



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 April 2021
EMA/PDCO/188066/2021
Human Medicines Division

Paediatric Committee (PDCO)

Agenda for the meeting on 20-23 April 2021

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

20 April 2021, 14:00- 19:00

21 April 2021, 08:30- 19:00

22 April 2021, 08:30- 19:00

23 April 2021, 08:30- 13:00

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 20-23 April 2021. See 20-23 April 2021 PDCO minutes (to be published post May 2021 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 20-23 April 2021

1.3. Adoption of the minutes

PDCO minutes for 23-26 March 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-002735-PIP01-19

Cardioplegia / For induction of cardioplegia in paediatric patients of all ages undergoing cardiac surgery to correct congenital heart malformation in operations requiring CPB support

Day 120 opinion

Action: For adoption

Cardiovascular Diseases

2.1.2. Sotatercept - EMEA-002756-PIP01-19

Pulmonary arterial hypertension

Day 120 opinion

Action: For adoption

Cardiovascular Diseases

2.1.3. Human plasma derived c1-inhibitor - EMEA-002818-PIP01-20

Treatment of hereditary angioedema (HAE)

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.4. Iscalimab - EMEA-002842-PIP01-20

Prophylaxis of solid organ transplant rejection

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.5. Ravulizumab - EMEA-001943-PIP03-20

Treatment of myasthenia gravis

Day 120 opinion

Action: For adoption

Neurology

2.1.6. Erdafitinib - EMEA-002042-PIP02-20

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

Day 120 opinion

Action: For adoption

Oncology

2.1.7. Talazoparib - EMEA-002066-PIP01-20

Treatment of Ewing sarcoma

Day 120 opinion

Action: For adoption

Oncology

2.1.8. Atropine - EMEA-002744-PIP01-19

Treatment of myopia

Day 120 opinion

Action: For adoption

Ophthalmology

2.1.9. Naproxen sodium / Sumatriptan - EMEA-002959-PIP01-21

Acute treatment of migraine attacks

Day 60 opinion

Action: For adoption

Neurology

2.1.10. Savolitinib - EMEA-002627-PIP02-21

Treatment of malignant renal neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.1.11. Synthetic hypericin - Orphan - EMEA-002956-PIP01-21

Soligenix NL B.V; Cutaneous T-Cell Lymphoma

Day 60 opinion

Action: For adoption

Oncology

2.1.12. EMEA-002895-PIP02-21

Treatment of macular oedema due to central or tributary (branch) retinal vein occlusion /
Treatment of diabetic retinopathy / Treatment of choroidal neovascularisation

Day 60 opinion

Action: For adoption

Ophthalmology

2.1.13. Zorecimeran - EMEA-002986-PIP01-21

Prevention of coronavirus disease 2019 (COVID-19)

Day 60 opinion

Action: For adoption

Vaccines / Infectious Diseases

[2.1.14. Bamlanivimab - EMEA-002952-PIP01-21](#)

Treatment of coronavirus disease 2019 (COVID-19)

Day 120 opinion

Action: For adoption

Infectious Diseases

[2.1.15. Etesevimab - EMEA-002966-PIP01-21](#)

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. Afatinib - EMEA-C-001596-PIP02-17-M02](#)

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

Day 60 opinion

Action: For adoption

Oncology

[2.2.2. Secukinumab - EMEA-C-000380-PIP01-08-M04](#)

Novartis Europharm Ltd; Treatment of psoriasis

Day 30 opinion

Action: For adoption

Dermatology

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Liquid ethalonic extract 30 per cent (w/w) of Allium cepa L. (fresh bulb) and Citrus limon (L.) Burm. f. (fresh fruit), Paullinia cupana Kunth, Theobroma cacao L. - EMEA-001835-PIP01-15-M05

LEGACY HEALTHCARE; Treatment of alopecia

Day 60 opinion

Action: For adoption

Dermatology

2.3.2. Denosumab - EMEA-000145-PIP02-12-M04

Amgen Europe B.V.; Treatment of Osteoporosis

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.3. Sotagliflozin - EMEA-001517-PIP02-14-M03

Guidehouse Germany GmbH; Treatment of type 1 diabetes mellitus

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.4. Linaclotide - EMEA-000927-PIP01-10-M06

Allergan Pharmaceuticals International Limited; Treatment of functional constipation

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.5. Betibeglogene autotemcel - Orphan - EMEA-001665-PIP01-14-M05

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

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.6. [Setmelanotide - Orphan - EMEA-002209-PIP01-17-M02](#)

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

Day 60 opinion

Action: For adoption

Nutrition

2.3.7. [Venetoclax - Orphan - EMEA-002018-PIP02-16-M04](#)

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

Day 60 opinion

Action: For adoption

Oncology / Haematology-Hemostaseology

2.4. **Opinions on Re-examinations**

No items

2.5. **Opinions on Review of Granted Waivers**

No items

2.6. **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.

2.6.1. [Tirzepatide - EMEA-C1-002360-PIP01-18](#)

Eli Lilly and Company Ltd; Treatment of type 2 diabetes mellitus

Day 1 letter

Action: For information

Endocrinology-Gynaecology-Fertility-Metabolism

2.6.2. [Palovarotene - EMEA-C2-001662-PIP01-14-M04](#)

Ipsen Pharma; Treatment of fibrodysplasia ossificans progressiva

Day 1 letter

Action: For information

Other

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. Finerenone - EMEA-001623-PIP03-20

Treatment of heart failure

Day 90 discussion

Action: For discussion

Cardiovascular Diseases

3.1.2. Macitentan - Orphan - EMEA-001032-PIP03-19

Janssen-Cilag International N.V.; Treatment of functional univentricular heart disease with total cavo-pulmonary connection

Day 90 discussion

Action: For discussion

Cardiovascular Diseases

3.1.3. Ralinepag - Orphan - EMEA-002432-PIP02-20

United Therapeutics Corporation; Treatment of pulmonary arterial hypertension

Day 90 discussion

Action: For discussion

Cardiovascular Diseases

3.1.4. Allogeneic skin-derived ABCB5-positive mesenchymal stem cells - Orphan - EMEA-002875-PIP01-20

RHEACELL GmbH & Co. KG; Treatment of epidermolysis bullosa

Day 90 discussion

Action: For discussion

Dermatology

3.1.5. Adeno-associated viral vector serotype 8 containing the human glucose-6-phosphatase gene (DTX401) - Orphan - EMEA-002734-PIP01-19

Ultragenyx Germany GmbH; Glycogen storage disease type Ia / Treatment of glycogen

storage disease type Ia

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.6. [Pyridoxal 5'-phosphate monohydrate - Orphan - EMEA-002404-PIP01-18](#)

Medicure Pharma Europe Limited; Pyridox(am)ine 5'-phosphate oxidase (PNPO) deficiency

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.7. [Maralixibat Chloride - Orphan - EMEA-001475-PIP04-20](#)

Mirum Pharmaceuticals Inc.; Treatment of biliary atresia

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.8. [Odevixibat - Orphan - EMEA-002054-PIP03-20](#)

Albireo AB; Treatment of Alagille syndrome

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.9. [Recombinant monoclonal antibody to sialic acid-binding Ig-like lectin 8 - Orphan - EMEA-002856-PIP01-20](#)

Allakos Inc; Treatment of eosinophilic gastrointestinal inflammatory disorders

Day 90 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.10. [Bamlanivimab - EMEA-002952-PIP01-21](#)

Treatment of coronavirus disease 2019 (COVID-19)

Day 90 discussion

Action: For discussion

Infectious Diseases

[3.1.11. Etesevimab - EMEA-002966-PIP01-21](#)

Treatment of coronavirus disease 2019 (COVID-19)

Day 90 discussion

Action: For discussion

Infectious Diseases

[3.1.12. Pralsetinib - EMEA-002575-PIP02-20](#)

Treatment of thyroid neoplasms / Treatment of paediatric patients from 12 years to less than 18 years of age with RET-altered thyroid tumours who require systemic therapy and have no satisfactory alternative treatment options

Day 90 discussion

Action: For discussion

Oncology

[3.1.13. Autologous selected renal cells - EMEA-002844-PIP01-20](#)

Treatment of chronic kidney disease

Day 90 discussion

Action: For discussion

Uro-nephrology

[3.1.14. EMEA-002958-PIP01-21](#)

Treatment of hypertrophic cardiomyopathy

Day 60 discussion

Action: For discussion

Cardiovascular Diseases

[3.1.15. EMEA-002962-PIP01-21](#)

Treatment of elevated cholesterol

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.16. Drospirenone - EMEA-001495-PIP02-21

Treatment of endometriosis

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.17. Poly(oxy-1,2-ethanediyl), alpha-hydro-omega-methoxy, ether with N-[[[2-[[6-[[1-[3-[[3-(2,3-dihydroxypropoxy)propyl]amino]-3-oxopropyl]-2,5-dioxo-3-pyrrolidinyl]thio]hexyl]amino]ethyl]amino]carbonyl]-2-methylalanyl-teriparatide (2:1) - Orphan - EMEA-002955-PIP01-21

Ascendis Pharma Bone Diseases A/S; Treatment of hypoparathyroidism

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.18. Tildacerfont - Orphan - EMEA-002970-PIP01-21

Spruce Biosciences, Inc.; Treatment of congenital adrenal hyperplasia

Day 60 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.19. Nangibotide - EMEA-002953-PIP01-21

Septic shock / Treatment of septic shock in children

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.20. Tosatoxumab - Orphan - EMEA-002506-PIP03-21

Aridis Pharmaceuticals Inc; Treatment of *Staphylococcus aureus* pneumonia

Day 60 discussion

Action: For discussion

Infectious Diseases / Pneumology - Allergology

3.1.21. Human SARS-CoV-2 immunoglobulin - EMEA-002911-PIP01-20

Treatment of coronavirus disease 2019 (COVID-19) / Treatment of hospitalised patients

with COVID-19 disease

Day 60 discussion

Action: For discussion

Other

Note: Withdrawal request received on 9 April 2021

3.1.22. Human SARS-CoV-2 immunoglobulin - EMEA-002912-PIP01-20

Treatment of coronavirus disease 2019 (COVID-19)

Day 60 discussion

Action: For discussion

Other

Note: Withdrawal request received on 7 April 2021

3.1.23. Selatogrel - EMEA-002967-PIP01-21

Treatment of acute myocardial infarction (AMI)

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.24. SERALUTINIB - Orphan - EMEA-002972-PIP01-21

Gossamer Bio 002 Limited; Treatment of pulmonary arterial hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.25. Vupanorsen - EMEA-002973-PIP01-21

Prevention of cardiovascular events in patients at high risk for a future cardiovascular event
/ Treatment of hypertriglyceridemia

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.1.26. Ruxolitinib - EMEA-002618-PIP03-21

Atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.1.27. Mannitol - EMEA-002968-PIP01-21

Bowel cleansing prior to clinical procedure

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.1.28. Benzylamine derivative of benzofuran - EMEA-002974-PIP01-21

Treatment of paroxysmal nocturnal haemoglobinuria

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.29. Anti-C1s Humanized IgG4 Monoclonal Antibody - EMEA-002903-PIP02-21

Treatment of cold agglutinin disease

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology / Neurology

3.1.30. Ravulizumab - EMEA-001943-PIP04-20

Aquaporin-4 antibody-positive neuromyelitis optica spectrum disorder

Day 30 discussion

Action: For discussion

Neurology

3.1.31. Satralizumab - Orphan - EMEA-001625-PIP02-21

Roche Registration GmbH; Treatment of myasthenia gravis

Day 30 discussion

Action: For discussion

Neurology

3.1.32. Vatiquinone - EMEA-001238-PIP03-21

Treatment of Friedreich Ataxia

Day 30 discussion

Action: For discussion

Neurology

3.1.33. EMEA-002975-PIP01-21

Visualisation of prostate specific membrane antigen (PSMA) overexpressing tumors

Day 30 discussion

Action: For discussion

Oncology

3.1.34. Datopotamab deruxtecan - EMEA-002976-PIP01-21

Treatment of non-small cell lung cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.35. Human Papilloma Virus Type 16 E6 001-032/Human Papilloma Virus Type 16 E6 019-050/Human Papilloma Virus Type 16 E6 041-065/Human Papilloma Virus Type 16 E6 055-080/Human Papilloma Virus Type 16 E6 085-109/Human Papilloma Virus Type 16 E6 091-122/Human Papilloma Virus Type 16 E6 127-158 / Human Papilloma Virus Type 16 E6 071-095/Human Papilloma Virus Type 16 E6 109-140/Human Papilloma Virus Type 16 E7 001-035/Human Papilloma Virus Type 16 E7 022-056/Human Papilloma Virus Type 16 E7 064-098 - EMEA-001055-PIP02-21

HPV16 positive malignancies / Treatment of HPV16 positive malignancies

Day 30 discussion

Action: For discussion

Oncology

3.1.36. Nirogacestat hydrobromide - Orphan - EMEA-002971-PIP01-21

SpringWorks Therapeutics, Inc; Treatment of desmoid tumours

Day 30 discussion

Action: For discussion

Oncology

3.1.37. Patritumab deruxtecan - EMEA-002977-PIP01-21

Treatment of non-small cell lung cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.38. Ribociclib - EMEA-002765-PIP02-21

Treatment of neuroblastoma

Day 30 discussion

Action: For discussion

Oncology

3.1.39. Trastuzumab deruxtecan - EMEA-002978-PIP01-21

Treatment of non-small cell lung cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.40. 2'-O-(2-methoxyethyl) phosphorothioate antisense oligonucleotide targeting CD49d RNA - Orphan - EMEA-002981-PIP01-21

Antisense Therapeutics Limited; Duchenne muscular dystrophy

Day 30 discussion

Action: For discussion

Other

3.1.41. Dapagliflozin propanediol monohydrate / Zibotentan - EMEA-002969-PIP01-21

Treatment of chronic kidney disease

Day 30 discussion

Action: For discussion

Other

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

FibroGen, Inc.; Duchenne muscular dystrophy

Day 30 discussion

Action: For discussion

Other

3.1.43. [Evenamide - EMEA-002519-PIP03-21](#)

Treatment of schizophrenia / Schizophrenia (chronic)

Day 30 discussion

Action: For discussion

Psychiatry

3.1.44. [Recombinant Neisseria meningitidis serogroup B protein 1 / Recombinant Neisseria meningitidis serogroup B protein 2 / Recombinant Neisseria meningitidis serogroup B protein 3 / Neisseria meningitidis serogroup B Protein based active substance - EMEA-002954-PIP02-21](#)

Prevention of meningococcal disease (serogroup B)

Day 30 discussion

Action: For discussion

Vaccines

3.1.45. [EMEA-002963-PIP01-21](#)

Treatment of Coronavirus disease 2019 (COVID-19)

Day 30 discussion

Action: For discussion

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. [Ticagrelor - EMEA-C4-000480-PIP01-08-M13](#)

AstraZeneca AB; Prevention of thromboembolic events

Day 30 discussion

Action: For discussion

Cardiovascular Diseases / Haematology-Hemostaseology

3.2.2. Velmanase alfa - EMEA-C-001056-PIP02-12-M01

Chiesi Farmaceutici S.p.A; Treatment of alpha-Mannosidosis

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.3. Mitapivat - EMEA-C1-002684-PIP01-19

Agios Netherlands B.V.; Treatment of pyruvate kinase deficiency

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Nemolizumab - EMEA-001624-PIP01-14-M03

Galderma International S.A.; Atopic dermatitis

Day 30 discussion

Action: For discussion

Dermatology

3.3.2. Bis-choline tetrathiomolybdate - Orphan - EMEA-002232-PIP02-19-M01

Alexion Europe S.A.S.; Wilson disease

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.3. Canagliflozin (1s)-1,5-anhydro-1-[3-[[5-(4-fluorophenyl)-2-thienyl]methyl]-4-methylphenyl]-D-glucitol hemihydrate - EMEA-001030-PIP01-10-M09

Janssen-Cilag International NV; Type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. Cotadutide - EMEA-002287-PIP01-17-M02

AstraZeneca AB; Treatment of Type 2 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. Romosozumab - EMEA-001075-PIP04-15-M03

UCB Pharma S.A.; Treatment of osteoporosis

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. Eluxadoline - EMEA-001579-PIP01-13-M04

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

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.7. Ozanimod hydrochloride - EMEA-001710-PIP03-17-M03

Celgene Europe B.V.; Treatment of ulcerative colitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.8. Garadacimab - EMEA-002726-PIP01-19-M01

CSL Behring GmbH; Prevention of hereditary angioedema attacks

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.9. Cotadutide - EMEA-002712-PIP01-19-M01

AstraZeneca AB; Treatment of non-alcoholic steatohepatitis (NASH)

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.10. Guselkumab - EMEA-001523-PIP03-18-M01

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. Rilzabrutinib - Orphan - EMEA-002438-PIP02-19-M01

Principia Biopharma, Inc.; Treatment of immune thrombocytopenia

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.12. Cobicistat / darunavir - EMEA-001280-PIP01-12-M04

Janssen-Cilag International NV; Treatment of HIV-1 infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.13. Dolutegravir (DTG) - EMEA-000409-PIP01-08-M06

ViiV Healthcare UK Limited; Treatment of Human Immunodeficiency Virus Type 1 (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.14. Ibalizumab - EMEA-002311-PIP01-17-M02

Theratechnologies Europe Limited; Treatment of human immunodeficiency virus Type 1 (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.15. Oseltamivir phosphate - EMEA-000365-PIP01-08-M12

Roche Registration GmbH; Treatment and prevention of influenza

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.16. Oteseconazole - EMEA-002392-PIP01-18-M01

Gedeon Richter Plc.; Treatment of vulvovaginal candidiasis

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.17. Peramivir - EMEA-001856-PIP02-16-M02

BioCryt Ireland Limited; Treatment of influenza

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.18. Tenofovir alafenamide - EMEA-001584-PIP01-13-M06

Gilead Sciences International Ltd.; Treatment of chronic Hepatitis B

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.19. Vaborbactam / meropenem - EMEA-001731-PIP01-14-M03

Menarini International Operations Luxembourg S.A.; Treatment of Gram-negative bacterial infections

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.20. Galcanezumab - EMEA-001860-PIP03-16-M05

Eli Lilly and Company Limited; Prevention of migraine headaches

Day 30 discussion

Action: For discussion

Neurology

Note: Withdrawal request received on 2 April 2021

3.3.21. Nivolumab - EMEA-001407-PIP02-15-M05

Bristol-Myers Squibb Pharma EEIG; Treatment of malignant neoplasms of the central nervous system / Treatment of malignant neoplasms of lymphoid tissue

Day 30 discussion

Action: For discussion

Oncology

3.3.22. Lanadelumab - Orphan - EMEA-001864-PIP01-15-M05

Shire Pharmaceuticals Ireland Limited; Treatment of hereditary angioedema

Day 30 discussion

Action: For discussion

Other

3.3.23. Ravulizumab (ALXN1210) - Orphan - EMEA-001943-PIP01-16-M06

Alexion Europe SAS; Treatment of atypical haemolytic uremic syndrome

Day 30 discussion

Action: For discussion

Uro-nephrology / Haematology-Hemostaseology

3.3.24. Ravulizumab (ALXN1210) - Orphan - EMEA-002077-PIP01-16-M04

Alexion Europe SAS; Paroxysmal nocturnal haemoglobinuria

Day 30 discussion

Action: For discussion

Uro-nephrology / Haematology-Hemostaseology

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 27 April 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

No items

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 items

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 items

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

No items

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

9.3.1. Non-clinical Working Group: D30 Products identified

PDCO member: Karen van Malderen

Action: For information

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.3.3. Renewal of the mandate of the Inter-Committee SAG Oncology/ request for nominations

Action: For information / discussion

9.4. Cooperation within the EU regulatory network

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

Action: For information

9.5. Cooperation with International Regulators

No items

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

No items

9.7. PDCO work plan

No items

9.8. Planning and reporting

No items

10. Any other business

10.1. COVID -19 update

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

11.3. Internal Operations

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

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/