29 January 2021
EMA/PDCO/74936/2021
Human Medicines Division

Paediatric Committee (PDCO)

Minutes for the meeting on 26-29 January 2021

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 Chairperson opened the meeting by welcoming all participants. Due to the current coronavirus (COVID-19) outbreak, and the associated EMA Business Continuity Plan (BCP), the meeting was held remotely.

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 based on the topics in the agenda of the current meeting, the Committee Secretariat announced the restricted involvement of some meeting participants in upcoming discussions as included in the pre-meeting list of participants and restrictions.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared.

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 and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 17 or more members were present in the room). All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

Due to restricted involvement, the Chair Koenraad Norga was replaced by the Vice-Chair Sabine Scherer for the discussion on agenda topics 2.1.14, 2.1.18, 2.3.36, 3.1.22 and 3.3.1.

1.2. Adoption of agenda

PDCO agenda for 26-29 January 2021

The agenda of the PDCO meeting 26-29 January 2021 was adopted.

1.3. Adoption of the minutes

PDCO minutes for 8-11 December 2020

The minutes of the PDCO meeting 8-11 December 2020 were adopted and will be published on the EMA website.

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. Delgocitinib - EMEA-002329-PIP02-20

LEO Pharma A/S; Treatment of dermatitis and eczema / treatment of chronic hand eczema / treatment of atopic dermatitis

Day 120 opinion

Dermatology

Summary of committee discussion:

A positive opinion was adopted at Day 120, including a waiver for a subset of the paediatric population on the grounds that clinical studies with delgocitinib cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset. A deferral was granted for quality and clinical studies of atopic dermatitis.

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

Neurocrine Therapeutics Ltd; Treatment of congenital adrenal hyperplasia

Day 120 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The PDCO re-discussed this application in line with the outcome conclusion from the D90 discussion, considering the additional information received by the applicant.
All other outstanding issues were considered resolved. Based on the assessment of this application, the PDCO agrees to a PIP and granting a deferral for crincerfont in the condition of treatment of congenital adrenal hyperplasia.

2.1.3. (S)-2-(5-((3-ethoxypyridin-2-yl)oxy)pyridin-3-yl)-N-(tetrahydrofuran 3 yl) pyrimidine-5-carboxamide (PF-06865571) - EMEA-002773-PIP01-20

Pfizer Europe MA EEIG; Treatment of non-alcoholic steatohepatitis (NASH)

Day 120 opinion

Gastroenterology-Hepatology

Summary of committee discussion:

A positive opinion was adopted on D120 including a deferral in a subset of children for the treatment of non-alcoholic steatohepatitis. A waiver for a subset of children on the grounds the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subsets and for another subset of children on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments was also adopted.

2.1.4. Crovalimab - EMEA-002709-PIP01-19

Roche Registration GmbH; Paroxysmal nocturnal hemoglobinuria (PNH) / atypical hemolytic uremic syndrome (aHUS)

Day 120 opinion

Haematology-Hemostaseology

Summary of committee discussion:

The PDCO agreed on a positive opinion for this PIP for crovalimab for the treatment of paroxysmal nocturnal haemoglobinuria (PNH) and the treatment of atypical haemolytic uremic syndrome (aHUS). A waiver was granted based on the grounds that the product does not represent a significant therapeutic benefit in a subset of children with PNH and in a subset of children with PNH. A deferral was granted for the completion of the PIP.

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

Amgen Europe B.V.; Systemic lupus erythematosus

Day 120 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

Prior to Day 120, the applicant provided the requested information regarding the outstanding issues.
The PDCO adopted a positive opinion on this PIP for the treatment of lupus erythematosus in a subset of children. The completion of this PIP is deferred. A waiver was granted for a subset of the paediatric population based on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2.1.6. Secukinumab - EMEA-000380-PIP06-19

Novartis Europharm Limited; Treatment of systemic lupus erythematosus

Day 120 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

In January 2021 the PDCO noted the responses of the applicant to the remaining issues outlined at D90 addressed during a consultation on a draft opinion.
Therefore, the PDCO agreed on a PIP for secukinumab in treatment on systemic lupus erythematosus (indication in Lupus nephritis) with a waiver for a subset of the paediatric population and a deferral. The PIP includes an RCT, a modelling study and an extrapolation analysis.

2.1.7. Tacrolimus - EMEA-001642-PIP02-20

Proveca Pharma Limited; 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 immunosupressive medical products in children aged from birth to less than 18 years.

Day 120 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

Taking into account responses received from the applicant to the PDCO's Day 90 comments, and based on the assessment of this application, the PDCO concluded on a positive opinion for a PIP for tacrolimus for all subsets of the paediatric population (from birth to less 18 years of age) in the conditions treatment of solid organ transplant rejection, and prevention of solid organ transplant rejection.

2.1.8. Telitacicept - EMEA-002824-PIP01-20

RemeGen, Ltd.; Treatment of systemic lupus erythematosus

Day 120 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

In January 2021 the PDCO noted the reply provided by the applicant, in the framework of a consultation of a draft opinion, on the issues raised at D90.
Therefore, the PDCO agreed an opinion for secukinumab for the treatment of systemic lupus erythematosus with a waiver in a subset of the paediatric population and a deferral. The PIP consists in a clinical study and a M&S analysis.

2.1.9. Bimekizumab - EMEA-002189-PIP04-20

UCB Biopharma SRL; Treatment of hidradenitis suppurativa / Treatment of moderate to severe hidradenitis suppurativa in adolescents from 12 years of age

Day 120 opinion

Immunology-Rheumatology-Transplantation / Dermatology

Summary of committee discussion:

Taking into account the responses received from the applicant following the Day 90 discussion, and based on the assessment of this application, the PDCO concluded on a positive opinion for a PIP for bimekizumab, as well as a deferral, and a waiver for a subset of the paediatric population 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), in the condition of treatment of hidradenitis suppurativa.

2.1.10. Rimegepant - EMEA-002812-PIP02-20

Biohaven Pharmaceuticals, Inc.; Acute treatment of migraine

Day 120 opinion

Neurology

Summary of committee discussion:

The PDCO in January 2020 noted that following consultation with the applicant on a draft opinion all the issues had been resolved. Therefore, the PDCO agreed a PIP for rimegepant in treatment of migraine headaches consisting in one quality study, 3 clinical studies and a modelling analysis with a waiver for a subset of the paediatric population and a deferral.

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 paediatric patients with relapsed or refractory AML or MDS, including JMML, from 28 days to less than 18 years of age

Day 120 opinion

Oncology

Summary of committee discussion:

The PDCO re-discussed this application in line with the comments made at the D90 discussion, noting no outstanding issues.
Based on the assessment of this application, the PDCO recommends agreeing to a PIP and granting a deferral and a waiver for a subset of patients based on the ground of lack of significant therapeutic benefit for imetelstat for the conditions of treatment of acute myeloid leukaemia (AML) and treatment of myelodysplastic syndromes (MDS), including juvenile myelomonocytic leukaemia (JMML).

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

Ophthalmology

Summary of committee discussion:

The PDCO re-discussed and endorsed its views expressed on day 90. Based on the assessment of this application and further discussions, the Paediatric Committee adopted a positive opinion, on the acceptance of the paediatric investigation plan with a waiver in a subset of children on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2.1.13. Seltorexant - EMEA-002746-PIP01-20

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

Day 120 opinion

Psychiatry

Summary of committee discussion:

Taking into account the applicant's responses to the Day 90 summary, and based on the assessment of this application, the PDCO concluded on a positive opinion for a PIP for seltorexant as well as a deferral, and a waiver for a subset of the paediatric population 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 a subset of the paediatric population on the grounds that the specific medicinal product is likely to be unsafe, in the condition of treatment of major depressive disorder (MDD).
The PDCO emphasises 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.

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

GlaxoSmithKline Biologicals SA; 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

Vaccines

Summary of committee discussion:

Based on the assessment of this application, the PDCO concluded on a positive opinion for a PIP for Respiratory Syncytial Virus (RSV) PreF3 recombinant Fusion protein, as well as a deferral, and a waiver for a subset of the female paediatric population on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subsets, in the condition of prevention of RSV- associated lower respiratory tract illness through maternal immunisation.
The PDCO emphasises 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.

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

Sandoz GmbH; Treatment of hypertension

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

Based on the assessment of this application the PDCO agrees with the applicant's request for a waiver. The PDCO recommends granting a waiver for hydrochlorothiazide / amlodipine / ramipril for all subsets of the paediatric population (from birth to 18 years of age) in the condition of "treatment of hypertension" on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.
The PDCO emphasises 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.

2.1.16. Olpasiran - EMEA-002910-PIP01-20

Amgen Europe B.V.; Prevention of cardiovascular events

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

Based on the assessment of this application, the PDCO agrees with the applicant's request for a waiver. The PDCO recommends granting a waiver for olpasiran for all subsets of the paediatric population (0 to 18 years of age) in the condition of prevention of cardiovascular events on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as studies in the paediatric population are not feasible.
The PDCO emphasises 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.

2.1.17. Canakinumab - EMEA-000060-PIP09-20

Novartis Europharm Limited; Schnitzler syndrome

Day 60 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

Based on the assessment of this application the PDCO agrees with the applicant's request for a waiver. The PDCO recommends granting a waiver in all paediatric age subsets from birth to less than 18 years of age for canakinumab (anti-interleukin-1β monoclonal antibody) for the treatment of Schnitzler syndrome, on the grounds of disease not occurring in children.
A positive Opinion on this full waiver request has therefore been adopted by the PDCO.

2.1.18. Secukinumab - EMEA-000380-PIP07-20

Novartis Europharm Limited; Treatment of thyroid eye disease

Day 60 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

The PDCO adopted a positive opinion at Day 60 on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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

Genzyme Europe B.V.; Treatment of immune thrombocytopenia

Day 60 opinion

Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology / Neurology

Summary of committee discussion:

Based on the assessment of this application the PDCO agrees with the applicant's request for a waiver. The PDCO recommends granting a waiver for Anti-C1s Humanized IgG4 Monoclonal Antibody that binds to and inhibits the classical complement pathway (CP) specific serine protease, C1s, thus inhibiting CP activity, for the treatment of immune thrombocytopenia purpura, on the grounds of lack of significant therapeutic benefit as clinical studies are not feasible.
A positive Opinion on this full waiver request has therefore been adopted by the PDCO.

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

Mitsubishi Tanabe Pharma GmbH; Amyotrophic lateral sclerosis

Day 60 opinion

Neurology

Summary of committee discussion:

The PDCO's view expressed at Day 30 was re-discussed and endorsed.
Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO agrees with the applicant's request for a waiver. The PDCO recommends granting a waiver for edaravone for all subsets of the paediatric population (0 to 18 years of age) in the condition of amyotrophic lateral sclerosis on the ground of lack of significant therapeutic benefit as clinical trials are not feasible.
The PDCO emphasises 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. Eptinezumab - EMEA-002243-PIP02-20

H. Lundbeck A/S; Prevention of cluster headache

Day 60 opinion

Neurology

Summary of committee discussion:

In January 2021, the PDCO confirmed the conclusion made at the previous meeting.
In conclusion, the PDCO recommends granting a waiver for eptinezumab for all subsets of the paediatric population (0 to 18 years of age) in the condition of prevention of cluster headache on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.
The PDCO emphasises 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 prevention of cluster headache 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.

2.1.22. Alpelisib - EMEA-002016-PIP04-20

Novartis Europharm Limited; Ovarian cancer

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO re-discussed this application in line with the outcome conclusions at D30.
Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO agrees with the applicant's request for a waiver. The PDCO recommends granting a waiver for alpelisib for all subsets of the paediatric population (0 to 18 years of age) in the conditions of 'treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)'; 'treatment of Fallopian tube carcinoma (excluding rhabdomyosarcoma and germ cell tumours)', and 'treatment of peritoneal carcinoma (excluding blastomas and sarcomas)', based on the ground that the diseases do not occur in children. Since the agreed waiver ground is disease not occurring, the possibility to apply this to all pharmaceutical forms and all routes of administrations was agreed to by the applicant.
The PDCO emphasises 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. Autologous CD4+ and CD8+ T cells genetically modified with a lentiviral vector encoding a B cell maturation antigen-specific chimeric antigen receptor (JCARH125) - EMEA-002909-PIP01-20

Celgene Europe B.V.; Treatment of mature B cell neoplasms

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO re-discussed this procedure at D60 during the January 2021 plenary.
The PDCO confirmed all the conclusions reached at D30 and, based on these, adopted a positive Opinion and agreed a product-specific waiver for autologous CD4+ and CD8+ T cells genetically modified with a lentiviral vector encoding a B cell maturation antigen-specific chimeric antigen receptor (JCARH125) for all subsets of the paediatric population (0 to 18 years of age) in the condition treatment of mature B-cell neoplasms on the grounds that this product is unlikely to provide significant therapeutic benefit since clinical studies would not be feasible.
The PDCO emphasises 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.

2.1.24. 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

Ophthalmology

Post-meeting note: Withdrawal request received on 13/01/2021

2.1.25. Isopropyl alcohol / Povidone (iodine) - EMEA-002902-PIP01-20

BD Switzerland Sàrl; Prevention of infection prior to invasive procedures

Day 60 opinion

Other

Summary of committee discussion:

The PDCO's view expressed at Day 30 was re-discussed and endorsed.
Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO agrees with the applicant's request for a waiver. The PDCO recommends granting a waiver for isopropyl alcohol / povidone-iodine for all subsets of the paediatric population (0 to 18 years of age) in the condition of prevention of infection prior to invasive procedures on the ground of lack of significant therapeutic benefit over existing products.
The PDCO emphasises 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.

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

Roche Registration GmbH; Idiopathic pulmonary fibrosis

Day 60 opinion

Pneumology - Allergology

Summary of committee discussion:

The PDCO's view expressed at Day 30 was re-discussed and endorsed.
The Applicant withdrew their application before Day 60 PDCO discussion.

Post-meeting note: The applicant withdrew the application on 29/01/2021.

2.1.27. Baricitinib - EMEA-001220-PIP07-20

Eli Lilly and Company Limited; Treatment of Covid-19

Day 60 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

The PDCO discussed on 28 January 2021 the application for bariticinib as revised in response to the PDCO request for modification also taking into account input received and the comments from the applicant on the draft opinion.
In conclusion, the PDCO recommends granting a paediatric investigation plan with a deferral for baricitinib in the condition treatment of coronavirus disease 2019 including a waiver for a subset of children based 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).

2.1.28. COVID-19 vaccine (Ad26.COV2-S (recombinant)) - EMEA-002880-PIP01-20

Janssen-Cilag International N.V.; Prevention of coronavirus disease-2019 (COVID-19)

Day 60 opinion

Vaccines / Infectious Diseases

Summary of committee discussion:

The PDCO discussed on 28 January 2021 the application for COVID-19 vaccine (Ad26.COV2-S (recombinant)) as revised in response to the PDCO request for modification.
In summary, all the issues identified at D30 with the implementation/changes specified above, were considered solved.
In conclusion, the PDCO recommends granting a paediatric investigation plan with a deferral for COVID-19 vaccine (Ad26.COV2-S (recombinant)) in the condition prevention of coronavirus disease 2019 (COVID-19) covering all subsets of the paediatric population.

2.1.29. Dupilumab - EMEA-001501-PIP08-20

sanofi-aventis recherche & développement; Chronic rhinosinusitis without nasal polyposis

Day 60 opinion

Oto-rhino-laryngology

Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO does not agree with the applicant's proposal.
Therefore, the committee concluded to grant a waiver on its own motion for dupilumab for all subsets of the paediatric population (from birth to 18 years of age) in the condition of "treatment of chronic rhinosinusitis without nasal polyposis" 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).
The PDCO emphasises 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.

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 item.

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 Human Immunodeficiency Virus (HIV-1) infection in paediatric population

Day 60 opinion

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/0018/2019 of 03/01/2019).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Proveca Pharma Limited; Treatment of heart failure

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

The PDCO discussed the updated proposed wording from the applicant before D60, which was found acceptable.
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/0357/2018 of 07 December 2018).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.3. Deucravacitinib - 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

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/0262/2019 of 19 July 2019).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Dermatology

Summary of committee discussion:

Taking into account the responses received from the applicant following the Day 30 discussion, and based on the review of the rationale submitted 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/0058/2014 of 06 March 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Boehringer Ingelheim International GmbH; Treatment of type 2 diabetes mellitus

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The PDCO confirmed the outcome of the Day 30 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/0201/2018 of 19 July 2018).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

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/0105/2020 of 18 March 2020).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

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/0353/2020 of 09/09/2020).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Boehringer Ingelheim International GmbH; Treatment of type 2 diabetes mellitus

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The PDCO confirmed the outcome of the Day 30 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/0204/2018 of 19 July 2018).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

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/0050/2019 of 29 January 2019).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

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

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/0321/2020 of 12 August 2020).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

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

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/0281/2020 of 12 August 2020).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

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

Day 60 opinion

Haematology-Hemostaseology

Summary of committee discussion:

All issues are now resolved following the Applicant's response .
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0160/2020 of 16 April 2020).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

Prior to Day 60 the applicant provided additional justifications, which were deemed acceptable by the PDCO. 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/0348/2017 of 1 December 2017).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

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

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

In January 2021 the PDCO confirmed the issues discussed at D30 .
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0216/2016 of 12/8/2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Infectious Diseases

Summary of committee discussion:

The PDCO noted the responses provided by the applicant after D30. Most of the issues have been clarified.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0395/2020 of 23/10/2020).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

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/0201/2020of 18/05/2020).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

argenx BV; Generalised myasthenia gravis

Day 60 opinion

Neurology

Summary of committee discussion:

The PDCO discussed and supported the Applicant's revised proposal to ensure that the paediatric programme is being pursued .
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/0097/2020 of 18/03/2020).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

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

Day 60 opinion

Neurology

Summary of committee discussion:

The PDCO re-discussed this procedure at D60 during the January 2021 plenary.
The PDCO confirmed all the conclusions reached at D30 and, based on those, adopted a positive Opinion on this modification.
Based on the review of the documentation submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be acceptable.
Therefore, the PDCO adopted a positive opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0080/2020 of 18 March 2020).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

Oncology

Summary of committee discussion:

The PDCO's views expressed at D30 were endorsed.
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/0150/2020 of 18 April 2020).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Oncology

Summary of committee discussion:

The PDCO re-discussed the proposed modification taking into account the clarification provided by the from applicant after D30 discussion.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0306/2019 of 10 September 2019).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Oncology

Summary of committee discussion:

The PDCO re-discussed the request for modification taking into account the clarification received by the applicant after D30 and their comments on the draft opinion.
In conclusion, 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 including the removal of the condition 'treatment of malignant neoplasms of haematopoietic tissue' 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/0256/2019 of 16 July 2019).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Oncology

Summary of committee discussion:

The PDCO re-discussed this procedure at D60 during the January 2021 plenary.
The PDCO confirmed all the conclusions reached at Day 30.
The PDCO agreed with the applicant's conclusions.
Based on the review of the documentation submitted by the applicant for modifying the agreed paediatric investigation plan and the additional information provided, the PDCO considered that the proposed changes could be acceptable.
Therefore, the PDCO adopted a positive opinion on the modification of the agreed PIP as set

in the Agency's latest decision (P/0201/2019 of 12 June 2019).
The new PDCO opinion on the modified agreed PIP supersedes the previous PDCO opinion.

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

Oncology

Summary of committee discussion:

The PDCO re-discussed this procedure at D60 during the January 2021 plenary meeting. Therefore, the PDCO decided that it was appropriate to grant a product-specific waiver on its own motion for all subsets of the paediatric population on the grounds that this medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

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

Oncology

Summary of committee discussion:

The PDCO's views expressed at D30 were endorsed.
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/0318/2019 of 11 September 2019).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Oncology

Summary of committee discussion:

The PDCO's views expressed at D30 were endorsed.

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/0401/2019 of 4 December 2019).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

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

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO re-discussed the request for modification taking into account the clarification received by the applicant after the D30 discussion and the comments from the Applicant on the draft opinion.
In conclusion, 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/0027/2018 of 5 March 2018).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Oncology

Summary of committee discussion:

The Applicant's clarification concerning the initial marketing authorisation application was noted. The issue identified at D30 was considered solved.
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/0326/2020 of 14 August 2020).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Oncology

Summary of committee discussion:

The PDCO re-discussed the request for modification taking into account the clarification provided by the applicant after the D30 discussion and the comments from the applicant on the draft opinion.
Therefore, based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0203/2019 of 12 June 2019).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Oncology

Summary of committee discussion:

The PDCO re-discussed the request for modification taking into account the clarification received by the applicant after D30 and their comments on the draft opinion.
In conclusion, 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 including the removal of the condition 'treatment of malignant neoplasms of haematopoietic tissue' 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/0245/2019 of 17 July 2019).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Oncology / Haematology-Hemostaseology

Summary of committee discussion:

The PDCO re-discussed this application, taking into consideration the additional information

received by the applicant.
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/0173/2020 of 13 May 2020).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

ReveraGen BioPharma Ltd; Treatment of Duchenne muscular dystrophy

Day 60 opinion

Other

Summary of committee discussion:

In January 2021 the PDCO noted the replies of the applicant to the issues raised at D30.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0032/2020 of 29/1/2020).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Janssen-Cilag International NV; Multiple sclerosis

Day 60 opinion

Other / Neurology

Summary of committee discussion:

In conclusion, 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/0128/2018 of 11/04/2018).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Pacira Ltd; Postsurgical analgesia

Day 60 opinion

Pain

Summary of committee discussion:

The PDCO discussed the clarification received from the applicant before D60. The comments were considered acceptable.
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/0036/2020 of 29 January 2020).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

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/0313/2020 of 14 August 2020).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

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/0305/2018 of 12/09/2018)
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Glaxo Group Limited; Mixed Asthma / Treatment of asthma where use of a combination product (long acting beta agonist and inhaled corticosteroid) is appropriate

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/0374/2020 of 9/9/2020).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Les Laboratoires Servier; Treatment of major depressive episodes

Day 60 opinion

Psychiatry

Summary of committee discussion:

The PDCO re-discussed the issues raised at Day 60 following the response from the Applicant received on 5 January 2021.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0432/2019 of 06/12/2019).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Gedeon Richter Plc.; Treatment of schizophrenia

Day 60 opinion

Psychiatry

Summary of committee discussion:

The PDCO discussed the applicant's modification request again at their January 2021 plenary.
Hence, the PDCO considered that the proposed changes could not be accepted at the current time.
The PDCO therefore adopted a negative Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0301/2018 of 12/09/2018).

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

Uro-nephrology

Summary of committee discussion:

Prior to Day 60 the applicant provided additional justifications for the proposed modifications, as requested by the PDCO.
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/0342/2020 of 09 September 2020).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

The following partial compliance check has concluded positively without PDCO discussion. The Committee has been informed in writing.

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

Jazz Pharmaceuticals Ireland Limited; Treatment of acute myeloid leukaemia

Day 60 letter

Oncology

2.7.2. 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 letter

Infectious Diseases

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

Novartis Europharm Limited; Treatment of chronic Graft versus Host Disease

Day 30 letter

Oncology

2.7.4. 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 letter

Vaccines

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

Dermatology

3.1.2. Ritlecitinib - EMEA-002451-PIP01-18

Alopecia areata

Day 90 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

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 ≥18 yrs and <24.0 yrs

Day 90 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.5. Risankizumab - EMEA-001776-PIP05-20

Hidradenitis suppurativa

Day 90 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

Aspa Therapeutics, Inc.; Treatment of Canavan disease / Treatment of Canavan disease in patients from birth to less than 18 years of age

Day 90 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

Day 90 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

Oncology

3.1.9. EMEA-002747-PIP01-20

Treatment of myasthenia gravis

Day 90 discussion

Other / Neurology

3.1.10. EMEA-002656-PIP01-19

Chikungunya disease

Day 90 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

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

Infectious Diseases

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

Reata Pharmaceuticals Inc.; Treatment of Friedreich's ataxia

Day 60 discussion

Neurology

3.1.14. Ublituximab - EMEA-002889-PIP02-20

Relapsing forms of multiple sclerosis (RMS)

Day 60 discussion

Neurology

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

PTC Therapeutics International Limited; Treatment of mitochondrial epilepsy

Day 60 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

Oncology

3.1.17. Iptacopan - EMEA-002705-PIP04-20

Atypical haemolytic uremic syndrome

Day 60 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

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

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

Pneumology - Allergology

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

Reata Pharmaceuticals Inc.; Treatment of Alport syndrome

Day 60 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

Vaccines

3.1.23. Ruxolitinib - EMEA-002618-PIP02-20

Vitiligo

Day 30 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

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

Diagnostic / Oncology

3.1.26. Glepaglutide - EMEA-002926-PIP01-20

Short bowel syndrome (SBS)

Day 30 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

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

Haematology-Hemostaseology

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

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

Day 30 discussion

Haematology-Hemostaseology

3.1.30. EMEA-002927-PIP01-20

Chronic idiopathic arthritis / Treatment of juvenile idiopathic arthritis

Day 30 discussion

Immunology-Rheumatology-Transplantation

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

Treatment of Sjögren's syndrome

Day 30 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

Immunology-Rheumatology-Transplantation / Dermatology / Gastroenterology-Hepatology

3.1.33. Cilgavimab - EMEA-002925-PIP01-20

Prevention or treatment of COVID-19

Day 30 discussion

Infectious Diseases

3.1.34. Islatravir - EMEA-002938-PIP01-20

Prevention of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Infectious Diseases

3.1.35. Tixagevimab - EMEA-002900-PIP01-20

Prevention or treatment of COVID-19

Day 30 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

Neurology

3.1.37. Branaplam - EMEA-002204-PIP02-20

Treatment of Huntington's Disease

Day 30 discussion

Neurology

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

Treatment of acute ischaemic stroke

Day 30 discussion

Neurology

3.1.39. Tavapadon - EMEA-002920-PIP01-20

Treatment of Parkinson's disease

Day 30 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

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

Oncology

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

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

Day 30 discussion

Oncology

3.1.43. Ensartinib - EMEA-002937-PIP01-20

Treatment of non-small-cell lung cancer

Day 30 discussion

Oncology

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

Hepatocellular carcinoma

Day 30 discussion

Oncology

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

Treatment of B-cell non-Hodgkin lymphoma

Day 30 discussion

Oncology

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

Treatment of malignant bladder neoplasms

Day 30 discussion

Oncology

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

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

Day 30 discussion

Oncology

3.1.48. Sabatolimab - EMEA-002931-PIP01-20

Treatment of myelodysplastic syndrome

Day 30 discussion

Oncology

3.1.49. Sintilimab - EMEA-002919-PIP01-20

Lung malignant neoplasm

Day 30 discussion

Oncology

3.1.50. Talazoparib - EMEA-002066-PIP02-20

Treatment of prostate malignant neoplasms / Treatment of breast malignant neoplasms

Day 30 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

Ophthalmology

3.1.52. Ligelizumab - EMEA-001811-PIP03-20

Treatment of food allergy

Day 30 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

Pneumology - Allergology

3.1.54. 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

Vaccines

3.1.55. 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

Vaccines

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

Cardiovascular Diseases

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

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

Day 30 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

Infectious Diseases

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

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

Day 30 discussion

Ophthalmology / Pneumology - Allergology

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

BioMarin International Limited; Treatment of neuronal ceroid lipofuscinosis Type 2 (NCL2)

Day 30 discussion

Other / Neurology

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

Day 30 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

Cardiovascular Diseases

3.3.3. Landiolol (hydrochloride) - EMEA-001150-PIP02-13-M04

AOP Orphan Pharmaceuticals AG; Treatment of supraventricular arrythmias

Day 30 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

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

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

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

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

Endocrinology-Gynaecology-Fertility-Metabolism

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

Akcea Therapeutics; Treatment of familial chylomicronemia syndrome

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

Janssen Biologics B.V.; Ulcerative colitis / Treatment of ulcerative colitis

Day 30 discussion

Gastroenterology-Hepatology

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

Mirum Pharmaceuticals; Treatment of Alagille syndrome (ALGS)

Day 30 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

Gastroenterology-Hepatology

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

BioMarin International Limited; Treatment of haemophilia A

Day 30 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

Immunology-Rheumatology-Transplantation

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

AbbVie Ltd; Treatment of atopic dermatitis

Day 30 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

Infectious Diseases

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

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

disease.

Day 30 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 rhinitis

Day 30 discussion

Pneumology - Allergology

3.3.19. Mometasone (furoate) / Indacaterol (acetate) - EMEA-001217-PIP01-11-M07

Novartis Europharm Limited; Treatment of asthma

Day 30 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

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 submission of applications with start of procedure 26 January 2021 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

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

5.1. New Scientific Advice

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

5.2. Ongoing Scientific Advice

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

5.3. Final Scientific Advice (Reports and Scientific Advice letters)

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

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.

6.1.2. Otenaproxesul - EMEA-09-2020

Antibe Therapeutics; All classes of medicinal products for treatment of primary and secondary osteoarthrosis / Treatment of the signs and symptoms of osteoarthritis and to

decrease the risk of developing upper gastrointestinal ulcers

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 not confirmed because the mechanism of action of the medicinal product was considered not directly targeting osteoarthrosis, but the pain and inflammation associated to osteoarthrosis.

Other potential paediatric interests of this medicine suggested by PDCO: chronic joint pain requiring long term analgesia secondary to for example juvenile idiopathic arthritis, systemic lupus erythematosus, Behçet's disease.

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

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

No items

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

In November 2020, Petra Dominikova resigned as member of the PDCO.

In December 2020, Michal Odermarsky was appointed as member of the PDCO by the European Commission to represent healthcare professionals and Sara Vennberg was appointed as alternate of the PDCO from Sweden.

In January 2021, Elena Kaisis was appointed as member of the PDCO from Cyprus, Dovile Zacharkiene and Silvijus Abramavicius have been appointed as member and alternate of the PDCO, respectively, from Lithuania and Roderick Houwen has been appointed as member of the PDCO from Netherlands.

Eirini Perikleous and Ann Marie Totterman have resigned from the Committee.

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

Summary of committee discussion:

The Chair of the Non-clinical Working Group (NcWG) identified the products which will require NcWG 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.

9.4. Cooperation within the EU regulatory network

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

No items

9.5. Cooperation with International Regulators

9.5.1. Feedback from FDA Cluster Teleconference

No items

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

No items

9.7. PDCO work plan

No items

9.8. Planning and reporting

No items

10. Any other business

10.1. COVID -19 update

Summary of committee discussion:

Updates on COVID19 treatments and vaccines.

10.2. Introduction of new Executive Director Emer Cooke

Summary of committee discussion:

Postponed to the next meeting.

10.3.

10.4. EMA review on Working Parties - update

Summary of committee discussion:

The Chair gave a brief update on the discussions relating to the restart of the working parties.

10.5. PDCO Member at the HMPC

Summary of committee discussion:

A reminder was circulated on the open call for an expert in paediatric medicines.

11. Breakout sessions

11.1. Paediatric oncology

Summary of committee discussion:

The group discussed non-clinical and clinical issues related to oncology paediatric developments.

11.2. Neonatology

Summary of committee discussion:

Appropriate endpoints for clinical studies in treatment of hypoxic ischaemic encephalopathy (HIE) were discussed.

11.3. Anti-viral monoclonal antibodies against Covid-19

11.4. Revision of Summary Report template

Summary of committee discussion:

The committee was updated on the progress concerning the revision of the summary report template.

11.5. Internal operations

Summary of committee discussion:

A meeting to discuss improvements on the plenary operations took place.

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 26- 29 January 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	When chairing the meeting: To be replaced for discussions, final deliberations and voting When not chairing the meeting: No participation in final deliberations and voting	2.1.14. Respiratory Syncytial Virus (RSV) PreF3 recombinant Fusion protein - EMEA-002821-PIP01-20 2.1.18. Otilimab - EMEA-001882-PIP03-20 2.3.36. Vilanterol / fluticasone furoate - EMEA-000431-PIP01-08-M12 3.1.22. Respiratory Syncytial Virus (RSV) PreF3 recombinant Fusion protein - EMEA-002904-PIP01-20 3.3.1. Ambrisentan - Orphan - EMEA-000434-PIP01-08-M08
Karl-Heinz Huemer	Member	Austria	No interests declared	
Johanna Wernsperger	Alternate	Austria	No interests declared	
Marleen Renard	Member	Belgium	No participation in final deliberations and voting on:	2.3.22. Ibrutinib - Orphan - EMEA-001397-PIP03-14-M05 3.2.1. Apixaban - EMEA-C3-000183-PIP01-08-M08
			No participation in discussion, final deliberations and voting on:	2.7.2. Ruxolitinib (phosphate) - EMEA-C1-000901-PIP04-17-M01 3.1.23. Ruxolitinib - EMEA-002618-PIP02-20
Karen Van Malderen	Alternate	Belgium	No interests declared	
Dimitar Roussinov	Member	Bulgaria	No restrictions applicable to this meeting	
Georgios Savva	Member	Cyprus	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Lucie Kravackova	Member	Czechia	No interests declared	
Nanna Borup Johansen	Member	Denmark	No interests declared	
Irja Lutsar	Member	Estonia	No interests declared	
Jana Lass	Alternate	Estonia	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 member)	Hungary	No interests declared	
Brian Aylward	Member	Ireland	No interests declared	
Sara Galluzzo	Member	Italy	No interests declared	
Dina Apele-Freimane	Member	Latvia	No restrictions applicable to this meeting	
Dovile Zacharkiene	Member	Lithuania	No interests declared	
Silvijus Abramaviciu s	Alternate	Lithuania	No restrictions applicable to this meeting	
Carola de Beaufort	Member (CHMP alternate)	Luxembourg	No interests declared	
Herbert Lenicker	Alternate	Malta	No interests declared	
Roderick Houwen	Member	Netherlands	No restrictions applicable to this meeting	
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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
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	
Eva Agurell	Member	Sweden	No interests declared	
Sara Vennberg	Alternate	Sweden	No interests declared	
Johannes Taminiau	Alternate	Healthcare Professionals' Representative	No interests declared	
Fernando Cabanas	Member	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Doina Plesca	Alternate	Healthcare Professionals' Representative	No interests declared	
Francesca Rocchi	Member	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Catherine Cornu	Alternate	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Jaroslav Sterba	Member	Patients' Organisation Representative	No interests declared	
Dimitrios Athanasiou	Member	Patients' Organisation Representative	No interests declared	
Tomasz Grybek	Alternate	Patients' Organisation Representative	No interests declared	
Michal Odermarsky	Alternate	Patients' Organisation Representative	No restrictions applicable to this meeting	
María Estela Moreno Martín	Expert - via telephone*	AEMPS, Spain	No interests declared	
Lutz Wiesner	Expert - via telephone*	BfArM, Germany	No interests declared	
Gaby Lydia Wangorsch	Expert - via telephone*	PEI, Germany	No interests declared	
Kristin Karlsson	Expert - via telephone*	MPA, Sweden	No restrictions applicable to this meeting	
Victor Mangas Sanjuan	Expert - via telephone*	AEMPS, Spain	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Dirk Mentzer	Expert - via telephone*	PEI, Germany	No interests declared	
Meeting run with support from relevant EMA staff				

* Experts were only 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/