22 July 2022
EMA/PDCO/625532/2022
Human Medicines Division

Paediatric Committee (PDCO)

Minutes for the meeting on 21-24 June 2022

Chair: Koenraad Norga – Vice-Chair: Sabine Scherer

Disclaimers

Some of the information contained in this set of minutes 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).

Of note, this set of minutes is a working document primarily designed for PDCO members and the work the Committee undertakes.

Note on access to documents

Some documents mentioned in the minutes 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

The Chair opened the meeting by welcoming all participants. Due to the current coronavirus (COVID-19) pandemic, and the associated EMA Business Continuity Plan (BCP), the meeting was held in-person with some members connected remotely (hybrid setting).

In accordance with the Agency's policy on handling of declarations of interests of scientific Committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and on the topics in the agenda of the meeting, the Committee Secretariat announced the restricted involvement of some Committee members, alternates and experts for concerned agenda topics.

Participants were asked to declare any changes, omissions or errors to their declared interests concerning the matters for discussion. No new or additional competing interest were declared. Restrictions applicable to this meeting are captured in the List of participants included in the minutes.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure. All decisions taken at this meeting were made in the presence of a quorum of members. All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

1.2. Adoption of agenda

The agenda for 21-24 June 2022 meeting was adopted with amendments.

1.3. Adoption of the minutes

The minutes for 17-20 May 2022 meeting were adopted and will be published on the EMA website.

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. Oxytocin - Orphan - EMEA-003148-PIP01-21

OT4B; Treatment of Prader-Willi syndrome

Day 120 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of Committee discussion:

The PDCO discussed at Day 120, during the June 2022 plenary meeting, an application for a paediatric investigation plan with a deferral for oxytocin for treatment of Prader Willi syndrome.
The Committee confirmed all conclusions reached at Day 90 and took into consideration further information provided by the applicant between Day 90 and Day 120.
The PDCO adopted a positive opinion on a paediatric investigation plan with a deferral.

2.1.2. Venglustat - Orphan - EMEA-001716-PIP06-21

Genzyme Europe B.V.; Treatment of Fabry disease

Day 120 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Note: Withdrawal request received on 15 June 2022

2.1.3. Efruxifermin - EMEA-003114-PIP01-21

Akero Therapeutics, Inc.; Treatment of non-alcoholic steatohepatitis

Day 120 opinion

Gastroenterology-Hepatology

Summary of Committee discussion:

Based on the assessment of this application and the additional information provided by the applicant, a positive opinion for the PIP for the proposed medicine for children and adolescents from 8 years to less than 18 years, in the condition of treatment of non-alcoholic steatohepatitis was adopted. The PDCO agreed on a waiver in a subset of children from birth to less than 8 years of age on the grounds the product does not represent a significant therapeutic benefit over existing treatments. The PDCO granted a deferral for the completion of this PIP.

2.1.4. Etrasimod L-arginine - EMEA-002713-PIP02-21

Arena Pharmaceuticals, Inc.; Treatment of Crohn's disease

Day 120 opinion

Gastroenterology-Hepatology

Summary of Committee discussion:

Based on the assessment of this application and the additional information provided by the applicant, a positive opinion for the PIP for the proposed medicine for children and adolescents from 2 years to less than 18 years, in the condition of treatment of Crohn’s disease was adopted. The PDCO agreed on a waiver in a subset of children from birth to less than 2 years of age on the grounds the product does not represent a significant therapeutic benefit over existing treatments. The PDCO granted a deferral for the completion of this

PIP.

2.1.5. Ritlecitinib - EMEA-002451-PIP02-21

Pfizer Europe MA EEIG; Treatment of ulcerative colitis

Day 120 opinion

Gastroenterology-Hepatology

Summary of Committee discussion:

Based on the assessment of this application and the additional information provided by the applicant, a positive opinion for the PIP for the proposed medicine for children and adolescents from 2 years to less than 18 years, in the condition of treatment of ulcerative colitis was adopted. The PDCO agreed on a waiver in a subset of children from birth to less than 2 years of age on the grounds the product does not represent a significant therapeutic benefit over existing treatments. The PDCO granted a deferral for the completion of this PIP.

2.1.6. Deucravacitinib - EMEA-002350-PIP04-21

Bristol-Myers Squibb International Corporation; Treatment of ulcerative colitis

Day 120 opinion

Immunology-Rheumatology-Transplantation

Summary of Committee discussion:

Based on the assessment of this application and the additional information provided by the applicant, a positive opinion for the PIP for the proposed medicine for children and adolescents from 2 years to less than 18 years, in the condition of treatment of ulcerative colitis was adopted. The PDCO agreed on a waiver in a subset of children from birth to less than 2 years of age on the grounds the product does not represent a significant therapeutic benefit over existing treatments. The PDCO granted a deferral for the completion of this PIP.

2.1.7. Gliadin protease - EMEA-003116-PIP01-21

Takeda Pharmaceuticals International AG; Treatment of coeliac disease

Day 120 opinion

Immunology-Rheumatology-Transplantation / Gastroenterology-Hepatology

Summary of Committee discussion:

Based on the assessment of this application and the additional information provided by the applicant, a positive opinion for the PIP for the proposed medicine for children from 6 years to less than 18 years of age, in the condition of treatment of coeliac disease was adopted including a deferral for the completion of the PIP. The PDCO agreed on a waiver in a subset of children on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the

specified paediatric subset(s).

2.1.8. Remibrutinib - EMEA-002582-PIP02-21

Novartis Europharm Limited; Treatment of multiple sclerosis

Day 120 opinion

Neurology

Summary of Committee discussion:

Based on the assessment of this application and the additional information provided by the applicant, a positive opinion on a PIP for remibrutinib in children from 10 years to less than 18 years of age was adopted in the condition of treatment of multiple sclerosis.
The PDCO agreed on a waiver in children from birth to less than 10 years of age on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.
The PDCO granted a deferral for the completion of this PIP.

2.1.9. (R)-tetrahydrofuran-3-yl 4-(6-(5-(4-ethoxy-1-isopropylpiperidin-4-yl) pyridin-2-yl)pyrrolo[1,2-b]pyridazin-4-yl)piperazine-1-carboxylate sesquisuccinate - Orphan - EMEA-003133-PIP01-21

Ipsen Pharma; Treatment of fibrodysplasia ossificans progressiva

Day 120 opinion

Other

Summary of Committee discussion:

In the written response, the applicant addressed the remaining issues raised by the Committee. Based on the assessment of this application and the additional information provided by the applicant, a positive opinion on a PIP for (R)-tetrahydrofuran-3-yl 4-(6-(5-(4-ethoxy-1-isopropylpiperidin-4-yl)pyridin-2-yl)pyrrolo[1,2-b]pyridazin-4-yl)piperazine-1-carboxylate sesquisuccinate in children and adolescents from 2 years to less than 18 years of age, in the condition of treatment of fibrodysplasia ossificans progressiva was adopted.
The PDCO recommended granting a waiver for children from birth to less than 2 years of age, on the grounds that the specific medicinal product is likely to be unsafe in this paediatric subset, and a deferral for the completion of this PIP.

2.1.10. Azelastine (hydrochloride) / mometasone (furoate) - EMEA-003122-PIP01-21

Lek Pharmaceuticals d.d.; Treatment of seasonal allergic rhinitis

Day 120 opinion

Oto-rhino-laryngology

Summary of Committee discussion:

In the written response, the applicant addressed the remaining issues raised by the Committee. Based on the assessment of this application and the additional information provided by the applicant, a positive opinion on a PIP for azelastine hydrochloride /

mometasone furoate in adolescents from 12 years to less than 18 years of age, in the condition of treatment of seasonal allergic rhinitis was adopted.
The PDCO agreed on a waiver in children from birth to less than 2 years of age on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset and in children 2 years to less than 12 years of age on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset.

2.1.11. ISIS 721744; a 2'-O-(2'-methoxyethyl) modified antisense oligonucleotide targeting prekallikrein (PKK) mRNA - EMEA-003112-PIP01-21

Ionis Pharmaceuticals; Treatment of hereditary angioedema

Day 120 opinion

Pneumology - Allergology / Haematology-Hemostaseology

Summary of Committee discussion:

Based on the assessment of this application and the additional information provided by the applicant, a positive opinion on a PIP for ISIS 721744 in children from 2 years to less than 18 years of age, in the condition of treatment of hereditary angioedema was adopted.
The PDCO agreed on a waiver in children from birth to less than 2 years of age on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.
The PDCO granted a deferral for the completion of this PIP.

2.1.12. (1R,2R)-2-[4-(5-methyl-1H-pyrazol-3-yl) benzoyl]-N-(4-oxo-6,7-dihydro-5H-pyrazolo [1,5-a]pyrazin-3-yl)cyclohexanecarboxamide (AZD5718) - EMEA-003098-PIP01-21

AstraZeneca AB; Treatment of proteinuric chronic kidney disease

Day 120 opinion

Uro-nephrology

Summary of Committee discussion:

The PDCO agreed on a positive opinion for a PIP for this product (AZD5718) for the treatment of proteinuric chronic kidney disease in children from 3 months to less than 18 years of age. A waiver was agreed for the age group below 3 months on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s). The completion of the paediatric development plan was deferred.

2.1.13. Lademirsen - Orphan - EMEA-003064-PIP01-21

Genzyme Europe B.V.; Treatment of Alport syndrome

Day 120 opinion

Uro-nephrology

Summary of Committee discussion:

The applicant satisfactorily addressed the outstanding issues from Day 90. The PDCO agreed on a positive opinion for a PIP for this product (lademirsen) for the treatment of Alport syndrome in children from 2 years to less than 18 years of age. A waiver was agreed for the age group below 2 years on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s). The completion of the paediatric development plan was deferred.

2.1.14. Pegcetacoplan - Orphan - EMEA-002600-PIP03-21

Apellis Ireland Limited; Treatment of glomerulonephritis and nephrotic syndrome

Day 120 opinion

Uro-nephrology

Summary of Committee discussion:

In the written response, the applicant addressed the remaining issues raised by the Committee. Based on the assessment of this application and the additional information provided by the applicant, a positive opinion for the PIP for pegcetacoplan for the paediatric population from 2 years to less than 18 years of age, in the condition of treatment of glomerulonephritis and nephrotic syndrome was adopted.
The PDCO agreed on a waiver in a subset of children from birth to below 2 years of age on the grounds of likely lack of safety.
The PDCO granted a deferral for the completion of this PIP.

2.1.15. Vibegron - EMEA-001415-PIP02-21

Urovant Sciences GmbH; Treatment of myoneurogenic bladder disorders

Day 120 opinion

Uro-nephrology

Summary of Committee discussion:

In the written response, the applicant addressed the remaining issues raised by the Committee. Based on the assessment of this application and the additional information provided by the applicant, a positive opinion for the PIP for the proposed medicine for paediatric patients from 6 months to less than 18 years of age in the condition of treatment of myoneurogenic bladder disorders was adopted. The PDCO agreed on a waiver in the paediatric population from birth to less than 6 months of age the paediatric population from birth to less than 6 months of age on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments. The PDCO granted a deferral for the completion of this PIP.

2.1.16. RSV F protein - EMEA-003094-PIP02-21

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

Day 120 opinion

Vaccines / Infectious Diseases

Summary of Committee discussion:

In the written response, the applicant addressed the remaining issues raised by the Committee.
Based on the assessment of this application and the additional information provided by the applicant, a positive opinion for the PIP for the proposed medicine for the paediatric population from 2 years to less than 18 years of age, in the condition of prevention of lower respiratory tract disease caused by respiratory syncytial virus was adopted. The PDCO agreed on a waiver in a subset of children on the grounds that the specific medicinal product is likely to be unsafe. The PDCO granted a deferral for the completion of this PIP.

2.1.17. Rosuvastatin (calcium) / acetylsalicylic acid - EMEA-003206-PIP01-22

CIPROS S.r.l.; Prevention of cardiovascular events

Day 60 opinion

Cardiovascular Diseases

Summary of Committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO agreed with the applicant's request for a waiver. The PDCO recommended granting a waiver for rosuvastatin (calcium) / acetylsalicylic acid for all subsets of the paediatric population (0 to 18 years of age) in the condition of prevention of cardiovascular events.

2.1.18. Atorvastatin / ezetimibe - EMEA-003205-PIP01-22

Verisfield Single Member S.A.; Treatment of hypercholesterolaemia / Prevention of cardiovascular events

Day 60 opinion

Cardiovascular Diseases

Summary of Committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO agreed with the applicant's request for a waiver. The PDCO recommended granting a waiver for atorvastatin / ezetimibe for all subsets of the paediatric population (0 to 18 years of age) in the condition of prevention of cardiovascular events and treatment of hypercholesterolaemia, on the grounds of absence of significant therapeutic benefit.

2.1.19. N-(6-(((2R,3S)-3,4-dihydroxybutan-2-yl)oxy)-2-((4-fluorobenzyl)thio)pyrimidin-4-yl)-3-methylazetidine-1-sulfonamide - EMEA-003223-PIP01-22

Aristea Therapeutics, Inc.; Treatment of palmoplantar pustulosis

Day 60 opinion

Dermatology

Summary of Committee discussion:

The PDCO discussed at Day 60, during the June 2022 plenary meeting, an application for a waiver for N-(6-(((2R,3S)-3,4-dihydroxybutan-2-yl)oxy)-2-((4-fluorobenzyl)thio)pyrimidin-4-yl)-3-methylazetidine-1-sulfonamide in the condition of treatment of palmoplantar pustulosis.
Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO agreed with the applicant's request for a waiver. The PDCO recommended granting a waiver for N-(6-(((2R,3S)-3,4-dihydroxybutan-2-yl)oxy)-2-((4-fluorobenzyl)thio)pyrimidin-4-yl)-3-methylazetidine-1-sulfonamide for all subsets of the paediatric population (0 to 18 years of age) in the condition of treatment of palmoplantar pustulosis.
The PDCO emphasised that the granting of a waiver for the condition mentioned above should not prevent the applicant from considering a development in the paediatric population in indications where there is a paediatric need. The PDCO identified psoriasis as an unmet need. In principle according to the Paediatric Regulation, incentives for the development for use in the paediatric population are available even if a waiver has been granted in another condition.

2.1.20. Nipocalimab - Orphan - EMEA-002559-PIP05-22

Janssen-Cilag International NV; Treatment of bullous pemphigoid

Day 60 opinion

Dermatology

Summary of Committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO agreed with the applicant's request for a waiver. The PDCO recommended granting a waiver for nipocalimab for all subsets of the paediatric population (birth to less than18 years of age) in the condition of bullous pemphigoid on the grounds of lack of safety for patients from birth to less than 2 years of age and on the grounds lack of significant therapeutic benefit for from 2 to less than 18 years of age.
The PDCO emphasised that the granting of a waiver for the condition mentioned above should not prevent the applicant from considering a development in the paediatric population in indications where there is a paediatric need. In principle according to the Paediatric Regulation, incentives for the development for use in the paediatric population are available even if a waiver has been granted in another condition.

2.1.21. Gold (Au) - EMEA-003211-PIP01-22

Clene Netherlands B.V.; Treatment of amyotrophic lateral sclerosis

Day 60 opinion

Neurology

Summary of Committee discussion:

Based on the assessment of this application and further discussions at the Paediatric

Committee, the PDCO agreed with the applicant's request for a waiver. The PDCO recommended granting a waiver for Gold (Au) for all subsets of the paediatric population (birth to less than 18 years of age) in the condition of treatment of amyotrophic lateral sclerosis (ALS) based on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.
The PDCO emphasised that the granting of a waiver for the condition mentioned above should not prevent the applicant from considering a development in the paediatric population in indications where there is a paediatric need. In principle according to the Paediatric Regulation, incentives for the development for use in the paediatric population are available even if a waiver has been granted in another condition.

2.1.22. Modakafusp alfa - EMEA-003217-PIP01-22

Takeda Pharma A/S; Treatment of multiple myeloma

Day 60 opinion

Oncology

Summary of Committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO agreed with the applicant's request for a waiver. The PDCO recommended granting a waiver for modakafusp alfa for all subsets of the paediatric population (birth to less than 18 years of age) in the condition of treatment of multiple myeloma. Since the agreed waiver ground is that the disease does not occur in the paediatric population, the possibility to apply this to all pharmaceutical forms and all routes of administrations was agreed to by the applicant.
The PDCO emphasised that the granting of a waiver for the condition mentioned above should not prevent the applicant from considering a development in the paediatric population in indications where there is a paediatric need. In principle according to the Paediatric Regulation, incentives for the development for use in the paediatric population are available even if a waiver has been granted in another condition.

2.1.23. Humanised monoclonal antibody of IgG1 subtype targeting NRP1 - EMEA-003214-PIP01-22

Boehringer Ingelheim International GmbH; Treatment of diabetic retinopathy

Day 60 opinion

Ophthalmology

Summary of Committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO agreed with the applicant's request for a waiver. The PDCO recommended granting a waiver for humanised monoclonal antibody of IgG1 subtype targeting NRP1 (BI 765128) for all subsets of the paediatric population (birth to less than 18 years of age) in the condition “treatment of diabetic retinopathy”.

2.1.24. Magnesium lactate dihydrate / tramadol (hydrochloride) - EMEA-003216-PIP01-22

Orphinic Scientific Bis Sp. z o.o.; Treatment of pain

Day 60 opinion

Other

Summary of Committee discussion:

The PDCO re-discussed at Day 60, during the June 2022 plenary meeting, an application for a product specific waiver for magnesium lactate dihydrate / tramadol (hydrochloride) for the "management of chronic pain in adults with osteoarthritis of the hip and/or knee" on the three grounds: lack of safety; disease/condition not occurring and lack of significant therapeutic benefit.
The PDCO agreed with all the conclusions reached at Day 30 and adopted a positive opinion at Day 60 on a product specific waiver for this product for all subsets of the paediatric population (from birth to less than 18 years of age) in the condition of "treatment of pain" on the grounds that the disease does not represent a significant therapeutic benefit over existing treatments for paediatric patients.
The PDCO emphasised that the granting of a waiver for the condition mentioned above should not prevent the applicant from considering a development in the paediatric population in indications where there is a paediatric need. In principle according to the Paediatric Regulation, incentives for the development for use in the paediatric population are available even if a waiver has been granted in another condition.

2.1.25. Pregabalin - EMEA-003221-PIP01-22

Adalvo Limited; Treatment of neuropathic pain associated with diabetic peripheral neuropathy / Treatment of postherpetic neuralgia

Day 60 opinion

Pain / Neurology

Summary of Committee discussion:

The PDCO discussed at Day 60, during the June 2022 plenary meeting, an application for a waiver pregabalin for all subsets of the paediatric population (0 to 18 years of age) in the condition of treatment of postherpetic neuralgia, treatment of neuropathic pain associated with diabetic peripheral neuropathy.
Based on the assessment of this application and further assessment of the applicant's comments, the PDCO refused the applicant's request for a waiver.
The PDCO identified paediatric peripheral neuropathy as an unmet need and that studies would be feasible in this indication which included those applied for by the applicant.
Consequently, the PDCO adopted a negative opinion on the application for a waiver.

2.1.26. Nebivolol (hydrochloride) / amlodipine (besilate) - EMEA-003226-PIP01-22

Menarini Ricerche S.p.A.; Treatment of hypertension

Day 30 opinion

Cardiovascular Diseases

Summary of Committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO agreed with the applicant's request for a waiver. The PDCO recommended granting a waiver for nebivolol (hydrochloride) / amlodipine (besilate) for all subsets of the paediatric population (0 to 18 years of age) in the condition of treatment of hypertension.
The PDCO emphasised that the granting of a waiver for the condition mentioned above should not prevent the applicant from considering a development in the paediatric population in indications where there is a paediatric need. In principle according to the paediatric regulation, incentives for the development for use in the paediatric population are available even if a waiver has been granted in another condition.

2.1.27. Nebivolol (hydrochloride) / valsartan - EMEA-003227-PIP01-22

Menarini Ricerche S.p.A.; Treatment of hypertension

Day 30 opinion

Cardiovascular Diseases

Summary of Committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO agreed with the applicant's request for a waiver. The PDCO recommended granting a waiver for nebivolol (hydrochloride) / valsartan for all subsets of the paediatric population (0 to 18 years of age) in the condition of treatment of hypertension.
The PDCO emphasised that the granting of a waiver for the condition mentioned above should not prevent the applicant from considering a development in the paediatric population in indications where there is a paediatric need. In principle according to the Paediatric Regulation, incentives for the development for use in the paediatric population are available even if a waiver has been granted in another condition.

2.1.28. Recombinant COVID-19 subunit nanoparticle (adjuvanted with AS03) (GBP510) - EMEA-003115-PIP01-21

SK Chemicals GmBH; Prevention of coronavirus disease 2019 (COVID-19)

Day 90 opinion

Vaccines

Summary of Committee discussion:

Based on the assessment of this application, the responses to D60 request for modification and the additional changes implemented in the development plan, a positive opinion for the PIP for the proposed medicine for the paediatric population from birth to less than 18 years of age, in the condition of prevention of coronavirus disease 2019 (COVID-19) was adopted.
The PDCO granted a deferral for the completion of this PIP.

2.1.29. Doxribtimine / doxecitine - Orphan - EMEA-003210-PIP01-22

Zogenix ROI Limited; Treatment of thymidine kinase 2 deficiency

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of Committee discussion:

In the written response, the applicant addressed the remaining issues raised by the Committee.
Based on the assessment of this application and the additional information provided by the applicant, a positive opinion for the PIP for the proposed medicine for the paediatric population from birth to less than 18 years of age in the condition of treatment of thymidine kinase 2 deficiency was adopted. The PDCO granted a deferral for the completion of this PIP.

2.2. Opinions on Compliance Check

2.2.1. Apixaban - EMEA-C-000183-PIP01-08-M08

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

Day 60 opinion

Cardiovascular Diseases

Summary of Committee discussion:

The PDCO took note of outcomes of preceding partial compliance check procedures:

- EMEA-C1-000183-PIP01-08
- EMEA-C2-000183-PIP01-08
- EMEA-C3-000183-PIP01-08-M08

The PDCO adopted on 24 June 2022 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0198/2020) of 20 May 2020.

2.2.2. Pegzilarginase - EMEA-C1-001925-PIP02-19

Immedica Pharma AB; Treatment of hyperargininaemia

Day 60 letter

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of Committee discussion:

The PDCO discussed the completed studies (Study 3, 4, 5 and 7) and considered that these are compliant with the latest Agency's Decision (P/0252/2020) of 15 July 2020.
The PDCO finalised this partially completed compliance procedure on 24 June 2022.

2.2.3. Dulaglutide - EMEA-C-000783-PIP01-09-M06

Eli Lilly & Company Limited; Treatment of type 2 diabetes mellitus

Day 30 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of Committee discussion:

The PDCO took note of outcomes of preceding partial compliance check procedures:

- EMEA-C1-000783-PIP01-09-M02
- EMEA-C2-000783-PIP01-09-M05

The PDCO adopted on 24 June 2022 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0409/2021) of 29 October 2021.
The PDCO considered that the following studies could be considered significant:
Study 4 (H9X-MC-GBGC).

2.2.4. Evolocumab - EMEA-C-001268-PIP01-12-M05

Amgen Europe B.V; Treatment of elevated cholesterol

Day 30 opinion

Cardiovascular Diseases

Summary of Committee discussion:

The PDCO took note of outcomes of preceding partial compliance check procedures:

- EMEA-C1-001268-PIP01-12
- EMEA-C2-001268-PIP01-12-M05

The PDCO adopted on 24 June 2022 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0105/2018) of 11 April 2018.

2.2.5. Human Fibrinogen - EMEA-C-001208-PIP01-11-M03

Octapharma Pharamzeutika Produktionsges.m.b.H; Treatment of congenital fibrinogen deficiency

Day 30 opinion

Haematology-Hemostaseology

Summary of Committee discussion:

The PDCO took note of outcomes of preceding partial compliance check procedures:

- EMEA-C1-001208-PIP01-11-M02

The PDCO adopted on 24 June 2022 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0258/2017) of 4 September 2017.

2.2.6. Tisagenlecleucel - EMEA-C-001654-PIP02-17-M01

Novartis Europharm Limited; Treatment of mature B cell neoplasms

Day 30 opinion

Oncology

Summary of Committee discussion:

The PDCO discussed at Day 30, during the June 2022 plenary meeting, an application for a full compliance check for tisagenlecleucel, for the treatment of mature B cell neoplasms.
The PDCO discussed the completed PIP study.
The PDCO adopted on 24 June 2022 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0323/2019) of 11 September 2019.

2.2.7. Ad26.ZEBOV (recombinant, replication-incompetent) - EMEA-C-002307-PIP01-17-M02

Janssen-Cilag International NV; Prevention of Ebola virus disease

Day 30 opinion

Vaccines

Summary of Committee discussion:

The PDCO discussed the compliance check request on the 22nd June 2022 and concluded that all elements of Study 3 (VAC52150EBL2004) were compliant.
The PDCO took note of outcomes of preceding partial compliance check procedures:

- EMEA-C1-002307-PIP01-17
- EMEA-C2-002307-PIP01-17-M01

The PDCO adopted on the 24th June 2022 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0307/2021) of 12 August 2021.

2.2.8. MVA-BN-Filo (recombinant, non-replicating) - EMEA-C-002308-PIP01-17-M02

Janssen-Cilag International NV; Prevention of Ebola virus disease

Day 30 opinion

Vaccines

Summary of Committee discussion:

The PDCO discussed the compliance check request on the 22nd June 2022 and concluded that all elements of Study 3 (VAC52150EBL2004) were compliant.
The PDCO took note of outcomes of preceding partial compliance check procedures:

- EMEA-C1-002308-PIP01-17
- EMEA-C2-002308-PIP01-17-M01

The PDCO adopted on the 24th June 2022 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0307/2021) of 12 August 2021.

2.2.9. Letermovir - EMEA-C1-001631-PIP01-14-M04

Merck Sharp & Dohme (Europe), Inc; Prevention of cytomegalovirus infection

Day 30 letter

Infectious Diseases

Summary of Committee discussion:

The PDCO discussed the completed study and considered that this is compliant with the latest Agency's Decision (P/0362/2019) of 4 November 2019.
The PDCO finalised this partially completed compliance procedure on 24 June 2022.

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Obinutuzumab - Orphan - EMEA-001207-PIP02-19-M01

Roche Registration GmbH; Treatment of systemic lupus erythematosus

Day 60 opinion

Antineoplastic and immunomodulating agents

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency’s latest decision (P/0050/2021 of 28 January 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.2. Chloroprocaine hydrochloride - EMEA-000639-PIP03-16-M02

Sintetica GmbH; Peripheral nerve block (local anaesthesia by perineural injection)

Day 60 opinion

Anaesthesiology

Summary of Committee discussion:

The Committee reviewed, discussed and confirmed the preliminary conclusions reached at Day 30. A negative opinion refusing the proposed modifications has been adopted.

2.3.3. Bempedoic acid - EMEA-001872-PIP01-15-M02

Esperion Therapeutics, Inc.; Treatment of elevated cholesterol

Day 60 opinion

Cardiovascular Diseases

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0185/2018 of 17 July 2018).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.4. Etripamil - EMEA-002303-PIP01-17-M03

Milestone Pharmaceuticals, Inc.; Treatment of supraventricular tachycardia

Day 60 opinion

Cardiovascular Diseases

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes (one year delay in the initiation and completion of the Study 1, and completion of the Study 2) could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0406/2020 of 23 October 2020).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.5. Omecamtiv mecarbil - EMEA-001696-PIP01-14-M02

Cytokinetics, Inc.; Treatment of heart failure

Day 60 opinion

Cardiovascular Diseases

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision. The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.6. Bimekizumab - EMEA-002189-PIP01-17-M03

UCB Biopharma SRL; Treatment of psoriasis

Day 60 opinion

Dermatology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be

accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0168/2021 of 14 April 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.7. Deucravacitinib - EMEA-002350-PIP01-18-M02

Bristol-Myers Squibb International Corporation; Treatment of psoriasis

Day 60 opinion

Dermatology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0325/2021 of 12 August 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.8. Fluciclovine (18F) - Orphan - EMEA-001644-PIP02-14-M03

Blue Earth Diagnostics Ireland Ltd; Diagnosis of amino acid metabolism in solid malignant tumours

Day 60 opinion

Diagnostic / Oncology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered the proposed request acceptable to modify the PIP into a product specific waiver based on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as the needs are now covered.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0492/2020 of 22 December 2020).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.9. Pegunigalsidase alfa - Orphan - EMEA-001828-PIP01-15-M03

Chiesi Farmaceutici S.p.A; Treatment of Fabry disease

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be

accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0193/2021 of 10 May 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.10. Cilofexor - Orphan - EMEA-002554-PIP02-19-M01

Gilead Sciences International Ltd.; Treatment of primary sclerosing cholangitis (DB96.2)

Day 60 opinion

Gastroenterology-Hepatology

Note: Withdrawal request received on 10 June 2022

2.3.11. Maralixibat chloride - Orphan - EMEA-001475-PIP02-13-M02

Mirum Pharmaceuticals; Treatment of Alagille syndrome

Day 60 opinion

Gastroenterology-Hepatology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0245/2021 of 9 July 2021).

2.3.12. Fidanacogene elaparvovec - Orphan - EMEA-002362-PIP02-19-M02

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

Day 60 opinion

Haematology-Hemostaseology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0382/2021 of 8 September 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.13. Rilzabrutinib - Orphan - EMEA-002438-PIP02-19-M02

Principia Biopharma, Inc.; Treatment of immune thrombocytopenia

Day 60 opinion

Immunology-Rheumatology-Transplantation

Summary of Committee discussion:

In the written response, the applicant addressed the remaining issues raised by the Committee.
Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0272/2021 of 8 July 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.14. Avibactam / ceftazidime - EMEA-001313-PIP01-12-M12

Pfizer Europe MA EEIG; Treatment of intra-abdominal infections / Treatment of urinary tract infections / Treatment of pneumonia / Treatment of infections due to aerobic gram-negative organisms

Day 60 opinion

Infectious Diseases

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0001/2022 of 7 January 2022).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.15. Bulevirtide - Orphan - EMEA-002399-PIP01-18-M01

Gilead Sciences International Ltd.; Treatment of chronic hepatitis D infection

Day 60 opinion

Infectious Diseases

Summary of Committee discussion:

The PDCO re-discussed at Day 60, during the June 2022 plenary meeting, this request for modification for bulevirtide for the treatment of chronic hepatitis D infection.
The applicant proposes to delete clinical Study 1 (MYR205, the only clinical study) from the PIP. This would result in extrapolation of efficacy and safety from adults to the paediatric population.
The PDCO agreed to the changes and adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0296/2019 of 26 August 2019).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.16. Casirivimab - EMEA-002964-PIP01-21-M02

Roche Registration GmbH; Treatment of coronavirus disease 2019 (COVID-19) / Prevention of coronavirus disease 2019 (COVID-19)

Day 60 opinion

Infectious Diseases

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0044/2022 of 3 February 2022).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.17. Enmetazobactam - EMEA-002240-PIP02-17-M01

Allecra Therapeutics GmbH; Treatment of urinary tract infections

Day 60 opinion

Infectious Diseases

Summary of Committee discussion:

PDCO rediscussed this modification at D60.
Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that an extension of the timelines is principally acceptable.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0093/2019 of 22 March 2019).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.18. Imdevimab - EMEA-002965-PIP01-21-M02

Roche Registration GmbH; Treatment of coronavirus disease 2019 (COVID-19) / Prevention of coronavirus disease 2019 (COVID-19)

Day 60 opinion

Infectious Diseases

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0044/2022 of 3 February 2022).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.19. Pretomanid - Orphan - EMEA-002115-PIP01-17-M05

Global Alliance for TB Drug Development; Treatment of multi-drug-resistant tuberculosis

Day 60 opinion

Infectious Diseases

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0507/2021 of 3 December 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.20. Rezafungin acetate - Orphan - EMEA-002319-PIP01-17-M02

Mundipharma GmbH; Treatment of invasive candidiasis

Day 60 opinion

Infectious Diseases

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0395/2021 of 8 September 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.21. Ritonavir / (1R,2S,5S)-N-{(1S)-1-cyano-2-[(3S)-2-oxopyrrolidin-3-yl]ethyl}-6,6-dimethyl-3-[3-methyl-N-(trifluoroacetyl)-L-valyl]-3-azabicyclo[3.1.0]hexane-2-carboxamide - EMEA-003081-PIP01-21-M01

Pfizer Europe MA EEIG; Treatment of coronavirus disease 2019 (COVID-19) / Prevention of coronavirus disease 2019 (COVID-19)

Day 60 opinion

Infectious Diseases

Note: Withdrawal request received on 23 June 2022

2.3.22. Eptinezumab - EMEA-002243-PIP01-17-M03

H. Lundbeck A/S; Prevention of migraine headaches

Day 60 opinion

Neurology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as

set in the Agency's latest decision (P/0091/2022 of 11 March 2022).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.23. Lasmiditan - EMEA-002166-PIP01-17-M06

Eli Lilly and Company Limited; Treatment of migraine with and without aura

Day 60 opinion

Neurology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0056/2021 of 29 January 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.24. Ravulizumab - EMEA-001943-PIP03-20-M01

Alexion Europe SAS; Treatment of myasthenia gravis

Day 60 opinion

Neurology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0230/2021 of 8 June 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.25. Rimegepant - EMEA-002812-PIP02-20-M01

Biohaven Pharmaceutical Ireland DAC; Treatment of migraine headaches

Day 60 opinion

Neurology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0063/2021 of 18 February 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.26. Setmelanotide - Orphan - EMEA-002209-PIP01-17-M03

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

Day 60 opinion

Nutrition

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed change to the inclusion criteria defining weight limit could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0215/2021 of 8 June 2021). The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.27. Bosutinib - EMEA-000727-PIP01-09-M06

Pfizer Europe MA EEIG; Treatment of chronic myeloid leukaemia

Day 60 opinion

Oncology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0368/2021 of 8 September 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.28. Larotrectinib - EMEA-001971-PIP03-18-M02

Bayer AG; Treatment of malignant neoplasms of the central nervous system

Day 60 opinion

Oncology

Summary of Committee discussion:

In the written response, the applicant addressed the remaining issues raised by the Committee.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0077/2021 of 17 March 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.29. Lenvatinib - EMEA-001119-PIP02-12-M08

Eisai GmbH; Treatment of follicular carcinoma / Treatment of papillary thyroid carcinoma / Treatment of osteosarcoma

Day 60 opinion

Oncology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0427/2020 of 21 October 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.30. Andexanet alfa - EMEA-001902-PIP01-15-M06

AstraZeneca AB; Prevention of factor Xa inhibitor associated haemorrhage / Treatment of factor Xa inhibitor associated haemorrhage

Day 60 opinion

Other

Note: Withdrawal request received on 17 June 2022

2.3.31. Setrusumab - Orphan - EMEA-002169-PIP01-17-M01

Mereo Biopharma 3 Ltd; Treatment of osteogenesis imperfecta

Day 60 opinion

Other

Note: Withdrawal request received on 10 June 2022

2.3.32. Vamorolone - Orphan - EMEA-001794-PIP02-16-M05

ReveraGen BioPharma Ltd; Treatment of Duchenne muscular dystrophy

Day 60 opinion

Other

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0515/2021 of 3 December 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.33. Ivacaftor / tezacaftor / elexacaftor - Orphan - EMEA-002324-PIP01-17-M03

Vertex Pharmaceuticals (Ireland) Limited; Treatment of cystic fibrosis

Day 60 opinion

Other / Pneumology - Allergology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0416/2021 of 29 October 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.34. Dermatophagoides farinae / dermatophagoides pteronyssinus - EMEA-001258-PIP01-11-M08

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

Day 60 opinion

Pneumology - Allergology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0160/2021 of 16 April 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.35. Brexpiprazole - EMEA-001185-PIP01-11-M08

Otsuka Pharmaceutical Development & Commercialisation Europe GmbH; Treatment of schizophrenia

Day 60 opinion

Psychiatry

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, including the additional information received since Day 30, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision. The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.36. Vortioxetine - EMEA-000455-PIP02-10-M09

H. Lundbeck A/S; Treatment of major depressive disorder

Day 60 opinion

Psychiatry

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, including the additional information received since Day 30, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision. The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.37. COVID-19 vaccine (ChAdOx1-S [recombinant]) - EMEA-002862-PIP01-20-M03

AstraZeneca AB; Prevention of coronavirus disease 2019 (COVID-19)

Day 60 opinion

Vaccines

Note: Withdrawal request received on 17 June 2022

2.3.38. Leniolisib phosphate - Orphan - EMEA-002989-PIP01-21-M01

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

Day 30 opinion

Immunology-Rheumatology-Transplantation

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0556/2021 of 31 December 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.39. Epcoritamab - Orphan - EMEA-002907-PIP01-20-M01

AbbVie Ltd; Treatment of mature B cell lymphoma

Day 30 opinion

Oncology

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0344/2021 of 12 August 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

2.3.40. MRNA-1273.529 / elasomeran - EMEA-002893-PIP01-20-M02

MODERNA BIOTECH SPAIN, S.L.; Prevention of coronavirus disease 2019 (COVID-19)

Day 30 opinion

Vaccines / Infectious Diseases

Summary of Committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0444/2021 of 22 November 2021).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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. Zilucoplan - EMEA-C1-002747-PIP01-20

UCB Pharma S.A; Treatment of myasthenia gravis

Day 30 letter

Other / Neurology

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. Ex vivo expanded autologous human keratinocytes containing epidermal stem cells genetically modified with a gamma-retroviral (RV) vector expressing the full-length LAMB3 cDNA - Orphan - EMEA-003137-PIP01-21

Holostem Terapie Avanzate s.r.l.; Treatment of junctional epidermolysis bullosa (JEB)

Day 90 discussion

Dermatology

3.1.2. Tezepelumab - EMEA-001613-PIP04-21

Treatment of chronic spontaneous urticaria

Day 90 discussion

Dermatology

3.1.3. EMEA-003143-PIP01-21

Treatment of ulcerative colitis

Day 90 discussion

Gastroenterology-Hepatology

Note: Withdrawal request received on 30 June 2022

3.1.4. Clazakizumab - EMEA-001371-PIP02-21

Treatment of chronic active antibody mediated rejection (AMR) in kidney transplantation

Day 90 discussion

Immunology-Rheumatology-Transplantation

3.1.5. Tocilizumab - EMEA-000309-PIP09-21

Treatment of systemic sclerosis

Day 90 discussion

Immunology-Rheumatology-Transplantation

3.1.6. Ibrexafungerp citrate - EMEA-002535-PIP04-21

Treatment of invasive candidiasis

Day 90 discussion

Infectious Diseases

3.1.7. Corticotropin - EMEA-003097-PIP01-21

Treatment of infantile spasms

Day 90 discussion

Neurology

3.1.8. Cannabidiol - EMEA-003176-PIP01-21

Treatment of fragile X syndrome (FXS)

Day 90 discussion

Psychiatry

3.1.9. Troriluzole - EMEA-003084-PIP02-21

Treatment of obsessive-compulsive disorder

Day 90 discussion

Psychiatry

3.1.10. Zuranolone - EMEA-003119-PIP01-21

Treatment of postpartum depression

Day 90 discussion

Psychiatry

3.1.11. Milvexian - EMEA-003220-PIP01-22

Prevention of thromboembolism

Day 60 discussion

Cardiovascular Diseases

3.1.12. Zilebesiran - EMEA-003218-PIP01-22

Treatment of hypertension

Day 60 discussion

Cardiovascular Diseases

3.1.13. Perflubutane - EMEA-003037-PIP02-22

Diagnostic evaluation of focal hepatic lesions

Day 60 discussion

Diagnostic / Oncology

3.1.14. Danuglipron - EMEA-002944-PIP02-22

Treatment of obesity / Treatment of chronic weight management/obesity

Day 60 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.15. Insulin human (rDNA) - EMEA-003194-PIP02-22

Treatment of type 2 diabetes mellitus

Day 60 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.16. Inclaclumab - EMEA-003219-PIP01-22

Treatment of sickle cell disease

Day 60 discussion

Haematology-Hemostaseology

3.1.17. Synthetic peptide of 20 amino acids comprising a T cell epitope from pro-insulin - EMEA-002379-PIP01-22

Treatment of type 1 diabetes mellitus

Day 60 discussion

Immunology-Rheumatology-Transplantation / Endocrinology-Gynaecology-Fertility-Metabolism / Vaccines

3.1.18. EMEA-003222-PIP01-22

Treatment of SCN8A developmental and epileptic encephalopathy

Day 60 discussion

Neurology

3.1.19. Satralizumab - Orphan - EMEA-001625-PIP04-22

Roche Registration GmbH; Treatment of autoimmune encephalitis

Day 60 discussion

Neurology

3.1.20. Autologous CD4+ and CD8+ T cells transduced with lentiviral vector encoding a chimeric antigen receptor (CAR) directed against CD19 and preserving the T cell phenotype of the leukapheresis starting material - EMEA-003212-PIP01-22

Treatment of mature B cell neoplasms

Day 60 discussion

Oncology

3.1.21. Fianlimab - EMEA-003207-PIP01-22

Treatment of melanoma

Day 60 discussion

Oncology

3.1.22. Humanised IgG2 monoclonal antibody against interleukin-6 - EMEA-003215-PIP01-22

Treatment of macular oedema

Day 60 discussion

Ophthalmology

3.1.23. Benzylamine derivative of benzofuran - EMEA-002974-PIP02-22

Treatment of C3 glomerulopathy

Day 60 discussion

Uro-nephrology

3.1.24. Hydrochlorothiazide / amlodipine / telmisartan - EMEA-003229-PIP01-22

Treatment of hypertension / I10 essential primary hypertension

Day 30 discussion

Cardiovascular Diseases

3.1.25. Perindopril tert-butylamin / rosuvastatin - EMEA-003228-PIP01-22

Treatment of hypertension / Treatment of dyslipidaemia / Prevention of cardiovascular events

Day 30 discussion

Cardiovascular Diseases

3.1.26. Valsartan / rosuvastatin - EMEA-003240-PIP01-22

Treatment of dyslipidaemia / Treatment of hypertension / Prevention of cardiovascular events

Day 30 discussion

Cardiovascular Diseases

3.1.27. Amlitelimab - EMEA-003233-PIP01-22

Treatment of atopic dermatitis

Day 30 discussion

Dermatology

3.1.28. CRN04777 - Orphan - EMEA-003242-PIP01-22

Crinetics Pharmaceuticals, Inc.; Treatment of congenital hyperinsulinism

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.29. EMEA-003241-PIP01-22

Treatment of sickle cell disease

Day 30 discussion

Haematology-Hemostaseology

3.1.30. Itolizumab - Orphan - EMEA-003208-PIP02-22

Biocon Pharma Malta-I Limited; Treatment of acute graft versus host disease

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.1.31. Cilgavimab / tixagevimab - EMEA-003079-PIP01-22

Prevention of coronavirus disease 2019 (COVID-19) / Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Infectious Diseases

3.1.32. Opelconazole - EMEA-003249-PIP01-22

Treatment of bronchopulmonary aspergillosis

Day 30 discussion

Infectious Diseases

3.1.33. Tetracycline / metronidazole / bismuth - EMEA-003224-PIP01-22

Treatment of *Helicobacter pylori* infection

Day 30 discussion

Infectious Diseases / Gastroenterology-Hepatology

3.1.34. Enibarcimab - EMEA-003244-PIP01-22

Treatment of sepsis

Day 30 discussion

Neonatology - Paediatric Intensive Care / Cardiovascular Diseases

3.1.35. Cemdisiran sodium - Orphan - EMEA-003237-PIP01-22

Regeneron Ireland DAC; Treatment of generalised myasthenia gravis (gMG)

Day 30 discussion

Neurology

3.1.36. Pegcetacoplan - EMEA-002600-PIP04-22

Treatment of amyotrophic lateral sclerosis

Day 30 discussion

Neurology

3.1.37. Pozelimab - EMEA-003238-PIP01-22

Treatment of generalised myasthenia gravis (gMG)

Day 30 discussion

Neurology

3.1.38. Suvecaltamide - EMEA-003248-PIP01-22

Treatment of essential tremor

Day 30 discussion

Neurology

3.1.39. Autologous CD4+ and CD8+ T cells transduced with lentiviral vector encoding a chimeric antigen receptor (CAR) directed against human B cell maturation antigen

(BCMA) and preserving the T cell phenotype of the leukapheresis starting material - EMEA-003231-PIP01-22

Treatment of multiple myeloma

Day 30 discussion

Oncology

3.1.40. Gallium 68-labelled prostate-specific membrane antigen-11 (68Ga-PSMA-11) - EMEA-003236-PIP01-22

Visualisation of prostate specific membrane antigen in prostate cancer

Day 30 discussion

Oncology

3.1.41. Golidocitinib - EMEA-003246-PIP01-22

Treatment of peripheral T cell lymphoma

Day 30 discussion

Oncology

3.1.42. Lutetium (177Lu) edotreotide - Orphan - EMEA-003245-PIP01-22

ITM Solucin GmbH; Treatment of somatostatin receptor (SSTR)-positive tumours

Day 30 discussion

Oncology

3.1.43. Monalizumab - EMEA-002751-PIP02-22

Treatment of lung cancer

Day 30 discussion

Oncology

3.1.44. Obinutuzumab - Orphan - EMEA-001207-PIP04-22

Roche Registration GmbH; Prevention of cytokine release syndrome

Day 30 discussion

Oncology

3.1.45. Oleclumab - EMEA-003234-PIP01-22

Treatment of pancreatic cancer / Treatment of lung cancer

Day 30 discussion

Oncology

3.1.46. Toripalimab - EMEA-003243-PIP01-22

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

Day 30 discussion

Oncology

3.1.47. Vepsitamab - EMEA-003230-PIP01-22

Treatment of gastrointestinal solid tumours malignant and unspecified expressing MUC17

Day 30 discussion

Oncology

3.1.48. Xevinapant - Orphan - EMEA-003235-PIP01-22

Merck Healthcare KGaA; Treatment of head and neck epithelial malignant neoplasms

Day 30 discussion

Oncology

3.1.49. Dimeric protein comprised of two disulfide-linked monomers, each being a fully human fusion protein consisting of a modified extracellular domain (ECD) of the human activin receptor type IIA (ActRIIA) fused to the fragment crystallizable (Fc) domain of human IgG1 Fc including the hinge region, CH2 and CH3 domains - EMEA-003239-PIP01-22

Treatment of myelodysplastic syndrome (MDS) and myelofibrosis (MF)

Day 30 discussion

Oncology / Haematology-Hemostaseology

3.1.50. Tinlarebant - Orphan - EMEA-003225-PIP01-22

Belite Bio, Inc; Treatment of Stargardt disease

Day 30 discussion

Ophthalmology

3.1.51. (S)-lactic acid - EMEA-003247-PIP01-22

Treatment of degenerative disc disease

Day 30 discussion

Other

Note: Withdrawal request received on 05 July 2022

3.1.52. Tirzepatide - EMEA-002360-PIP02-22

Treatment of obesity

Day 30 discussion

Other

3.1.53. Recombinant human ectonucleotide pyrophosphatase/phosphodiesterase 1 fused to the Fc fragment of IgG1 - Orphan - EMEA-003232-PIP01-22

Inozyme Pharma Ireland Limited; Treatment of ectonucleotide pyrophosphatase/phosphodiesterase 1 (ENPP1) deficiency

Day 30 discussion

Other / Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases

3.1.54. ABNCoV2 (AV2-cVLP-RBD SARS-CoV-2) - EMEA-003184-PIP01-22

Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Vaccines / Infectious Diseases

3.2. Discussions on Compliance Check

No item

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Aliskiren hemifumarate - EMEA-000362-PIP01-08-M06

NODEN PHARMA DAC; Treatment of heart failure / Treatment of hypertension

Day 30 discussion

Cardiovascular Diseases

Note: Withdrawal request received on 07 July 2022

3.3.2. Treprostinil - EMEA-000207-PIP01-08-M07

Ferrer Internacional, S.A.; Treatment of pulmonary arterial hypertension

Day 30 discussion

Cardiovascular Diseases

3.3.3. Evinacumab - EMEA-002298-PIP01-17-M04

Regeneron Ireland DAC; Treatment of elevated cholesterol

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. Guselkumab - EMEA-001523-PIP04-19-M01

Janssen-Cilag International N.V.; Treatment of ulcerative colitis: ICD K51

Day 30 discussion

Gastroenterology-Hepatology

3.3.5. Odevixibat - Orphan - EMEA-002054-PIP03-20-M01

Albireo AB; Treatment of Alagille syndrome

Day 30 discussion

Gastroenterology-Hepatology

3.3.6. Ustekinumab - EMEA-000311-PIP04-13-M05

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

Day 30 discussion

Gastroenterology-Hepatology

3.3.7. Plasma kallikrein inhibitor - EMEA-002723-PIP01-19-M01

KalVista Pharmaceuticals Ltd; Treatment of hereditary angioedema

Day 30 discussion

Haematology-Hemostaseology

3.3.8. Roxadustat - EMEA-001557-PIP01-13-M06

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

Day 30 discussion

Haematology-Hemostaseology

3.3.9. Vonicog alfa - EMEA-001164-PIP01-11-M06

Baxalta Innovations GmbH; Treatment of Von Willebrand disease

Day 30 discussion

Haematology-Hemostaseology

3.3.10. Apremilast - EMEA-000715-PIP02-11-M06

Amgen Europe B.V.; Treatment of juvenile psoriatic arthritis (JPsA) / Treatment of juvenile idiopathic arthritis (JIA)

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.3.11. Apremilast - EMEA-000715-PIP05-13-M05

Amgen Europe.B.V; Treatment of Behçet's disease

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.3.12. Baricitinib - EMEA-001220-PIP07-20-M01

Eli Lilly and Company Limited; Treatment of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.3.13. Belimumab - EMEA-000520-PIP02-13-M04

Glaxo Group Limited; Treatment of systemic lupus erythematosus

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.3.14. Grisnilimab setaritox / dafsolimab setaritox - Orphan - EMEA-002087-PIP01-16-M01

Xenikos B.V.; Treatment of acute graft versus host disease

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.3.15. Upadacitinib - EMEA-001741-PIP04-17-M03

AbbVie Ltd; Treatment of atopic dermatitis

Day 30 discussion

Immunology-Rheumatology-Transplantation / Dermatology

3.3.16. Baloxavir marboxil - EMEA-002440-PIP01-18-M03

Roche Registration GmbH; Treatment of influenza / Prevention of influenza

Day 30 discussion

Infectious Diseases

3.3.17. BNT162b2 / tozinameran - EMEA-002861-PIP02-20-M04

BioNTech Manufacturing GmbH; Prevention of coronavirus disease 2019 (COVID-19)

Day 30 discussion

Infectious Diseases

3.3.18. Cabotegravir - EMEA-001418-PIP01-13-M05

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

Day 30 discussion

Infectious Diseases

3.3.19. Cobicistat - EMEA-000969-PIP01-10-M06

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

Day 30 discussion

Infectious Diseases

3.3.20. Emtricitabine / tenofovir alafenamide - EMEA-001577-PIP02-14-M05

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

Day 30 discussion

Infectious Diseases

3.3.21. Lamivudine / dolutegravir - EMEA-001940-PIP01-16-M04

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

Day 30 discussion

Infectious Diseases

3.3.22. Rilpivirine - EMEA-000317-PIP02-18-M01

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

infection

Day 30 discussion

Infectious Diseases

3.3.23. Tenofovir alafenamide / rilpivirine / emtricitabine - EMEA-001679-PIP01-14-M02

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

Day 30 discussion

Infectious Diseases

3.3.24. Zoliflodacin - EMEA-002599-PIP01-19-M01

Entasis Therapeutic Inc.; Treatment of gonococcal infection

Day 30 discussion

Infectious Diseases

3.3.25. Fenfluramine hydrochloride - Orphan - EMEA-001990-PIP01-16-M05

Zogenix International Ltd; Treatment of Dravet syndrome

Day 30 discussion

Neurology

3.3.26. Ozanimod (hydrochloride) - EMEA-001710-PIP02-14-M07

Bristol-Myers Squibb Pharma EEIG; Treatment of multiple sclerosis

Day 30 discussion

Neurology

3.3.27. Peginterferon beta-1a - EMEA-001129-PIP01-11-M05

Biogen Idec Ltd; Treatment of multiple sclerosis

Day 30 discussion

Neurology

3.3.28. Cabozantinib - Orphan - EMEA-001143-PIP01-11-M05

Ipsen Pharma; Treatment of malignant solid tumours

Day 30 discussion

Oncology

3.3.29. Copanlisib - Orphan - EMEA-001757-PIP02-15-M03

Bayer AG; Treatment of mature B cell neoplasms / Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue)

Day 30 discussion

Oncology

3.3.30. Durvalumab - EMEA-002028-PIP01-16-M03

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

Day 30 discussion

Oncology

3.3.31. Tremelimumab - Orphan - EMEA-002029-PIP01-16-M03

AstraZeneca AB; Treatment of all conditions included in the category of malignant neoplasms (except central nervous system, haematopoeitic and lymphoid tissue) / Treatment of malignant neoplasms of haematologic and lymphoid tissue

Day 30 discussion

Oncology

3.3.32. Inotuzumab ozogamicin - Orphan - EMEA-001429-PIP01-13-M06

Pfizer Europe MA EEIG; Treatment of acute lymphoblastic leukaemia

Day 30 discussion

Oncology / Haematology-Hemostaseology

3.3.33. Lomitapide (as lomitapide mesylate) - EMEA-001124-PIP01-10-M05

Amryt Pharmaceuticals DAC; Treatment of heterozygous and homozygous familial hypercholesterolaemia

Day 30 discussion

Other

3.3.34. Cannabidiol / delta-9-tetrahydrocannabinol - EMEA-000181-PIP02-13-M01

GW Pharma (International) B.V; Treatment of pain

Day 30 discussion

Pain

3.3.35. Adrenaline (epinephrine) - EMEA-002749-PIP01-19-M02

ARS Pharmaceuticals IRL, Limited; Treatment of allergic reactions

Day 30 discussion

Pneumology - Allergology

3.3.36. Cholera vaccine, recombinant, live, oral (strain CVD 103-HgR) - EMEA-001490-PIP01-13-M03

Emergent Netherlands B.V.; Treatment of cholera disease caused by *Vibrio cholerae* serogroup O1

Day 30 discussion

Vaccines

4. Nominations

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

4.1. List of submissions of applications with start of procedure 11 July 2022 for Nomination of Rapporteur and Peer reviewer

Summary of Committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

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

Summary of Committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

4.3. Nominations for other activities

Summary of Committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

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.

5.1. New Scientific Advice

No item

6. Discussion on the applicability of class waivers

6.1. Discussions on the applicability of class waiver for products

6.1.1. AZD9833 (selective estrogen receptor degrader) - EMEA-01-2022

AstraZeneca AB; Treatment of hormone receptor positive breast cancer

Summary of Committee discussion:

The applicability of the class waiver as referred to in the Agency's Decision CW/0001/2015 to the planned therapeutic indication was confirmed.

Other potential paediatric interests of this medicine suggested by PDCO: none identified at this stage.

6.1.2. Donanemab - EMEA-03-2022

Eli Lilly and Company Limited; Slowing disease progression in patients with early symptomatic Alzheimer's disease

Summary of Committee discussion:

The applicability of the class waiver as referred to in the Agency's Decision CW/0001/2015 to the planned therapeutic indication was confirmed.

Other potential paediatric interests of this medicine suggested by PDCO: none identified at this stage.

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

The members of the PDCO took note of the products listed in the Annex B.

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. PDCO membership

The PDCO Chair welcomed Olivier Moes representing Luxemburg as the new Alternate Member.

The PDCO Chair thanked Martine Trauffler as her PDCO membership came to an end.

9.1.2. Vote by Proxy

No item

9.1.3. Mandate of PDCO Chairperson - call for nominations

Summary of Committee discussion:

The Committee was reminded about the Chair election planned to take place at the July 2022 plenary.

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

PDCO member: Tomáš Boráň

Summary of Committee discussion:

PDCO members were invited to the next strategic review and learning meeting in Prague.

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

Summary of Committee discussion:

The list of PIP-related CHMP procedures starting in May 2022, was presented to the PDCO members.

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

Summary of Committee discussion:

The Vice-Chair of the Non-clinical Working Party (NcWP) identified the products which will require NcWP evaluation and discussion.

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Summary of Committee discussion:

The Chair of the Formulation Working Group (FWG) identified the products which will require FWG evaluation and discussion.

9.3.3. EMA Emergency task force (ETF) - Invitation to nominate a new PDCO member

PDCO member: Koen Norga

Summary of Committee discussion:

The Chair provided the Committee an update on the call for nominations for the EMA ETF following the departure of Eva Agurell.

9.4. Cooperation within the EU regulatory network

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

No item

9.5. Cooperation with International Regulators

9.5.1. Paediatric Cluster Teleconference

Summary of Committee discussion:

The June 2022 agenda and minutes of the cluster were shared with the PDCO members for information.

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

Q2/2022 Update of the Business Pipeline report for the human scientific committees

Summary of Committee discussion:

The business pipeline report for Q2/2022 was provided for information.

10. Any other business

10.1. COVID-19 update

Summary of Committee discussion:

The update was cancelled.

10.2. Exparel liposomal - EMEA/H/C/004586/II/0005 PDCO consultation from CHMP

Summary of Committee discussion:

The PDCO discussed a draft response to be finalised at the next plenary meeting.

10.3. EU Survey Testing

Summary of Committee discussion:

The use of EU Survey for elections was practised and tested with the Committee.

10.4. Revision of the guideline on clinical investigation of medicinal products in the treatment or prevention of diabetes mellitus

PDCO members: Carine de Beaufort, Agnes Gyurasics

Summary of Committee discussion:

This item was postponed to the next PDCO meeting of July 2022.

11. Breakout sessions

11.1. Neonatology

Summary of Committee discussion:

Discussion on use of modelling and simulation methodologies in neonates.

11.2. Vaccines

Summary of Committee discussion:

Topics relevant to COVID vaccines were discussed.

11.3. Paediatric oncology

Summary of Committee discussion:

Members were informed about ongoing oncology activities and discussed about PIP-related issues.

The Chair thanked all participants and closed the meeting.

12. List of participants

List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 21-24 June 2022 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Koenraad Norga	Chair	Belgium	No interests declared	
Karl-Heinz Huemer	Member	Austria	No interests declared	
Marleen Renard	Member	Belgium	No participation in final deliberations and voting on:	2.2.1. Apixaban - EMEA-C-000183-PIP01-08-M08
Dimitar Roussinov	Member	Bulgaria	No restrictions applicable to this meeting	
Zena Gunther	Member	Cyprus	No interests declared	
Tomas Boran	Member	Czechia	No interests declared	
Tereza Bazantova	Alternate	Czechia	No interests declared	
Nanna Borup Johansen	Member	Denmark	No interests declared	
Louisa Braun Exner	Alternate	Denmark	No interests declared	
Irja Lutsar	Member	Estonia	No interests declared	
Jana Lass	Alternate	Estonia	No interests declared	
Pauliina Lehtolainen-Dalkilic	Member	Finland	No interests declared	
Anne Paavola	Alternate	Finland	No interests declared	
Sylvie Benchetrit	Member	France	No interests declared	
Dominique Ploin	Alternate	France	No interests declared	
Sabine Scherer	Member (Vice-Chair)	Germany	No interests declared	
Yuansheng Sun	Alternate	Germany	No interests declared	
Eleni Katsomiti	Member	Greece	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Ágnes Gyurasics	Member (CHMP alternate)	Hungary	No interests declared	
Brian Aylward	Member	Ireland	No interests declared	
Sara Galluzzo	Member	Italy	No interests declared	
Dina Apele-	Member	Latvia	No restrictions	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Freimane			applicable to this meeting	
Dovile Zacharkiene	Member	Lithuania	No interests declared	
Carola de Beaufort	Member	Luxembourg	No restrictions applicable to this meeting	
Olivier Moes	Alternate	Luxembourg	No interests declared	
Herbert Lenicker	Alternate	Malta	No interests declared	
Roderick Houwen	Member	Netherlands	No participation in final deliberations and voting on:	3.3.5. Odevixibat - Orphan - EMEA-002054-PIP03-20-M01
Maaike van Dartel	Alternate	Netherlands	No interests declared	
Siri Wang	Member	Norway	No interests declared	
Anette Solli Karlsen	Alternate	Norway	No interests declared	
Marek Migdal	Member	Poland	No restrictions applicable to this meeting	
Helena Fonseca	Member	Portugal	No interests declared	
Hugo Tavares	Alternate	Portugal	No interests declared	
Dana Gabriela Marin	Member (CHMP alternate)	Romania	No interests declared	
Peter Sisovsky	Member	Slovakia	No interests declared	
Peter Szitanyi	Alternate	Slovakia	No interests declared	
Stefan Grosek	Member	Slovenia	No interests declared	
Fernando de Andrés Trelles	Member	Spain	No interests declared	
Maria Jesus Fernández Cortizo	Alternate	Spain	No interests declared	
Kristin Karlsson	Member	Sweden	No restrictions applicable to this meeting	
Johannes Taminiau	Member	Healthcare Professionals' Representative	No interests declared	
Fernando Cabanas	Member	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Francesca Rocchi	Member	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Jaroslav Sterba	Member	Patients' Organisation Representative	No restrictions applicable to this meeting	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Dimitrios Athanasiou	Member	Patients' Organisation Representative	No interests declared	
Tomasz Grybek	Alternate	Patients' Organisation Representative	No interests declared	
María Estela Moreno Martín	Expert - via telephone*	Spain	No interests declared	
Maija Tarkkanen	Expert - via telephone*	Finland	No interests declared	
David Khan	Expert - via telephone*	Sweden	No interests declared	
Gaby Wangorsch	Expert - via telephone*	Germany	No interests declared	
Frederike Lentz	Expert - via telephone*	Germany	No interests declared	
Flora Musuamba Tshinanu	Expert - via telephone*	Belgium	No restrictions applicable to this meeting	
Pieter Colin	Expert - via telephone*	Belgium	No interests declared	
Anne Mari Lone	Expert - via telephone*	Norway	No restrictions applicable to this meeting	
Charlotta Bergquist	Expert - via telephone*	Sweden	No interests declared	
Meeting run with support from relevant EMA staff				
* Experts were evaluated against the agenda topics or activities they participated in				

13. 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/