



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

22 January 2021
EMA/PDCO/1681/2021
Human Medicines Division

Paediatric Committee (PDCO)

Agenda for the meeting on 26-29 January 2021

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

26 January 2021, 14:00- 19:00

27 January 2021, 08:30- 19:00

28 January 2021, 08:30- 19:00

29 January 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 26-29 January 2021. See January 2021 PDCO minutes (to be published post February 2021 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 26-29 January 2021

1.3. Adoption of the minutes

PDCO minutes for 8-11 December 2020

2. Opinions

Disclosure of some information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

2.1. Opinions on Products

2.1.1. EMEA-002329-PIP02-20

Treatment of dermatitis and eczema / Treatment of chronic hand eczema / Treatment of atopic dermatitis

Day 120 opinion

Action: For adoption

Dermatology

2.1.2. Crinecerfont- Orphan - EMEA-002700-PIP01-19

Neurocrine Therapeutics Ltd; Treatment of congenital adrenal hyperplasia

Day 120 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.1.3. EMEA-002773-PIP01-20

Treatment of non-alcoholic steatohepatitis (NASH)

Day 120 opinion

Action: For adoption

Gastroenterology-Hepatology

2.1.4. Crovalimab - EMEA-002709-PIP01-19

Paroxysmal nocturnal hemoglobinuria (PNH)

Day 120 opinion

Action: For adoption

Haematology-Hemostaseology

2.1.5. Rozibafusp alfa - EMEA-002815-PIP01-20

Systemic lupus erythematosus

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.6. Secukinumab - EMEA-000380-PIP06-19

Treatment of systemic lupus erythematosus

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.7. Tacrolimus - EMEA-001642-PIP02-20

Solid organ transplant rejection / Prophylaxis of transplant rejection in liver, kidney or heart allograft recipients (children aged from birth to less than 18 years) / Treatment of allograft rejection resistant to treatment with other immunosuppressive medical products in children aged from birth to less than 18 years

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.8. Telitacicept - EMEA-002824-PIP01-20

Treatment of systemic lupus erythematosus

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.9. Bimekizumab - EMEA-002189-PIP04-20

Treatment of hidradenitis suppurativa / Treatment of moderate to severe hidradenitis suppurativa in adolescents from 12 years of age

Day 120 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Dermatology

2.1.10. Rimegepant - EMEA-002812-PIP02-20

Treatment of migraine headaches

Day 120 opinion

Action: For adoption

Neurology

2.1.11. Imetelstat - Orphan - EMEA-001910-PIP03-20

Geron Corporation; Treatment of Acute Myeloid Leukemia (AML), Treatment of Myelodysplastic Syndromes (MDS), including Juvenile Myelomonocytic Leukemia (JMML) / Treatment of pediatric patients with relapsed or refractory AML or MDS, including JMML, from 28 days to less than 18 years of age

Day 120 opinion

Action: For adoption

Oncology

2.1.12. Linear single strand of deoxyribonucleic acid (encoding human retinitis pigmentosa GTPase regulator [RPGR]) packaged in a recombinant adeno-associated virus protein capsid of serotype 5 (AAV5-hRKp.RPGR) - Orphan - EMEA-002827-PIP01-20

MeiraGTx UK II Ltd; Retinitis pigmentosa / RPGR mutation-associated X-linked retinitis pigmentosa

Day 120 opinion

Action: For adoption

Ophthalmology

2.1.13. Seltorexant - EMEA-002746-PIP01-20

Major depressive disorder (MDD)

Day 120 opinion

Action: For adoption

Psychiatry

2.1.14. Respiratory Syncytial Virus (RSV) PreF3 recombinant Fusion protein - EMEA-002821-PIP01-20

Prevention of medically assessed RSV- associated lower respiratory tract illness through maternal immunization / Active immunization of pregnant women during the second and third trimester of pregnancy to prevent medically assessed respiratory syncytial virus (RSV) -associated lower respiratory tract illness (LRTI) in infants by transfer of maternal antibodies

Day 120 opinion

Action: For adoption

Vaccines

2.1.15. Hydrochlorothiazide / Amlodipine / Ramipril - EMEA-002906-PIP01-20

Treatment of hypertension

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.16. Olpasiran - EMEA-002910-PIP01-20

Prevention of cardiovascular events

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.1.17. Canakinumab - EMEA-000060-PIP09-20

Schnitzler Syndrome

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.18. Otilimab - EMEA-001882-PIP03-20

Treatment of COVID-19

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

Note: Withdrawal request received on 07/01/2021

2.1.19. Secukinumab - EMEA-000380-PIP07-20

Treatment of thyroid eye disease

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.1.20. Anti-C1s Humanized IgG4 Monoclonal Antibody - EMEA-002903-PIP01-20

Immune thrombocytopenia purpura

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology / Neurology

2.1.21. Edaravone - Orphan - EMEA-002897-PIP01-20

Mitsubishi Tanabe Pharma GmbH; Amyotrophic lateral sclerosis

Day 60 opinion

Action: For adoption

Neurology

2.1.22. Eptinezumab - EMEA-002243-PIP02-20

Prevention of cluster headache

Day 60 opinion

Action: For adoption

Neurology

2.1.23. Alpelisib - EMEA-002016-PIP04-20

Ovarian cancer

Day 60 opinion

Action: For adoption

Oncology

2.1.24. Autologous CD4+ and CD8+ T cells genetically modified with a lentiviral vector encoding a B cell maturation antigen-specific chimeric antigen receptor - EMEA-002909-PIP01-20

Treatment of mature B cell neoplasms

Day 60 opinion

Action: For adoption

Oncology

2.1.25. EMEA-002895-PIP01-20

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

Day 60 opinion

Action: For adoption

Ophthalmology

Note: Withdrawal request received on 13/01/2021

2.1.26. Isopropyl alcohol / Povidone-iodine - EMEA-002902-PIP01-20

Prevention of infection prior to invasive procedures

Day 60 opinion

Action: For adoption

Other

2.1.27. Recombinant human pentraxin-2 - Orphan - EMEA-002878-PIP02-20

Roche Registration GmbH; Idiopathic pulmonary fibrosis

Day 60 opinion

Action: For adoption

Pneumology – Allergology

2.1.28. Dupilumab - EMEA-001501-PIP08-20

Chronic rhinosinusitis without nasal polyposis

Day 60 opinion

Action: For adoption

Oto-rhino-laryngology

2.1.29. EMEA-002880-PIP01-20

Prevention of coronavirus disease-2019 (COVID-19)

Day 60 opinion

Action: For adoption

Vaccines / Infectious Diseases

2.1.30. Baricitinib - EMEA-001220-PIP07-20

Treatment of Covid-19

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation / Infectious Diseases

2.2. Opinions on Compliance Check

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

No items

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Lamivudine (3TC) / Abacavir (ABC) / Dolutegravir (DTG) - EMEA-001219-PIP01-11-M05

ViiV Healthcare UK Limited; Treatment of Human Immunodeficiency Virus (HIV-1) infection / Treatment Human Immunodeficiency Virus (HIV-1) infection in paediatric population

Day 60 opinion

Action: For adoption

2.3.2. Enalapril maleate - EMEA-001706-PIP01-14-M03

Proveca Pharma Limited; Treatment of Heart Failure

Day 60 opinion

Action: For adoption

Cardiovascular Diseases

2.3.3. 6-cyclopropaneamido-4-{{2-methoxy-3-(1-methyl-1H-1,2,4 triazol-3-yl)phenyl}amino}-N-(2H3)methylpyridazine-3-carboxamide) - EMEA-002350-PIP01-18-M01

Bristol-Myers Squibb International Corporation; Treatment of psoriasis / Treatment of moderate to severe plaque psoriasis in paediatric patients 6 years of age and older

Day 60 opinion

Action: For adoption

Dermatology

2.3.4. Tildrakizumab - EMEA-001451-PIP01-13-M01

Almirall, S.A; Psoriasis / Treatment of moderate to severe plaque psoriasis in patients from 6 to less than 18 years of age who are candidates for systemic therapy

Day 60 opinion

Action: For adoption

Dermatology

2.3.5. Empagliflozin - EMEA-000828-PIP01-09-M08

Boehringer Ingelheim International GmbH; Treatment of type 2 diabetes mellitus

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.6. Evinacumab - EMEA-002298-PIP01-17-M02

Regeneron Ireland DAC; Treatment of elevated cholesterol / Treatment of homozygous familial hypercholesterolemia (HoFH)

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.7. Exenatide - EMEA-000689-PIP01-09-M11

AstraZeneca AB; Non Insulin dependent diabetes mellitus (excluding treatment with thiazolidinediones), Non Insulin dependent diabetes mellitus (treatment including thiazolidinediones), Non Insulin dependent diabetes mellitus - in combination with insulin (with or without oral antidiabetics) / Treatment of Type 2 diabetes mellitus

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.8. Linagliptin - EMEA-000498-PIP01-08-M09

Boehringer Ingelheim International GmbH; Treatment of type 2 diabetes mellitus

Day 60 opinion

Action: For adoption

Endocrinology-Gynaecology-Fertility-Metabolism

2.3.9. Ozanimod hydrochloride - EMEA-001710-PIP04-17-M02

Celgene Europe B.V.; Treatment of Crohn's disease / Treatment of moderate to severe active Crohn's disease

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.10. Ustekinumab - EMEA-000311-PIP04-13-M04

Janssen-Cilag International NV; Crohn's disease / Treatment of Crohn's disease

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.11. Ustekinumab - EMEA-000311-PIP05-17-M02

Janssen-Cilag International NV; Ulcerative Colitis / Treatment of ulcerative colitis

Day 60 opinion

Action: For adoption

Gastroenterology-Hepatology

2.3.12. Roxadustat - EMEA-001557-PIP01-13-M05

Astellas Pharma Europe B.V.; Treatment of anaemia due to chronic disorders

Day 60 opinion

Action: For adoption

Haematology-Hemostaseology

2.3.13. Sarilumab - EMEA-001045-PIP01-10-M02

sanofi-aventis recherche & développement; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis)

Day 60 opinion

Action: For adoption

Immunology-Rheumatology-Transplantation

2.3.14. Cabotegravir - EMEA-001418-PIP02-15-M01

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

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.15. Islatravir / Doravirine - EMEA-002707-PIP01-19-M01

Merck Sharp & Dohme (Europe), Inc.; Treatment of human immunodeficiency virus-1 (HIV-1) infection

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.16. Remdesivir - EMEA-002826-PIP01-20-M01

Gilead Sciences International Ltd.; Coronavirus disease 2019 (COVID-19) / for the treatment of paediatric patients aged from birth to < 18 years (weighing < 40kg) with coronavirus disease 2019 (COVID-19)

Day 60 opinion

Action: For adoption

Infectious Diseases

2.3.17. Efgartigimod alfa - Orphan - EMEA-002597-PIP01-19-M01

argenx BV; Generalised myasthenia gravis

Day 60 opinion

Action: For adoption

Neurology

2.3.18. Eladocagene exuparvovec - Orphan - EMEA-002435-PIP01-18-M02

PTC Therapeutic International Limited; Aromatic L-Amino Acid Decarboxylase (AADC) Deficiency / Treatment of Aromatic L-Amino Acid Decarboxylase (AADC) Deficiency

Day 60 opinion

Action: For adoption

Neurology

2.3.19. Bintrafusp alfa - Orphan - EMEA-002586-PIP01-19-M01

Merck Europe B.V.; Treatment of all conditions included in the category of malignant neoplasms (except central nervous system neoplasms, haematopoietic and lymphoid tissue neoplasms) / Treatment of paediatric patients from 0 to <18 years of age with solid malignant tumours

Day 60 opinion

Action: For adoption

Oncology

2.3.20. Cobimetinib - EMEA-001425-PIP01-13-M05

Roche Registration GmbH; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue) with Ras, Raf or MEK pathway activation / Treatment of children with a paediatric solid malignant tumour with known or expected Ras, Raf or MEK pathway activation, at first relapse or refractory to initial treatment

Day 60 opinion

Action: For adoption

Oncology

2.3.21. Durvalumab - EMEA-002028-PIP01-16-M02

AstraZeneca AB; Treatment of malignant neoplasms of haematopoietic and lymphoid tissue / Treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoietic and lymphoid tissue) / Treatment of paediatric patients from birth to less than 18 years old with a paediatric haematological malignancy/ Treatment of paediatric patients from birth to less than 18 years old with a paediatric solid tumour

Day 60 opinion

Action: For adoption

Oncology

2.3.22. Ibrutinib - Orphan - EMEA-001397-PIP03-14-M05

Janssen-Cilag International N.V.; Treatment of mature B-cell neoplasm / Treatment of children from 1 year to less than 18 years of age with newly-diagnosed and relapsed/refractory mature B-cell lymphoma, that is, diffuse large B-cell lymphoma or Burkitt and Burkitt-like lymphoma

Day 60 opinion

Action: For adoption

Oncology

2.3.23. Idecabtagene vicleucel - Orphan - EMEA-002369-PIP01-18-M02

Celgene Europe B.V.; Treatment of mature B-cell neoplasms / Treatment of paediatric patients with relapsed or refractory BCMA+ B-cell non-Hodgkin lymphoma

Day 60 opinion

Action: For adoption

Oncology

2.3.24. Larotrectinib - EMEA-001971-PIP02-16-M03

Bayer AG; Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours, haematopoietic and lymphoid tissue neoplasms) / Treatment of paediatric patients from birth to less than 18 years of age with advanced solid tumours harbouring an NTRK fusion

Day 60 opinion

Action: For adoption

Oncology

2.3.25. Larotrectinib - EMEA-001971-PIP03-18-M01

Bayer AG; Treatment of malignant neoplasms of the central nervous system / Treatment of paediatric patients from birth to less than 18 years of age with a primary CNS tumour harbouring an NTRK fusion

Day 60 opinion

Action: For adoption

Oncology

2.3.26. Midostaurin - Orphan - EMEA-000780-PIP01-09-M06

Novartis Europharm Limited; Treatment of acute myeloid leukaemia, Treatment of malignant mastocytosis, Treatment of mast cell leukaemia

Day 60 opinion

Action: For adoption

Oncology

2.3.27. Nivolumab / relatlimab - EMEA-002727-PIP01-19-M01

Bristol-Myers Squibb International Corporation; Treatment of melanoma /
Relatlimab/nivolumab fixed dose combination for treatment of unresectable or metastatic
melanoma in patients from 12 to 18 years

Day 60 opinion

Action: For adoption

Oncology

2.3.28. Palbociclib - EMEA-002146-PIP01-17-M02

Pfizer Europe MA EEIG; Treatment of Ewing sarcoma / Treatment of refractory or recurrent
Ewing sarcoma

Day 60 opinion

Action: For adoption

Oncology

2.3.29. Tremelimumab - EMEA-002029-PIP01-16-M02

AstraZeneca AB; Treatment of malignant neoplasms of haematopoietic and lymphoid tissue
/ Treatment of all conditions included in the category of malignant neoplasms (except
central nervous system, haematopoietic and lymphoid tissue) / Treatment of paediatric
patients from birth to less than 18 years old with a paediatric haematological malignancy /
Treatment of paediatric patients from birth to less than 18 years old with a paediatric solid
tumour

Day 60 opinion

Action: For adoption

Oncology

2.3.30. Gilteritinib (as fumarate) - Orphan - EMEA-002064-PIP01-16-M03

Astellas Pharma Europe B.V.; Treatment of acute myeloid leukemia / Treatment of patients
from 6 months to less than 18 years of age with relapsed or refractory FLT3/ITD positive
acute myeloid leukaemia or newly-diagnosed FLT3/ITD positive acute myeloid leukaemia

Day 60 opinion

Action: For adoption

Oncology / Haematology-Hemostaseology

2.3.31. Vamorolone - Orphan - EMEA-001794-PIP02-16-M03

ReveraGen BioPharma Ltd; Treatment of Duchenne muscular dystrophy

Day 60 opinion

Action: For adoption

Other

2.3.32. Ponesimod - EMEA-000798-PIP01-09-M03

Janssen-Cilag International NV; Multiple sclerosis

Day 60 opinion

Action: For adoption

Other / Neurology

2.3.33. Bupivacaine - EMEA-000877-PIP03-17-M02

Pacira Ltd; Postsurgical analgesia

Day 60 opinion

Action: For adoption

Pain

2.3.34. Glycopyrronium bromide / Formoterol fumarate dihydrate / Beclometasone dipropionate - EMEA-001875-PIP02-18-M03

Chiesi Farmaceutici S.p.A.; Treatment of asthma / Regular treatment of asthma in patients not controlled with medium-high doses of inhaled corticosteroids and long-acting beta2-agonists

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.35. Interferon beta-1a - Orphan - EMEA-002238-PIP01-17-M01

Faron Pharmaceuticals Ltd.; Treatment of Acute Respiratory Distress Syndrome (ARDS)

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.36. Vilanterol / fluticasone furoate - EMEA-000431-PIP01-08-M12

Glaxo Group Limited; Treatment of asthma

Day 60 opinion

Action: For adoption

Pneumology - Allergology

2.3.37. Agomelatine - EMEA-001181-PIP01-11-M06

Les Laboratoires Servier; Major depressive episodes

Day 60 opinion

Action: For adoption

Psychiatry

2.3.38. Cariprazine (hydrochloride) - EMEA-001652-PIP01-14-M03

Gedeon Richter Plc.; Treatment of schizophrenia

Day 60 opinion

Action: For adoption

Psychiatry

2.3.39. Synthetic double-stranded siRNA oligonucleotide directed against lactate dehydrogenase A mRNA and containing four modified nucleosides which form a ligand cluster of four N-acetylgalactosamine residues (DCR-PHXC) - Orphan - EMEA-002493-PIP01-18-M02

Dicerna Ireland Limited; Primary hyperoxaluria

Day 60 opinion

Action: For adoption

Uro-nephrology

2.4. Opinions on Re-examinations

No items

2.5. Opinions on Review of Granted Waivers

No items

2.6. Finalisation and adoption of opinions

No items

2.7. Partial Compliance Checks completed by EMA

For the following partial compliance checks, no need to refer them to PDCO Committee for discussion, were identified by the PME coordinator and PDCO Rapporteur. The PDCO has been informed in writing.

2.7.1. Cobicistat / elvitegravir / Tenofovir alafenamide / emtricitabine - EMEA-C2-001460-PIP01-13-M05

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

Day 30 discussion

Action: For information

Infectious Diseases

2.7.2. Ruxolitinib (phosphate) - EMEA-C1-000901-PIP04-17-M01

Novartis Europharm Limited; Treatment of chronic Graft versus Host Disease

Day 30 discussion

Action: For information

Oncology

3. Discussion of applications

Disclosure of some information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

3.1. Discussions on Products D90-D60-D30

3.1.1. Dupilumab - EMEA-001501-PIP07-20

Treatment of chronic spontaneous urticaria

Day 90 discussion

Action: For discussion

Dermatology

3.1.2. Ritlecitinib - EMEA-002451-PIP01-18

Alopecia areata

Day 90 discussion

Action: For discussion

Dermatology

3.1.3. Hydroxypropyl- β -cyclodextrin - Orphan - EMEA-002839-PIP01-20

Cyclo Therapeutics Inc; Niemann Pick disease type C / Treatment of Niemann Pick type C1 disease in children, adolescents and adults

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.4. Pioglitazone hydrochloride / Spironolactone / Metformin hydrochloride - EMEA-002187-PIP01-17

Treatment of polycystic ovary syndrome (PCOS) / Treatment of adolescent polycystic ovary syndrome (PCOS) in post-menarche adolescents <18 yrs and young adult women \geq 18 yrs and <24.0 yrs

Day 90 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.5. Risankizumab - EMEA-001776-PIP05-20

Hidradenitis suppurativa

Day 90 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Dermatology

3.1.6. Adeno-associated virus, serotype 9 (AAV9)-based non-replicating, self-complementary recombinant vector containing an expression cassette for the human ASPA transgene (scAAV9-CB6-hASPAopt) - Orphan - EMEA-002779-PIP01-20

Treatment of Canavan disease / Treatment of Canavan disease in patients from birth to less than 18 years of age

Day 90 discussion

Action: For discussion

Neurology

3.1.7. [1-\[\[\[4-\(4-fluoro-2-methyl-1H-indol-5-yloxy\)-6-methoxyquinolin-7-yl\]oxy\]methyl\]cyclopropanamine-dihydrochloride - Orphan - EMEA-002486-PIP03-20](#)

Advenchen Laboratories, LLC.; Treatment of soft tissue sarcomas / Treatment of alveolar soft part sarcoma / Treatment of synovial sarcoma

Day 90 discussion

Action: For discussion

Oncology

3.1.8. [Surufatinib - EMEA-002750-PIP01-19](#)

Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours and myeloid neoplasms)

Day 90 discussion

Action: For discussion

Oncology

3.1.9. [EMEA-002747-PIP01-20](#)

Treatment of myasthenia gravis

Day 90 discussion

Action: For discussion

Other / Neurology

3.1.10. [EMEA-002656-PIP01-19](#)

Chikungunya disease

Day 90 discussion

Action: For discussion

Vaccines

3.1.11. [Allogeneic multi-virus specific T lymphocytes targeting BK Virus, cytomegalovirus, human herpes virus-6, Epstein Barr virus and adenovirus - Orphan - EMEA-002908-PIP01-20](#)

AlloVir International DAC; Treatment of viral diseases in haematopoietic stem cell transplantation / Treatment of virus-associated haemorrhagic cystitis in allogeneic haematopoietic stem cell transplantation recipients / Pre-emptive treatment of cytomegalovirus disease in allogeneic haematopoietic stem cell transplantation recipients / Pre-emptive treatment of adenovirus disease in allogeneic haematopoietic stem cell transplantation recipients

Day 60 discussion

Action: For discussion

Infectious Diseases

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

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

Day 60 discussion

Action: For discussion

Infectious Diseases

3.1.13. Omaveloxolone - Orphan - EMEA-002487-PIP01-18

Reata Pharmaceuticals Inc.; Treatment of Friedreich's ataxia

Day 60 discussion

Action: For discussion

Neurology

3.1.14. Ublituximab - EMEA-002889-PIP02-20

Relapsing forms of multiple sclerosis (RMS)

Day 60 discussion

Action: For discussion

Neurology

3.1.15. Vatiquinone - Orphan - EMEA-001238-PIP02-20

PTC Therapeutics International Limited; Treatment of mitochondrial epilepsy

Day 60 discussion

Action: For discussion

Neurology

3.1.16. Epcoritamab - EMEA-002907-PIP01-20

Treatment of mature B-cell lymphoma / Treatment of paediatric patients with relapsed/refractory aggressive mature B-cell lymphoma

Day 60 discussion

Action: For discussion

Oncology

3.1.17. Iptacopan - EMEA-002705-PIP04-20

Atypical haemolytic uremic syndrome

Day 60 discussion

Action: For discussion

Other / Haematology-Hemostaseology

3.1.18. Brensocatib - EMEA-002905-PIP01-20

Non-cystic fibrosis bronchiectasis (NCFBE) / Treatment of NCFBE for reducing exacerbations

Day 60 discussion

Action: For discussion

Pneumology - Allergology

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

Lung Therapeutics, Inc.; Treatment of infectious pleural effusion / Treatment of infected, non-draining pleural effusions including complicated parapneumonic pleural effusion (CPE), empyema and other forms of pleural space infection

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.20. Thienopyrimidine Derivative - EMEA-002901-PIP01-20

Treatment of fibrosing ILDs / Treatment of chronic fibrosing interstitial lung diseases (ILD)

Day 60 discussion

Action: For discussion

Pneumology - Allergology

3.1.21. Bardoxolone methyl - Orphan - EMEA-002488-PIP01-18

Reata Pharmaceuticals Inc.; Treatment of Alport syndrome

Day 60 discussion

Action: For discussion

Uro-nephrology

3.1.22. Respiratory Syncytial Virus (RSV) Pref3 recombinant Fusion protein - EMEA-002904-PIP01-20

Prevention of lower respiratory tract disease caused by respiratory syncytial virus / Active immunization in the prevention of respiratory syncytial virus (RSV)-associated lower respiratory tract disease (LRTD) in subjects aged 2 to 18 years who are at high risk of RSV-associated LRTD

Day 60 discussion

Action: For discussion

Vaccines

3.1.23. Ruxolitinib phosphate - EMEA-002618-PIP02-20

Vitiligo

Day 30 discussion

Action: For discussion

Dermatology

3.1.24. Single strain of non-genetically modified Prevotella histicola - EMEA-002933-PIP01-20

Psoriasis / Treatment of mild to moderate plaque psoriasis in patients ≥ 2 years to < 18 years

Day 30 discussion

Action: For discussion

Dermatology

3.1.25. Fluoride 18-labelled Prostate-Specific Membrane Antigen-1007 ([¹⁸F]PSMA-1007) - EMEA-002918-PIP01-20

Diagnosis of prostate cancer

Day 30 discussion

Action: For discussion

Diagnostic / Oncology

3.1.26. Glepaglutide - EMEA-002926-PIP01-20

Short bowel syndrome (SBS)

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

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

Forma Therapeutics, Inc.; Sickle cell disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.28. Concizumab - Orphan - EMEA-002326-PIP04-20

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

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.29. Sutimlimab - Orphan - EMEA-002542-PIP03-20

Genzyme Europe B.V.; Treatment of cold agglutinin disease

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.1.30. EMEA-002927-PIP01-20

Chronic idiopathic arthritis / Treatment of juvenile idiopathic arthritis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.31. Anti-IL-7Ra monoclonal antibody - EMEA-002930-PIP01-20

Treatment of Sjögren's syndrome

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.1.32. EMEA-002928-PIP01-20

Treatment of plaque psoriasis / Treatment of moderate-to-severe plaque psoriasis in

children and adolescents age 6 to <18 years who are candidates for systemic therapies

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Dermatology / Gastroenterology-Hepatology

3.1.33. [Cilgavimab - EMEA-002925-PIP01-20](#)

Prevention or treatment of COVID-19

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.34. [Islatravir - EMEA-002938-PIP01-20](#)

Prevention of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.35. [Tixagevimab - EMEA-002900-PIP01-20](#)

Prevention or treatment of COVID-19

Day 30 discussion

Action: For discussion

Infectious Diseases

3.1.36. [Anti-alpha-synuclein human monoclonal antibody - EMEA-002936-PIP01-20](#)

Multiple System Atrophy / Parkinson's disease

Day 30 discussion

Action: For discussion

Neurology

3.1.37. [Branaplam - EMEA-002204-PIP02-20](#)

Treatment of Huntington's disease

Day 30 discussion

Action: For discussion

Neurology

3.1.38. Oxygen / Argon - EMEA-002921-PIP01-20

Treatment of acute ischaemic stroke

Day 30 discussion

Action: For discussion

Neurology

3.1.39. Tavapadon - EMEA-002920-PIP01-20

Treatment of Parkinson's disease

Day 30 discussion

Action: For discussion

Neurology

3.1.40. 2-((4S)-6-(4-chlorophenyl)-1-methyl-4H-benzo[C]isoxazolo[4,5-e]azepin-4-yl) acetamide monohydrate - Orphan - EMEA-002923-PIP01-20

Constellation Pharmaceuticals Inc.; Treatment of myelofibrosis

Day 30 discussion

Action: For discussion

Oncology

3.1.41. Crisantaspase - EMEA-002934-PIP01-20

Treatment of Acute lymphoblastic leukaemia / lymphoma / Acute lymphoblastic leukaemia (ALL)/lymphoblastic lymphoma (LBL)

Day 30 discussion

Action: For discussion

Oncology

3.1.42. Encequidar - Orphan - EMEA-002913-PIP01-20

Athenex Inc.; Breast cancer / Soft tissue sarcoma / Breast cancer / Angiosarcoma

Day 30 discussion

Action: For discussion

Oncology

3.1.43. Ensartinib - EMEA-002937-PIP01-20

Treatment of non-small-cell lung cancer

Day 30 discussion

Action: For discussion

Oncology

3.1.44. Humanised recombinant IgG4, Anti-PD-1 monoclonal antibody - EMEA-002939-PIP01-20

Hepatocellular carcinoma

Day 30 discussion

Action: For discussion

Oncology

3.1.45. Loncastuximab tesirine - EMEA-002665-PIP02-20

Treatment of B-cell non-Hodgkin Lymphoma

Day 30 discussion

Action: For discussion

Oncology

3.1.46. Nadofaragene firadenovec - EMEA-002376-PIP02-20

Treatment of malignant bladder neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.1.47. Paclitaxel - Orphan - EMEA-002894-PIP01-20

Athenex Inc.; Breast cancer / Soft tissue sarcoma / Breast cancer / Angiosarcoma

Day 30 discussion

Action: For discussion

Oncology

3.1.48. Sabatolimab - EMEA-002931-PIP01-20

Treatment of myelodysplastic syndrome

Day 30 discussion

Action: For discussion

Oncology

3.1.49. Sintilimab - EMEA-002919-PIP01-20

Lung malignant neoplasm

Day 30 discussion

Action: For discussion

Oncology

3.1.50. Talazoparib - EMEA-002066-PIP02-20

Treatment of prostate malignant neoplasms / Treatment of breast malignant neoplasms

Day 30 discussion

Action: For discussion

Oncology

3.1.51. Sepofarsen - Orphan - EMEA-002717-PIP02-20

ProQR Therapeutics; Treatment of inherited retinal disorders / Treatment of Leber congenital amaurosis due to the C2991 +1655A>G mutation in the CEP290 gene (p.Cys998X)

Day 30 discussion

Action: For discussion

Ophthalmology

3.1.52. Ligelizumab - EMEA-001811-PIP03-20

Treatment of food allergy

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.53. Sodium chloride solution 4.2% (w/v) / 3,5-diamino-6-chloro-N-(N-(4-(4-(2-(hexyl((2S,3R,4R,5R)-2,3,4,5,6-pentahydroxyhexyl)amino)ethoxy)phenyl)butyl)-carbamimidoyl)pyrazine-2-carboxamide - Orphan - EMEA-002935-PIP01-20

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

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.1.54. Recombinant protein derived from the SARS CoV2 prefusion Spike delta TM protein - EMEA-002915-PIP01-20

Prevention of Covid-19 / Prevention of Covid-19 disease / Prevention of Covid-19 infection

Day 30 discussion

Action: For discussion

3.1.55. Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) recombinant (r) spike (S) protein nanoparticle vaccine (SARS CoV-2 rS) - EMEA-002941-PIP01-20

Prevention of Covid-19 caused by SARS-Cov-2 infection / Active immunisation for the prevention of mild, moderate, and severe disease caused by SARS-CoV-2 in children 6 months through 17 years of age

Day 30 discussion

Action: For discussion

3.2. Discussions on Compliance Check

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

3.2.1. Apixaban - EMEA-C3-000183-PIP01-08-M08

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

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.2.2. Corifollitropin alfa - EMEA-C-000306-PIP01-08-M04

Merck Sharp & Dohme B.V.; Treatment of hypogonadotropic hypogonadism

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.3. Sofosbuvir / Velpatasvir - EMEA-C-001646-PIP01-14-M02

Gilead Sciences Ireland UC; Treatment of chronic hepatitis C

Day 30 discussion

Action: For discussion

Infectious Diseases

3.2.4. Cytarabine (liposomal combination) / Daunorubicin (liposomal combination) - EMEA-C2-001858-PIP02-16-M03

Jazz Pharmaceuticals Ireland Limited; Treatment of acute myeloid leukaemia

Day 60 discussion

Action: For adoption

Oncology

3.2.5. Bilastine - EMEA-C1-000347-PIP02-16-M02

FAES FARMA, S.A.; Treatment of allergic conjunctivitis

Day 30 discussion

Action: For discussion

Ophthalmology / Pneumology - Allergology

3.2.6. Cerliponase alfa - EMEA-C-001362-PIP01-12-M03

BioMarin International Limited; Treatment of Neuronal Ceroid Lipofuscinosis Type 2 (NCL2)

Day 30 discussion

Action: For discussion

Other / Neurology

3.2.7. Live, attenuated, chimeric dengue virus, serotype 3 / Live, attenuated, chimeric dengue virus, serotype 4 / Live, attenuated dengue virus, serotype 2 / Live, attenuated, chimeric dengue virus, serotype 1 - EMEA-C1-001888-PIP01-15-M01

Takeda Vaccines, Inc.; Prevention of dengue fever

Day 30 discussion

Action: For discussion

Vaccines

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Ambrisentan - Orphan - EMEA-000434-PIP01-08-M08

Glaxo Group Limited; Treatment of Pulmonary Arterial Hypertension / Treatment of Pulmonary Arterial Hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.2. Azilsartan medoxomil - EMEA-000237-PIP01-08-M09

Takeda Development Centre Europe Ltd; Treatment of hypertension / Essential (primary) hypertension, Secondary hypertension

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.3. Landiolol Hydrochloride - EMEA-001150-PIP02-13-M04

AOP Orphan Pharmaceuticals AG; Treatment of supraventricular arrhythmias

Day 30 discussion

Action: For discussion

Cardiovascular Diseases

3.3.4. Bimekizumab - EMEA-002189-PIP01-17-M02

UCB Biopharma SRL; Treatment of psoriasis / Treatment of moderate to severe chronic plaque psoriasis in children from the age of 6 years and older

Day 30 discussion

Action: For discussion

Dermatology

3.3.5. Gadopiclenol - EMEA-001949-PIP01-16-M04

Guerbet; Diagnostic / MRI in brain (intracranial), spine and associated tissues to detect and visualize areas with disruption of the blood brain barrier (BBB) and/or abnormal vascularity

Day 30 discussion

Action: For discussion

Diagnostic

3.3.6. Gadopiclenol - EMEA-001949-PIP02-18-M01

Guerbet; Diagnostic / Detection and visualization of disorders or lesions with suspected abnormal vascularity in various body regions

Day 30 discussion

Action: For discussion

Diagnostic

3.3.7. Ethinyl estradiol / Dienogest - EMEA-002229-PIP01-17-M02

Chemo Research; Contraception / Treatment of women with polycystic ovary syndrome (PCOS) who are not seeking pregnancy / Oral contraception

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.8. Ladarixin - EMEA-002642-PIP01-19-M03

Dompé farmaceutici S.p.A; Treatment of type 1 diabetes / Treatment of new-onset type 1 diabetes mellitus

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.9. Volanesorsen - Orphan - EMEA-001915-PIP01-15-M03

Akcea Therapeutics; Familial Chylomicronemia Syndrome

Day 30 discussion

Action: For discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.10. Golimumab - EMEA-000265-PIP02-11-M03

Janssen Biologics B.V.; Ulcerative Colitis ICD: K51 / Treatment of ulcerative colitis

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.11. Maralixibat - Orphan - EMEA-001475-PIP02-13-M01

Mirum Pharmaceuticals; Treatment of Alagille Syndrome (ALGS)

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.12. Potassium chloride / Sodium chloride / Citric acid, anhydrous / Sodium citrate / Simeticone / Sodium sulphate, anhydrous / Macrogol 4000 - EMEA-001356-PIP02-12-M04

Alfasigma S.p.A.; Any clinical procedures requiring a clean bowel e.g. bowel endoscopy or

radiology

Day 30 discussion

Action: For discussion

Gastroenterology-Hepatology

3.3.13. Valoctocogene roxaparvovec - Orphan - EMEA-002427-PIP01-18-M01

BioMarin International Limited; Treatment of Haemophilia A

Day 30 discussion

Action: For discussion

Haematology-Hemostaseology

3.3.14. Upadacitinib - EMEA-001741-PIP01-14-M04

AbbVie Ltd; Treatment of Chronic Idiopathic Arthritis / Treatment of Juvenile Idiopathic Arthritis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation

3.3.15. Upadacitinib - EMEA-001741-PIP04-17-M02

AbbVie Ltd; Treatment of atopic dermatitis

Day 30 discussion

Action: For discussion

Immunology-Rheumatology-Transplantation / Dermatology

3.3.16. Oritavancin (diphosphate) - EMEA-001270-PIP01-12-M03

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

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.17. Tenofovir (disoproxil fumarate) - EMEA-000533-PIP01-08-M10

Gilead Sciences International Limited; Treatment of chronic viral hepatitis B / Treatment of chronic hepatitis B in paediatric patients from 2 years of age with compensated liver disease

Day 30 discussion

Action: For discussion

Infectious Diseases

3.3.18. [Dermatophagoides farinae / Dermatophagoides pteronyssinus - EMEA-001258-PIP01-11-M07](#)

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

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.19. [Mometasone \(furoate\) / Indacaterol \(acetate\) - EMEA-001217-PIP01-11-M07](#)

Novartis Europharm Limited; Treatment of asthma

Day 30 discussion

Action: For discussion

Pneumology - Allergology

3.3.20. [Peanut flour - EMEA-001734-PIP01-14-M05](#)

Aimmune Therapeutics Inc; Peanut allergy / Peanut oral immunotherapy for the reduction in clinical reactivity to accidental exposure in peanut children and adults

Day 30 discussion

Action: For discussion

Pneumology - Allergology

4. Nominations

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

4.1. [List of letters of intent received for submission of applications with start of procedure 26 January 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

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

6. Discussion on the applicability of class waivers

Disclosure of some information related to this section cannot be released 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. Paclitaxel - EMEA-12-2020

Athenex Inc.; First-generation taxoid medicinal products / Breast malignant neoplasms

Action: For adoption

6.1.2. Otenaproxesul - EMEA-09-2020

Antibe Therapeutics; All classes of medicinal products for treatment of primary and secondary osteoarthritis / Treatment of the signs and symptoms of osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers

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 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

Nomination of a new member of the Formulation Working Group

PDCO member: Brian Aylward

Action: For information

9.4. Cooperation within the EU regulatory network

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

Action: For information

9.5. Cooperation with International Regulators

9.5.1. Feedback from FDA Cluster Teleconference

Action: For information

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

10.2. Introduction of new Executive Director Emer Cooke

Action: For information

11. Breakout sessions

11.1. Paediatric oncology

Action: For discussion on Tuesday, 12:00 - 13:00

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/