA-002474-PIP02-18-M01

Chemo Research, S.L.; Contraception

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.7. Etrasimod L-arginine - EMEA-002713-PIP01-19-M02

Arena Pharmaceuticals, Inc.; Treatment of ulcerative colitis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.8. Golimumab - EMEA-000265-PIP02-11-M04

Janssen Biologics B.V.; Treatment of ulcerative colitis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.9. Insulin human - EMEA-002116-PIP01-17-M01

ELGAN Pharma Ltd; Treatment of intestinal malabsorption in preterm infants

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.10. [Maralixibat chloride - Orphan - EMEA-001475-PIP03-17-M03](#)

Mirum Pharmaceuticals; Treatment of progressive familial intrahepatic cholestasis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.11. [Tofacitinib - EMEA-000576-PIP03-12-M06](#)

Pfizer Europe MA EEIG; Treatment of ulcerative colitis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.12. [Marstacimab - Orphan - EMEA-002285-PIP02-19-M02](#)

Pfizer Europe MAA EEIG; Treatment of congenital haemophilia B / Treatment of congenital haemophilia A

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.13. [Secukinumab - EMEA-000380-PIP06-19-M01](#)

Novartis Europharm Limited; Treatment of systemic lupus erythematosus

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.14. [Cefiderocol - EMEA-002133-PIP01-17-M03](#)

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.15. Gepotidacin - EMEA-002443-PIP01-18-M01

GlaxoSmithKline Trading Services Limited; Treatment of uncomplicated urinary tract infections (uUTI)

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.16. Gepotidacin - EMEA-002443-PIP02-18-M01

GlaxoSmithKline Trading Services Limited; Treatment of uncomplicated urogenital gonorrhoea (GC)

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.17. Maribavir - Orphan - EMEA-000353-PIP02-16-M02

Takeda Pharmaceuticals International AG Ireland Branch; Treatment of cytomegalovirus (CMV) infection

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.18. Taniborbactam / cefepime - EMEA-002576-PIP01-19-M01

Venatorx Pharmaceuticals, Inc.; Treatment of gram-negative bacterial infections

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.19. D-Sorbitol / naltrexone HCl / (RS)-baclofen - Orphan - EMEA-002164-PIP01-17-M03

Pharnext SA; Treatment of Charcot-Marie-Tooth disease type 1A

Day 60 opinion

Action: For adoption. Oral explanation to be held on Thursday, 8 September 2022 at 14:00

Neurology

2.3.20. [Diroximel fumarate - EMEA-002685-PIP02-19-M01](#)

Biogen Netherlands B.V; Treatment of multiple sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.3.21. [Ocrelizumab - EMEA-000310-PIP03-10-M06](#)

Roche Registration GmbH; Treatment of multiple sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.3.22. [Rozanolixizumab - Orphan - EMEA-002681-PIP01-19-M01](#)

UCB Pharma S.A.; Treatment of myasthenia gravis

Day 60 opinion

Action: For adoption

Neurology

2.3.23. [Enasidenib - Orphan - EMEA-001798-PIP02-16-M01](#)

Bristol-Myers Squibb Pharma EEIG; Treatment of acute myeloid leukaemia

Day 60 opinion

Action: For adoption

Oncology / Haematology-Hemostaseology

2.3.24. [Atropine sulphate - EMEA-002545-PIP01-19-M01](#)

Fondazione Per La Ricerca Farmacologica Gianni Benzi Onlus; Treatment of myopia

Day 60 opinion

Action: For adoption

Ophthalmology

2.3.25. [Alpelisib - Orphan - EMEA-002016-PIP03-19-M02](#)

Novartis Europharm Limited; Treatment of PIK3CA related overgrowth spectrum

Day 60 opinion

Action: For adoption

Other

2.3.26. [Atidarsagene autotemcel - Orphan - EMEA-001765-PIP02-15-M04](#)

Orchard Therapeutics (Netherlands) B.V.; Treatment of metachromatic leukodystrophy

Day 60 opinion

Action: For adoption

Other

2.3.27. [Burosumab: Human recombinant IgG1 monoclonal antibody to fibroblast growth factor 23 \(FGF23\); KRN23 - Orphan - EMEA-001659-PIP01-15-M06](#)

Kyowa Kirin Holdings B.V.; Treatment of X-linked hypophosphataemia

Day 60 opinion

Action: For adoption

Other

2.3.28. [Eliglustat - Orphan - EMEA-000461-PIP02-11-M05](#)

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. [Begelomab - Orphan - EMEA-001744-PIP01-14-M01](#)

ADIENNE S.r.l SU; Treatment of acute graft versus host disease (aGvHD)

Day 60 opinion

Action: For adoption

Other / Immunology-Rheumatology-Transplantation

Note: Withdrawal request received on 31 August 2022

2.3.30. [Bupivacaine - EMEA-000877-PIP03-17-M04](#)

Pacira Ltd; Postsurgical analgesia

Day 60 opinion

Action: For adoption

Pain

2.3.31. Finerenone - EMEA-001623-PIP01-14-M05

Bayer AG; Treatment of chronic kidney disease

Day 60 opinion

Action: For adoption

Uro-nephrology

2.3.32. Meningococcal group Y oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / recombinant *Neisseria meningitidis* group B Protein 961c / recombinant *Neisseria meningitidis* group B Protein 287- 953 / meningococcal group C oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / meningococcal group A oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / meningococcal group W-135 oligosaccharides conjugated to *Corynebacterium diphtheriae* CRM197 protein / recombinant *Neisseria meningitidis* group B Protein 936-741 / outer membrane vesicles (OMV) from *N. meningitidis* strain NZ 98/254 - EMEA-001260-PIP01-11-M02

GlaxoSmithKline Biologicals SA; Prevention of meningococcal meningitis

Day 60 opinion

Action: For adoption

Vaccines

2.3.33. Ad26.RSV.preF - EMEA-002172-PIP02-17-M02

Janssen-Cilag International NV; Prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV)

Day 60 opinion

Action: For adoption

Vaccines / Infectious Diseases

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. Leniolisib - EMEA-C2-002989-PIP01-21-M01

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

Day 30 letter

Action: For information

Other

2.7.2. Danicopan - EMEA-C1-002310-PIP01-17

Alexion Europe SAS; Treatment of paroxysmal nocturnal haemoglobinuria

Day 30 letter

Action: For information

Haematology-Hemostaseology

2.7.3. Ravulizumab - EMEA-C1-001943-PIP04-20

Alexion Europe SAS; Treatment of neuromyelitis optica spectrum disorders

Day 30 letter

Action: For information

Neurology

2.7.4. Influenza virus (inactivated, split) Hemagglutinin-strain A (H3N2 subtype) / Influenza virus (inactivated, split) Hemagglutinin-strain B (Yamagata lineage) / Influenza virus (inactivated, split) Hemagglutinin-strain A (H1N1 subtype) / Influenza virus (inactivated, split) Hemagglutinin-strain B (Victoria lineage) - EMEA-C2-002359-PIP01-18-M04

Sanofi Pasteur; Prevention of influenza infection

Day 30 letter

Action: For information

Vaccines

2.7.5. Iptacopan - EMEA-C1-002705-PIP03-20

Novartis Europharm Limited; Treatment of paroxysmal nocturnal haemoglobinuria

Day 30 letter

Action: For information

Other / 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. Cedirogant - EMEA-003142-PIP02-21

Treatment of psoriasis

Day 90 discussion

Action: For discussion

Dermatology

3.1.2. Ruxolitinib - EMEA-002618-PIP03-21

Treatment of atopic dermatitis

Day 90 discussion

Action: For discussion

Dermatology

3.1.3. Sirolimus - Orphan - EMEA-003168-PIP01-21

Desitin Arzneimittel GmbH; Treatment of tuberous sclerosis

Day 90 discussion

Action: For discussion

Dermatology

3.1.4. Manganese - EMEA-003035-PIP02-21

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

Day 90 discussion

Action: For discussion

Diagnostic

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

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

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

Treatment of obesity

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

Treatment of myasthenia gravis

Day 90 discussion

Action: For discussion

Neurology

3.1.8. [Exenatide acetate - Orphan - EMEA-003183-PIP02-22](#)

Invex Therapeutics Ltd; Treatment of idiopathic intracranial hypertension

Day 90 discussion

Action: For discussion

Neurology

3.1.9. [Camidanlumab tesirine - EMEA-003160-PIP01-21](#)

Treatment of Hodgkin lymphoma

Day 90 discussion

Action: For discussion

Oncology

3.1.10. [Emactuzumab - Orphan - EMEA-003172-PIP01-21](#)

Synox Therapeutics Limited; Treatment of tenosynovial giant cell tumour, local and diffuse type / Treatment of tenosynovial giant cell tumour (TGCT)

Day 90 discussion

Action: For discussion

Oncology

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

Treatment of ulcerative colitis

Day 90 discussion

Action: For discussion

Other

3.1.12. EMEA-003165-PIP01-21

Treatment of chronic kidney disease

Day 90 discussion

Action: For discussion

Uro-nephrology

3.1.13. 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 / 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 90 discussion

Action: For discussion

Vaccines

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

Prevention of coronavirus disease 2019 (COVID-19)

Day 90 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.1.15. Adapalene, micronised / benzoyl peroxide, hydrous / clindamycin - EMEA-003263-PIP01-22

Treatment of acne vulgaris

Day 60 discussion

Action: For discussion

Dermatology

3.1.16. Humanised monoclonal antibody derivative against fibroblast growth factor receptor 3 - Orphan - EMEA-003253-PIP01-22

Genzyme Europe B.V.; Treatment of achondroplasia

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.17. Crovalimab - EMEA-002709-PIP03-22

Treatment of Guillain-Barré syndrome (GBS)

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.18. Luspatercept - Orphan - EMEA-001521-PIP03-22

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

Day 60 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.19. Obinutuzumab - Orphan - EMEA-001207-PIP05-22

Roche Registration GmbH; Treatment of glomerulonephritis and nephrotic syndrome

Day 60 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.20. Zilovetamab vedotin - Orphan - EMEA-003257-PIP01-22

Merck Sharp & Dohme (Europe) Inc.; Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoietic, and lymphoid tissue) / Treatment of malignant neoplasms of haematopoietic and lymphoid tissue

Day 60 discussion

Action: For discussion

Oncology

3.1.21. Retatrutide - EMEA-003258-PIP01-22

Treatment of obesity

Day 60 discussion

Action: For discussion

Other

3.1.22. Aticaprant - EMEA-003251-PIP01-22

Treatment of major depressive disorder

Day 60 discussion

Action: For discussion

Psychiatry

3.1.23. Lacutamab - Orphan - EMEA-003281-PIP01-22

Innate Pharma SA; Treatment of cutaneous T cell lymphoma

Day 30 discussion

Action: For discussion

Oncology

3.1.24. Soluble guanylate cyclase (sGC) stimulator - EMEA-003266-PIP01-22

Treatment of pulmonary arterial hypertension

Day 30 discussion

Action: For discussion

3.1.25. [Tigulixostat - EMEA-003272-PIP01-22](#)

Treatment of hyperuricemia in primary gout

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.26. [EMEA-002612-PIP02-22](#)

Treatment of sickle cell disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.27. [2-\[4-Methoxy-3-\(2-m-tolyl-ethoxy\)-benzoylamino\]-indan-2-carboxylic acid - Orphan - EMEA-003282-PIP01-22](#)

Horizon Therapeutics Ireland DAC; Treatment of systemic sclerosis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.28. [Efgartigimod alfa - EMEA-002597-PIP08-22](#)

Treatment of immune-mediated necrotising myopathy / Treatment of polymyositis (including antisynthetase syndrome) / Treatment of dermatomyositis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.29. [Namilumab - EMEA-003275-PIP01-22](#)

Treatment of sarcoidosis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.30. Albaconazole - EMEA-003279-PIP01-22

Treatment of vulvovaginal candidiasis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.31. Asunercept - Orphan - EMEA-003201-PIP01-22

Apogenix AG; Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.32. Fosmanogepix - EMEA-003280-PIP01-22

Treatment of invasive fungal infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.33. Vilobelimab - EMEA-003080-PIP03-22

Treatment of severe coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.34. Nipocalimab - EMEA-002559-PIP06-22

Treatment of chronic inflammatory demyelinating polyradiculoneuropathy

Day 30 discussion

Action: For discussion

Neurology

3.1.35. Ocrelizumab - EMEA-000310-PIP05-22

Treatment of multiple sclerosis

Day 30 discussion

Action: For discussion

Neurology

3.1.36. [EMEA-003271-PIP01-22](#)

Treatment of focal onset seizures

Day 30 discussion

Action: For discussion

Neurology

3.1.37. [EMEA-003278-PIP01-22](#)

Treatment of small cell lung cancer / Treatment of non-small cell lung cancer (NSCLC)

Day 30 discussion

Action: For discussion

Oncology

3.1.38. [Adult differentiated autologous T cells from peripheral blood, expanded and transduced with a lentivirus to express a chimeric antigen receptor with anti-CD19 specificity \(A3B1\) conjugated with the co-stimulatory regions 4-1BB and CD3z - EMEA-003264-PIP01-22](#)

Treatment of acute lymphoblastic leukaemia

Day 30 discussion

Action: For discussion

Oncology

3.1.39. [EMEA-003274-PIP01-22](#)

Treatment of melanoma

Day 30 discussion

Action: For discussion

Oncology

3.1.40. [Cobolimab - EMEA-003273-PIP01-22](#)

Treatment of non-small cell lung cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.41. Pembrolizumab / favezelimab - EMEA-003104-PIP02-22

Treatment of Hodgkin lymphoma

Day 30 discussion

Action: For discussion

Oncology

3.1.42. Pembrolizumab / vibostolimab - EMEA-003063-PIP02-22

Treatment of Hodgkin lymphoma

Day 30 discussion

Action: For discussion

Oncology

3.1.43. Pemigatinib - Orphan - EMEA-002370-PIP03-22

Incyte Biosciences Distribution B.V.; Treatment of myeloid / lymphoid neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.1.44. Vusolimogene oderparepvec - EMEA-003265-PIP01-22

Treatment of cutaneous squamous cell carcinoma

Day 30 discussion

Action: For discussion

Oncology

3.1.45. EMEA-003269-PIP01-22

Treatment of mastocytosis

Day 30 discussion

Action: For discussion

Oncology / Haematology-Hemostaseology

3.1.46. 1-(4-(6-chloropyridazin-3-yl)piperazin-1-yl)-2-(4-cyclopropyl-3-fluorophenyl)ethan-1-one - Orphan - EMEA-003268-PIP01-22

Bridge Bio Europe B.V.; Treatment of pantothenate kinase-associated neurodegeneration

Day 30 discussion

Action: For discussion

Other

3.1.47. EMEA-002612-PIP03-22

Prevention of pulmonary dysfunction

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.48. Immunoglobulin G4 [228-proline], anti-(*Betula alleghaniensis* allergen Bet v 1) (human monoclonal γ 4-chain), disulphide with human monoclonal κ -chain,dimer / immunoglobulin G4 [227-proline], anti-(*Betula alleghaniensis* allergen Bet v 1) (human monoclonal γ 4-chain), disulphide with human monoclonal κ -chain,dimer / immunoglobulin G4 [224-proline], anti-(*Betula alleghaniensis* allergen Bet v 1) (human monoclonal γ 4-chain), disulphide with human monoclonal κ -chain,dimer - EMEA-003270-PIP01-22

Treatment of allergic rhinitis with or without conjunctivitis in birch tree pollen allergic patients

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.49. EMEA-003276-PIP01-22

Treatment of post-traumatic stress disorder

Day 30 discussion

Action: For discussion

Psychiatry

3.1.50. Live attenuated respiratory syncytial virus (RSV) - EMEA-003277-PIP01-22

Prevention of respiratory syncytial virus (RSV) diseases

Day 30 discussion

Action: For discussion

Vaccines

3.1.51. MVA-BN-RSV - EMEA-003185-PIP01-22

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

Day 30 discussion

Action: For discussion

Vaccines / Infectious Diseases

3.2. Discussions on Compliance Check

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

3.2.1. [Lebrikizumab - EMEA-C1-002536-PIP01-18-M01](#)

Eli Lilly and Company Limited; Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.2.2. [Baricitinib - EMEA-C2-001220-PIP01-11-M06](#)

Eli Lilly and Company; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

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

BrePco Biopharma Limited; Treatment of vascular hypotensive disorders

Day 30 discussion

Action: For discussion

Neonatology - Paediatric Intensive Care

3.2.4. [Brivaracetam - EMEA-C-000332-PIP01-08-M16](#)

UCB Pharma S.A.; Treatment of epilepsy with partial onset seizures

Day 30 discussion

Action: For discussion

Neurology

3.2.5. Eladocagene exuparvovec - EMEA-C-002435-PIP01-18-M02

PTC Therapeutics International Limited; Treatment of aromatic L-amino acid decarboxylase deficiency

Day 30 discussion

Action: For discussion

Neurology

3.2.6. Vamorolone - EMEA-C1-001794-PIP02-16-M05

ReveraGen BioPharma Ltd; Treatment of Duchenne muscular dystrophy

Day 30 discussion

Action: For discussion

Other

3.2.7. Vosoritide - EMEA-C4-002033-PIP01-16-M02

BioMarin International Limited; Treatment of achondroplasia

Day 30 discussion

Action: For discussion

Other

3.2.8. Agomelatine - EMEA-C-001181-PIP01-11-M06

Les Laboratoires Servier; Treatment of major depressive episodes

Day 30 discussion

Action: For discussion

Psychiatry

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Birch bark extract - EMEA-001299-PIP01-12-M01

Amryt AG; Treatment of skin injuries

Day 30 discussion

Action: For discussion

Dermatology

3.3.2. Brodalumab - EMEA-001089-PIP02-13-M03

LEO Pharma A/S; Treatment of psoriasis

Day 30 discussion

Action: For discussion

Dermatology

3.3.3. Glycopyrronium bromide - EMEA-002383-PIP01-18-M02

Dr. August Wolff GmbH & Co. KG - Arzneimittel; Treatment of hyperhidrosis

Day 30 discussion

Action: For discussion

Dermatology

3.3.4. Gadoquatrane - EMEA-002778-PIP01-20-M01

Bayer AG; Diagnosis by evaluation of any known or suspected clinical condition with contrast enhanced magnetic resonance imaging

Day 30 discussion

Action: For discussion

Diagnostic

3.3.5. Inclisiran sodium - EMEA-002214-PIP01-17-M01

Novartis Europharm Ltd.; Treatment of elevated cholesterol

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. Saxagliptin - EMEA-000200-PIP01-08-M10

AstraZeneca AB; Treatment of type 2 diabetes

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.7. Vedolizumab - EMEA-000645-PIP04-20-M01

Takeda Pharma A/S; Treatment of pouchitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.8. Recombinant human A disintegrin and metalloprotease with thrombospondin type-1 Motifs 13 (rADAMTS13) - Orphan - EMEA-001160-PIP01-11-M03

Baxalta Innovations GmbH; Treatment of thrombotic thrombocytopenic purpura

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.9. Voxelotor - Orphan - EMEA-002356-PIP02-20-M01

Global Blood Therapeutics Netherlands B. V.; Treatment of sickle cell disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.10. Guselkumab - EMEA-001523-PIP03-18-M02

Janssen-Cilag International NV; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.11. Risankizumab - EMEA-001776-PIP01-15-M01

AbbVie Ltd; Treatment of psoriasis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Dermatology / Gastroenterology-Hepatology

3.3.12. Bedaquiline (fumarate) - Orphan - EMEA-000912-PIP01-10-M06

Janssen-Cilag International NV; Treatment of multi-drug resistant tuberculosis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.13. Rilpivirine (RPV) / dolutegravir (DTG) - EMEA-001750-PIP01-15-M06

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.14. Sulbactam / durlobactam - EMEA-002807-PIP01-20-M01

Entasis Therapeutics Inc.; Treatment of infections due to organisms of the *Acinetobacter baumannii-calcoaceticus* complex

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.15. Ataluren - Orphan - EMEA-000115-PIP01-07-M12

PTC Therapeutics International, Limited; Treatment of dystrophinopathy

Day 30 discussion

Action: For discussion

Neurology

3.3.16. Binimetinib - EMEA-001454-PIP03-15-M02

Pierre Fabre Médicament; Treatment of melanoma

Day 30 discussion

Action: For discussion

Oncology

3.3.17. Encorafenib - EMEA-001588-PIP01-13-M02

Pierre Fabre Médicament; Treatment of melanoma

Day 30 discussion

Action: For discussion

Oncology

3.3.18. Epcoritamab - Orphan - EMEA-002907-PIP01-20-M02

AbbVie Ltd; Treatment of mature B cell lymphoma

Day 30 discussion

Action: For discussion

Oncology

3.3.19. Isatuximab - EMEA-002205-PIP01-17-M03

Sanofi-Aventis Recherche & Développement; Treatment of malignant neoplasms of the haematopoietic and lymphoid tissue

Day 30 discussion

Action: For discussion

Oncology

3.3.20. Bilastine - EMEA-000347-PIP02-16-M04

Faes Farma S.A.; Treatment of allergic conjunctivitis

Day 30 discussion

Action: For discussion

Ophthalmology

3.3.21. Sodium chloride solution 4.2% (w/v) / idrevloride, 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-M02

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

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.22. Lanthanum carbonate hydrate - EMEA-000637-PIP02-10-M07

Takeda Pharmaceuticals International AG Ireland Branch; Treatment of hyperphosphataemia

Day 30 discussion

Action: For discussion

Uro-nephrology

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 12 September 2022 for Nomination of Rapporteur and Peer reviewer

Action: For adoption

4.2. Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver

Action: For adoption

4.3. Nominations for other activities

Action: For adoption

5. Scientific Advice Working Party (SAWP) and Paediatric Committee (PDCO) Interaction

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

6. Discussion on the applicability of class waivers

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

6.1. Discussions on the applicability of class waiver for products

No item

7. Discussion on the inclusion of an indication within a condition in an agreed PIP/waiver

7.1. Discussion on the possibility to include an indication within a condition in an agreed PIP/waiver

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

Action: For information

9.1.2. Vote by Proxy

No item

9.1.3. Election of PDCO Vice-Chairperson

Action: For adoption

9.1.4. Strategic Review and Learning Meeting (SRLM) – Prague, 6 – 7 October 2022

PDCO member: Tomáš Boráň

Action: For information

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

No item

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

9.3.1. Non-clinical Working Party: D30 Products identified

PDCO member: Karen van Malderen

Action: For information

9.3.2. Formulation Working Group

Call for interest for the position of the Formulation Working Group chairperson

PDCO member: Brian Aylward

Action: For information

9.3.3. EMA Emergency task force (ETF) – PDCO nominations

PDCO member: Koenraad Norga

Action: For information

9.4. Cooperation within the EU regulatory network

9.4.1. European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA)

Annual meeting of the European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA) to be held on 4 October 2022

Action: For information

9.4.2. PDCO / Health technology assessment (HTA) interaction – update on current initiatives

Action: For information

9.5. Cooperation with International Regulators

9.5.1. Paediatric Cluster Teleconference

No item

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

No item

9.7. PDCO work plan

No item

9.8. Planning and reporting

9.8.1. EMA Business Pipeline activity and Horizon scanning

Q3/2022 Update of the Business Pipeline report for the human scientific committees

Action: For information

10. Any other business

10.1. COVID-19 update

Action: For information

10.2. PIP-related CHMP procedures

PDCO member: Sabine Scherer

Action: For information

10.3. Webinar series on 'Improving academia-industry collaborative trials' organised by Accelerate

Action: For information

11. Breakout sessions

11.1. Paediatric oncology

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

11.2. Neonatology

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/