29 January 2019
EMA/PDCO/877036/2018
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Minutes of the meeting on 11-14 December 2018

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

11 December 2018, 14:00- 19:00, room 3E

12 December 2018, 08:30- 19:00, room 3E

13 December 2018, 08:30- 19:00, room 3E

14 December 2018, 08:30- 13:00, room 3E

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 Paediatric Committee undertakes.

Further information with relevant explanatory notes can be found at the end of this document.

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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Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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1. Introductions

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

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. 23 or more members were present in the room). All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

1.2. Adoption of agenda

The agenda was adopted and will be published on the EMA website.

1.3. Adoption of the minutes

The minutes of the November 2018 PDCO 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. Turoctocog alfa pegol - Orphan - EMEA-001174-PIP03-18

Novo Nordisk A/S; Treatment of congenital haemophilia A

Day 60 opinion

Haematology-Hemostaseology

Summary of committee discussion:

Based on the assessment of this application, the Paediatric Committee adopted an Opinion

on the refusal of a Paediatric Investigation Plan and a deferral and on the granting of a product-specific waiver for turoctocog alfa pegol, for subcutaneous use, for all subsets of the paediatric population (0 to 18 years of age) in the condition 'Treatment of congenital haemophilia A', on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2.1.2. Etripamil - EMEA-002303-PIP01-17

Milestone Pharmaceuticals Inc.; Treatment of supraventricular tachycardia / Treatment of acute paroxysmal supraventricular tachycardia (PSVT)

Day 120 opinion

Cardiovascular Diseases

Summary of committee discussion:

The PDCO adopted a positive Opinion on the PIP of etripamil for the treatment of supraventricular arrhythmia.

2.1.3. Givosiran - Orphan - EMEA-002048-PIP02-18

Alnylam UK Limited; Treatment of Acute Hepatic Porphyria (AHP)

Day 120 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

A positive Opinion on a product specific full waiver on PDCO's was adopted at Day 120.

2.1.4. 5-(3-{(1S)-1-[(2-hydroxyethyl)amino]-2,3-dihydro-1H-inden-4-yl}-1,2,4-oxadiazol-5-yl)-2-[(propan-2-yl)oxy]benzonitrile monohydrochloride - EMEA-001710-PIP04-17

Celgene Europe Limited; Treatment of Crohn's disease

Day 90 opinion

Gastroenterology-Hepatology

Summary of committee discussion:

The PDCO discussed the responses to the Day 90 issues.

2.1.5. A positive Opinion was adopted.Filgotinib - EMEA-001619-PIP03-16

Gilead Sciences International Ltd.; Ulcerative colitis (UC), Crohn's disease (CD) / Treatment of paediatric patients 2 years of age and older with moderately-to-severely active ulcerative colitis, Treatment of paediatric patients 2 years of age and older with moderately-to-severely active Crohn's disease

Day 120 opinion

Gastroenterology-Hepatology

Summary of committee discussion:

The PDCO acknowledged the Applicant's responses to the Day 90 issues.
A positive Opinion was adopted.

2.1.6. Ianalumab - EMEA-002338-PIP01-18

Novartis Europharm Limited; Autoimmune hepatitis (AIH) / Treatment of autoimmune hepatitis in patients aged 8 years to <18 years in whom steroids and/or azathioprine are contraindicated, are not tolerated, or do not provide an adequate response

Day 90 opinion

Gastroenterology-Hepatology

Summary of committee discussion:

The PDCO discussed the Applicant's responses to the Day 90 issues. A positive Opinion was adopted.

2.1.7. Rilpivirine (as free base) - EMEA-000317-PIP02-18

Janssen-Cilag International N.V.; Treatment of human immunodeficiency virus (HIV-1) infection / In combination with cabotegravir long acting, treatment of HIV-1 infection in pediatric patients from 6 to less than 18 years of age who are virologically suppressed (HIV-1 RNA <50 copies/mL) and no known or suspected resistance to either rilpivirine or cabotegravir

Day 120 opinion

Infectious Diseases

Summary of committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO adopted a positive Opinion on this PIP of rilpivirine solution for injection for the treatment of human immunodeficiency virus (HIV-1) infection.

2.1.8. Pexidartinib - Orphan - EMEA-001939-PIP03-16

Daiichi Sankyo Inc; Benign soft tissue neoplasms except tenosynovial giant cell tumour, tenosynovial giant cell tumour / Treatment of debilitating tenosynovial giant cell tumour (TGCT), also known as pigmented villonodular synovitis (PVNS) and giant cell tumour of the tendon sheath (GCT-TS), in paediatric patients from 6 to 18 years where there is no other acceptable treatment

Day 120 opinion

Oncology

Summary of committee discussion:

The PDCO's views expressed at Day 90 were endorsed.
In conclusion, the PDCO recommended granting a waiver for pexidartinib for all subsets of the paediatric population (from birth to 18 less than years of age) in the condition of treatment of benign soft tissue neoplasms.
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.

2.1.9. Split influenza virus, inactivated containing antigens equivalent to the B-like strain (Yamagata lineage) / split influenza virus, inactivated containing antigens equivalent to the B-like strain (Victoria lineage) / split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain / split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain - EMEA-002359-PIP01-18

Sanofi Pasteur; Prevention of influenza infection

Day 120 opinion

Vaccines

Summary of committee discussion:

Based on the responses to the request for modifications and the additional information provided by the Applicant before Day 90, the PDCO adopted a positive Opinion on this PIP for prevention of influenza infection.

2.1.10. Amlodipine / atorvastatin / ramipril - EMEA-002416-PIP01-18

Midas Pharma GmbH; Treatment of essential hypertension (ICD9: 401, ICD10: I10), Treatment of familial hypercholesterolemia (ICD9: 272.0, ICD10: E78.0) / For adults with hypertension and elevated cholesterol already controlled with ramipril, amlodipine and atorvastatin given concurrently at the same dose level as in the FDC (substitution indication).

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

The PDCO agreed an opinion granting a waiver for atorvastatin / amlodipine / ramipril for all subsets of the paediatric population (from birth to less than 18 years of age) in the conditions 'Treatment of hypertension' and 'Treatment of hypercholesterolemia'.

2.1.11. Indapamide / telmisartan - EMEA-002462-PIP01-18

PRO.MED.CS a.s.; 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 granted a waiver for telmisartan / indapamide for all subsets of the paediatric population (0 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.

2.1.12. Rifamycin sodium - EMEA-002450-PIP01-18

CRINOS S.P.A.; Acute infections diarrhoea

Day 60 opinion

Infectious 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 rifamycin for all subsets of the paediatric population (0 to 18 years of age) in the condition of 'Treatment of acute infectious diarrhoea (AID)'. A positive Opinion was adopted.
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.

2.1.13. Amantadine hydrochloride - EMEA-002460-PIP01-18

Adamas Pharmaceuticals LLC; Treatment of Parkinson's disease and parkinsonism

Day 60 opinion

Neurology

Summary of committee discussion:

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 amantadine (hydrochloride) for all subsets of the paediatric population (0 to 18 years of age) in the condition 'Treatment of Parkinson's disease and parkinsonism'.
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. Binimetinib - EMEA-001454-PIP05-18

PIERRE FABRE MEDICAMENT; Treatment of colorectal carcinoma

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO discussed the requested waiver the entire population for binimetinib for the treatment of colorectal carcinoma, taking into account the information provided by the

Applicant .
The PDCO therefore recommended granting a waiver for binimetinib for all subsets of the paediatric population (from birth to less than 18 years of age) in the condition of treatment of colorectal carcinoma.
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. Encorafenib - EMEA-001588-PIP03-18

PIERRE FABRE MEDICAMENT; Treatment of colorectal carcinoma

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO discussed the requested waiver for the entire population for encorafenib for the treatment of colorectal carcinoma, taking into account the information provided by the Applicant.
The PDCO therefore recommended granting a waiver for encorafenib for all subsets of the paediatric population (from birth to less than 18 years of age) in the condition of treatment of colorectal carcinoma.
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.

2.1.16. Fibroblast activation protein alpha-targeted interleukin 2 variant immunocytokine - EMEA-002465-PIP01-18

Roche Registration GmbH; Treatment of Non-small cell lung cancer Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO discussed the requested waiver taking also into account the additional information provided by the Applicant.
The views expressed at D30 were endorsed. The PDCO therefore agreed with the Applicant's request for a waiver and recommends granting a waiver for fibroblast activation protein alpha-targeted interleukin 2 variant immunocytokine for all subsets of the paediatric population (from birth to less than 18 years of age) in the condition 'treatment of non-small cell lung cancer' on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.
The PDCO however 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.
In this regard the Applicant is also reminded that according to Article 16 of the Paediatric Regulation (Regulation (EC) No 1901/2006), applications for agreement on a waiver or a PIP should be submitted, unless duly justified, not later than upon completion of the human pharmacokinetic (PK) studies in order to ensure early dialogue between the Applicant and the Paediatric Committee and also to identify, considering the pharmacological properties of the medicinal product, the conditions for which the treatment of the drug could be of benefit to paediatric patients.

2.1.17. Technetium (^{99m}Tc) trofolastat chloride - EMEA-002441-PIP01-18

ROTOP Pharmaka GmbH; Treatment of prostate carcinoma

Day 60 opinion

Oncology / Uro-nephrology

Summary of committee discussion:

The PDCO discussed this procedure at Day 60 during its December 2018 meeting.
The Committee took into consideration all the points discussed at Day 30. In addition, it considered the information provided by the Applicant after Day 30 and agreed on a waiver for the condition 'Visualisation of prostate specific membrane antigen in prostate cancer'.

2.1.18. Human ciliary neurotrophic factor - Orphan - EMEA-002477-PIP01-18

LE4D Ltd; Treatment of Macular Telangiectasia Type 2

Day 60 opinion

Ophthalmology

Summary of committee discussion:

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 human ciliary neurotrophic factor for all subsets of the paediatric population (0 to 18 years of age) in the condition 'Treatment of macular telangiectasia Type 2'.
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.

2.2. 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

2.2.1. Liraglutide - EMEA-C-000128-PIP01-07-M08

Novo Nordisk; Treatment of type 2 diabetes mellitus

Day 30 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

A positive Opinion on a full compliance check was adopted by the PDCO.

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Azilsartan medoxomil - EMEA-000237-PIP01-08-M08

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

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

Based on the review of the rationale submitted in the application for modifying the agreed paediatric investigation plan, the PDCO considered that some but not all proposed changes could be accepted, as summarised in the Day 30 discussion.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0210/2015) of 2 October 2015.
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.2. Regadenoson - EMEA-000410-PIP01-08-M04

GE Healthcare AS; Myocardial perfusion disturbances

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

The PDCO discussed the application including the new information submitted after Day 30 and considered the proposed modifications acceptable. A positive Opinion has therefore been adopted. The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.3. Gadopiclenol - EMEA-001949-PIP01-16-M03

GUERBET; Detection and visualization of areas with disruption of the blood brain barrier and/or abnormal vascularity for the central nervous system (CNS) for diagnostic purposes.

Day 60 opinion

Diagnostic

Summary of committee discussion:

Based on the review of the rationale submitted in 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.

2.3.4. 2-hydroxypropyl-ß-cyclodextrin (HP-ß-CD) - Orphan - EMEA-001866-PIP01-15-M03

Mallinckrodt Pharmaceuticals Ireland Ltd; Treatment of Niemann-Pick disease, type C

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The PDCO discussed the Applicant's responses to the PDCO questions from the November PDCO meeting for this Request for Modification for 2-hydroxypropyl-ß-cyclodextrin (HP-ß-CD) for the treatment of Niemann-Pick disease, type C during its December 2018 meeting.
A positive Opinion has been adopted by the PDCO.
The Applicant's responses to the PDCO questions were deemed overall acceptable by the PDCO.

2.3.5. Empagliflozin - EMEA-000828-PIP04-16-M02

Boehringer Ingelheim International GmbH; Treatment of type 1 diabetes mellitus

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The PDCO discussed the Applicant’s responses to the Day 30 question for this Request for Modification procedure for empagliflozin for treatment of type 1 diabetes (T1D), as adjunct to insulin, during its December 2018 meeting.
The PDCO adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency’s latest decision (P/0165/2018 of 15/06/2018), along the lines of the above discussion.
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.6. Ethinyl estradiol / dienogest - EMEA-002229-PIP01-17-M01

Exeltis France S.A.; Contraception / Oral contraception

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/0017/2018 of 30 January 2018).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.7. Semaglutide - EMEA-001441-PIP01-13-M02

Novo Nordisk A/S; Treatment of Diabetes Mellitus type 2

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The views expressed at D30 were endorsed.
Based on the review of the rationale submitted in 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/0334/2016 of 02/12/2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.8. Naloxegol (as naloxegol oxalate) - EMEA-001146-PIP01-11-M04

Kyowa Kirin Pharmaceutical Development Limited; Treatment of opioid-induced constipation

Day 60 opinion

Gastroenterology-Hepatology

Summary of committee discussion:

Based on the review of the rationale submitted in 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.

2.3.9. Potassium sulphate / magnesium sulphate heptahydrate / sodium sulphate anhydrous - EMEA-000816-PIP02-10-M02

IPSEN Pharma; Diagnostic of organic and/or functional bowel diseases / In adults and children from 6 months of age for bowel cleansing prior to any procedure requiring a clean bowel (e.g. bowel visualisation including endoscopy and radiology or surgical procedure). not a treatment for constipation.

Day 60 opinion

Gastroenterology-Hepatology

Summary of committee discussion:

Based on the review of the rationale submitted by the Applicant for modifying the agreed paediatric investigation plan, the PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision at their December 2018 meeting (P/0169/2016 of 17/6/2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.10. Fostemsavir (tromethamine) - EMEA-001687-PIP01-14-M03

ViiV Healthcare UK Ltd; Treatment of human immunodeficiency virus (HIV-1) infection / Treatment of HIV-1 infection as part of a combination therapy in paediatric patients who have no more than 2 remaining available fully active antiretroviral therapies.

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

The PDCO noted at its December meeting the replies and clarifications provided by the Applicant to the points previously raised at Day 30.
Based on the review of the rationale submitted in the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed change could be supported.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0198/2016 of 15/7/2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.11. Rilpivirine (RPV) / dolutegravir (DTG) - EMEA-001750-PIP01-15-M02

ViiV Healthcare UK Limited; B24 Unspecified Human Immunodeficiency Virus (HIV) disease / Treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

The PDCO at its December 2018 meeting discussed the replies received from the Applicant and further clarifications received.

The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0028/2017 of 10/2/2017).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.12. Bivalent anti-human myostatin adnectin recombinant human IgG1-Fc fusion protein - EMEA-001793-PIP01-15-M03

Roche Registration GmbH; Treatment of Duchenne Muscular Dystrophy / Treatment of Duchenne Muscular Dystrophy in patients aged 2 years and older

Day 60 opinion

Neurology

Summary of committee discussion:

The PDCO discussed this procedure at Day 60 during its December 2018 meeting.
The PDCO took into account the discussion at Day 30, evaluated the information provided by the applicant after Day 30 .

Taking the above into consideration, the PDCO agreed with the changes requested by the Applicant and adopted a positive Opinion at Day 60.

2.3.13. Ocrelizumab - EMEA-000310-PIP03-10-M03

Roche Registration GmbH; Multiple Sclerosis / Treatment of Relapsing Remitting Multiple Sclerosis (RRMS)

Day 60 opinion

Neurology

Summary of committee discussion:

The PDCO discussed this procedure at Day 60 during its December 2018 meeting.
Based on the review of the rationale submitted in 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/0009/2017 of 31/01/2017).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.14. Venetoclax - Orphan - EMEA-002018-PIP02-16-M01

AbbVie Ltd; Treatment of haematopoietic and lymphoid malignant neoplasms, Treatment of solid tumour malignant neoplasms / Treatment of a specific paediatric hematopoietic and lymphoid malignant neoplasm or of a solid malignant neoplasm as agreed by PDCO, in patients from 1 month to 18 years of age

Day 60 opinion

Oncology / Haematology-Hemostaseology

Summary of committee discussion:

Based on the review of the rationale submitted in the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The additional information provided by the Applicant has been noted by the PDCO.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0235/2017 issued on 9 August 2017).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.15. Birch pollen extract - EMEA-000809-PIP01-09-M01

Allergy Therapeutics (UK) Ltd; J.30.1 Allergic rhinitis due to pollen H10.1 Acute atopic conjunctivitis / allergic rhinitis/allergic conjunctivitis

Day 60 opinion

Pneumology - Allergology

Summary of committee discussion:

Based on the assessment of Applicant's responses, the PDCO considered that the proposed changes could be accepted

The PDCO adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/217/2010 of 29 October 2010).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.16. Split influenza virus, inactivated containing antigen equivalent to A/ California/7/2009(H1N1)-like strain (A/California/7/2009 (NYMC X-179A)), adjuvanted - EMEA-000669-PIP01-09-M02

Sanofi Pasteur SA; Influenza / Prevention of infection by pandemic influenza virus (H1N1 strain) in the context of a pandemic

Day 60 opinion

Vaccines

Summary of committee discussion:

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

2.3.17. Entrectinib - EMEA-002096-PIP01-16-M01

Roche Registration GmbH; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms) / For the treatment of paediatric patients with NTRK fusion-positive solid tumours

Day 30 opinion

Oncology

Summary of committee discussion:

The PDCO discussed the modification request at its December 2018 meeting.
In conclusion, based on the review of the rationale submitted in the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted. the PDCO adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0270/2018 of 16 August 2018) at Day 30.
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

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

2.7.1. Bempedoic acid - EMEA-C1-001872-PIP01-15-M01

Esperion Therapeutics, Inc; Treatment of elevated cholesterol

Cardiovascular Diseases

Summary of committee discussion:

The partial compliance check has been finalised with a confirmation of compliance of all those studies contained in the agreed paediatric investigation plan that were subject of this procedure.

2.7.2. Nivolumab - EMEA-C2-001407-PIP02-15-M02

Bristol-Myers Squibb Pharma EEIG; Treatment of malignant neoplasms of lymphoid tissue

Oncology

Summary of committee discussion:

The partial compliance check has been finalised with a confirmation of compliance of all those studies contained in the agreed paediatric investigation plan that were subject of this procedure.

2.7.3. Cefiderocol - EMEA-C1-002133-PIP01-17

Shionogi Limited; Treatment of infections due to aerobic Gram-negative bacteria

Infectious Diseases

Summary of committee discussion:

The partial compliance check has been finalised with a confirmation of compliance of all those studies contained in the agreed paediatric investigation plan that were subject of this procedure.

2.7.4. Ceftolozane / tazobactam - EMEA-C1-001142-PIP02-16

Merck Sharp & Dohme (Europe), Inc.; Treatment of pneumonia

Infectious Diseases

Summary of committee discussion:

The partial compliance check has been finalised with a confirmation of compliance of all those studies contained in the agreed paediatric investigation plan that were subject of this procedure.

2.7.5. Amikacin (sulfate) - EMEA-C4-000525-PIP01-08-M06

Insmed Limited; Treatment of nontubercolous mycobacterial (NTM) lung infection

Pneumology - Allergology

Summary of committee discussion:

The partial compliance check has been finalised with a confirmation of compliance of all those studies contained in the agreed paediatric investigation plan that were subject of this procedure.

2.7.6. Empagliflozin - EMEA-C2-000828-PIP04-16-M01

Boehringer Ingelheim International GmbH; Treatment of type 1 diabetes mellitus

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The partial compliance check has been finalised with a confirmation of compliance of all those studies contained in the agreed paediatric investigation plan that were subject of this procedure.

2.7.7. Ivacaftor - EMEA-C9-000335-PIP01-08-M13

Vertex Pharmaceuticals (Europe) Limited; Treatment of cystic fibrosis

Other

Summary of committee discussion:

The partial compliance check has been finalised with a confirmation of compliance of all those studies contained in the agreed paediatric investigation plan that were subject of this procedure

2.7.8. Semaglutide - EMEA-C1-001441-PIP02-15-M01

Novo Nordisk A/S; Treatment of type 2 diabetes mellitus

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The partial compliance check has been finalised with a confirmation of compliance of all those studies contained in the agreed paediatric investigation plan that were subject of this procedure.

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. Mavacamten - EMEA-002231-PIP01-17

Treatment of Hypertrophic Cardiomyopathy / Treatment of obstructive Hypertrophic Cardiomyopathy

Day 90 discussion

Cardiovascular Diseases

3.1.2. Dihomo-γ-linolenic acid (DGLA) - EMEA-002364-PIP02-18

Treatment of atopic dermatitis / Treatment of mild to moderate atopic dermatitis

Day 90 discussion

Dermatology

3.1.3. Chemically modified recombinant human sulfamidase - Orphan - EMEA-002380-PIP01-18

Swedish Orphan Biovitrum AB (publ); Mucopolysaccharidosis type IIIA (MPS IIIA)

Day 90 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.4. (6aR,10aR)-1-Hydroxy-6,6-dimethyl-3-(2-methyl-2-octanyl)-6a,7,10,10a-tetrahydro-6H-benzo[c]chromene-9-carboxylic acid - Orphan - EMEA-002069-PIP02-17

Corbus Pharmaceuticals Holdings Inc; Treatment of systemic sclerosis

Day 90 discussion

Immunology-Rheumatology-Transplantation

3.1.5. Allogeneic CD34+ umbilical cord blood cells cultured ex vivo with Notch ligand Delta1 - Orphan - EMEA-002271-PIP01-17

Nohla Therapeutics, Inc.; Treatment in Haematopoietic Stem Cell Transplantation (HSCT) in patients with malignant disease / Patients with high risk haematologic malignancies undergoing myeloablative cord blood transplant (CBT)

Day 90 discussion

Immunology-Rheumatology-Transplantation

3.1.6. Guselkumab - EMEA-001523-PIP03-18

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondyloarthritis, PsA and juvenile idiopathic arthritis [JIA]) / Treatment of juvenile idiopathic arthritis (juvenile psoriatic arthritis [jPsA])

Day 90 discussion

Immunology-Rheumatology-Transplantation

3.1.7. EMEA-002240-PIP02-17

Treatment of Urinary Tract Infections

Day 90 discussion

Infectious Diseases

3.1.8. Pretomanid - Orphan - EMEA-002115-PIP01-17

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

Day 90 discussion

Infectious Diseases

3.1.9. Ridinilazole - EMEA-002250-PIP02-17

Clostridium difficile Infection (CDI) and recurrence of CDI / Treatment of Clostridium difficile Infection (CDI) and reducing the recurrence of CDI

Day 90 discussion

Infectious Diseases

3.1.10. Isoflurane - EMEA-002320-PIP01-17

Sedation

Day 90 discussion

Neonatology - Paediatric Intensive Care

3.1.11. Avapritinib - Orphan - EMEA-002358-PIP02-18

Blueprint Medicines Corporation; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid tissue neoplasms) / Treatment of paediatric patients with advanced solid tumors harboring mutations in either KIT or PDGFRα.

Day 90 discussion

Oncology

3.1.12. Spartalizumab - EMEA-002351-PIP01-18

Treatment of melanoma / Treatment of adolescent patients with melanoma containing BRAF V600 activating mutations

Day 90 discussion

Oncology

3.1.13. (R)-azasetron (as besylate) - Orphan - EMEA-002165-PIP02-18

Sensorion SA; Ototoxicity, poisoning due to cisplatin, Sudden Sensorineural Hearing Loss /

Treatment of Sudden Sensorineural Hearing Loss, Prevention of cisplatin-induced ototoxicity

Day 90 discussion

Oto-rhino-laryngology

3.1.14. EMEA-002324-PIP01-17

Treatment of Cystic Fibrosis

Day 90 discussion

Pneumology - Allergology

3.1.15. EMEA-002191-PIP02-17

Treatment of Cystic Fibrosis

Day 90 discussion

Pneumology - Allergology

3.1.16. Molgramostim - Orphan - EMEA-002282-PIP01-17

Savara ApS; Treatment of pulmonary alveolar proteinosis / Treatment of children from 6 to less than 18 years with autoimmune pulmonary alveolar proteinosis

Day 90 discussion

Pneumology - Allergology

3.1.17. Recombinant Influenza Hemagglutinin-strain B (Yamagata lineage) / Recombinant Influenza Hemagglutinin-strain B (Victoria lineage) / Recombinant Influenza Hemagglutinin-strain A (H3N2 subtype) / Recombinant Influenza Hemagglutinin-strain A (H1N1 subtype) - EMEA-002418-PIP01-18

Prevention of influenza infection

Day 90 discussion

Vaccines

3.1.18. Ralinepag - EMEA-002432-PIP01-18

Treatment of pulmonary arterial hypertension / Treatment of pulmonary arterial hypertension WHO Group I to improve exercise capacity and to delay clinical worsening

Day 60 discussion

Cardiovascular Diseases

3.1.19. Livoletide - Orphan - EMEA-002455-PIP01-18

Millendo Therapeutics SAS; Treatment of Prader-Willi syndrome

Day 60 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.20. Emricasan - EMEA-002457-PIP01-18

Non-alcoholic steatohepatitis (NASH) / Treatment of NASH with moderate to severe liver fibrosis (F2-F4) in patients aged 8 to less than 18 years old

Day 60 discussion

Gastroenterology-Hepatology

3.1.21. Tropifexor - EMEA-002471-PIP01-18

Non-alcoholic steatohepatitis / Treatment of NASH with moderate to severe liver fibrosis (F2/F3) in paediatric patients from 8 to less than 18 years of age

Day 60 discussion

Gastroenterology-Hepatology

3.1.22. Humanized bispecific antibody against IL-4 and IL-13 - EMEA-001804-PIP03-18

Treatment of systemic sclerosis / Treatment of juvenile systemic sclerosis

Day 60 discussion

Immunology-Rheumatology-Transplantation

3.1.23. Humanized Anti-CD19, Fc Engineered, Monoclonal Antibody - Orphan - EMEA-002414-PIP01-18

Xencor, Inc.; Immunoglobulin G4-Related Disease / The treatment of adults, adolescents and children (> 23 months of age) with Immunoglobulin G4-Related Disease

Day 60 discussion

Immunology-Rheumatology-Transplantation

3.1.24. Vedolizumab - EMEA-000645-PIP03-18

ICD-9-CM 279.51 / ICD-10-CM D89.810 - Other disorders involving the immune mechanism, not elsewhere classified: acute graft-versus-host disease

Day 60 discussion

Immunology-Rheumatology-Transplantation / Gastroenterology-Hepatology

3.1.25. Gepotidacin - EMEA-002443-PIP01-18

Treatment of Uncomplicated Urinary Tract Infections (uUTI) / Treatment of uncomplicated urinary tract infections (acute cystitis) in children aged >6 years to <18 years

Day 60 discussion

Infectious Diseases

3.1.26. Gepotidacin - EMEA-002443-PIP02-18

Treatment of uncomplicated Urogenital Gonorrhea (GC) / Treatment of uncomplicated urogenital gonorrhea in children aged ≥ 14 to <18 years

Day 60 discussion

Infectious Diseases

3.1.27. Recombinant adeno-associated viral vector serotype 2 carrying the gene for the human aromatic L-amino acid decarboxylase protein - Orphan - EMEA-002435-PIP01-18

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

Day 60 discussion

Neurology

3.1.28. Niraparib (as tosylate monohydrate) - Orphan - EMEA-002268-PIP02-18

Tesaro UK Ltd; Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid malignancies) / The combination therapy is for the treatment of patients ≥6 months to <18 years of age who have been diagnosed with recurrent solid tumours that exhibit a breast cancer susceptibility gene (BRCA)ness mutational signature (mutational signature 3).

Day 60 discussion

Oncology

3.1.29. anti PD-1 monoclonal antibody - EMEA-002463-PIP01-18

Treatment of all conditions included in the category of malignant neoplasms (except haematopoietic and lymphoid malignancies) / The combination therapy is for the treatment of patients ≥6 months to <18 years of age who have been diagnosed with recurrent solid tumours that exhibit a breast cancer susceptibility gene (BRCA)ness mutational signature (mutational signature 3).

Day 60 discussion

Oncology

3.1.30. EMEA-002446-PIP01-18

Ichtyoses / Treatment of ichthyosis associated with Sjögren-Larsson Syndrome (SLS)

Day 60 discussion

Other / Endocrinology-Gynaecology-Fertility-Metabolism / Dermatology

3.1.31. EMEA-001976-PIP02-18

Asthma / Treatment to control persistent asthma

Day 60 discussion

Pneumology - Allergology

3.1.32. Amlodipine besylate / rosuvastatin calcium - EMEA-002456-PIP01-18

Treatment of Hypertension, Treatment of dyslipidemia, Treatment of ischemic coronary artery disorders, Prevention of cardiovasular events

Day 30 discussion

Cardiovascular Diseases

3.1.33. EMEA-002451-PIP01-18

Alopecia Areata

Day 30 discussion

Dermatology

3.1.34. EMEA-002475-PIP01-18

Treatment of Generalized Pustular Psoriasis / treatment of patients with acute or chronic Generalized Pustular Psoriasis (GPP) and for the prevention of flares

Day 30 discussion

Dermatology

3.1.35. EMEA-002470-PIP01-18

Actinic Keratosis in adults

Day 30 discussion

Dermatology

3.1.36. EMEA-002464-PIP01-18

Treatment of atopic dermatitis / Treatment of patients with moderate-to-severe atopic dermatitis

Day 30 discussion

Dermatology

3.1.37. Trifarotene Cream HE1 - EMEA-001492-PIP02-18

Treatment of Lamellar Ichthyosis

Day 30 discussion

Dermatology

3.1.38. Norethisterone acetate / estradiol / relugolix - EMEA-002428-PIP01-18

Treatment of symptoms associated with uterine fibroids

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.39. EMEA-002448-PIP01-18

Treatment of NASH / Treatment of NASH with moderate to severe liver fibrosis

Day 30 discussion

Gastroenterology-Hepatology

3.1.40. C1 esterase inhibitor (human) - EMEA-000568-PIP02-18

Treatment of hereditary angioedema

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.1.41. Liposomal ciclosporin A (L-CsA) - Orphan - EMEA-002344-PIP02-18

Breath Therapeutics GmbH; Treatment of Bronchiolitis obliterans Syndrome (BOS)

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.1.42. Baloxavir marboxil - EMEA-002440-PIP01-18

Prevention of Influenza, Treatment of Influenza / Treatment of influenza type A/B in otherwise healthy, high risk and hospitalised patients, Prevention (post exposure prophylaxis) of influenza type A/B. Reduction of transmission of influenza type A/B

Day 30 discussion

Infectious Diseases

3.1.43. Hydrocortisone - EMEA-002305-PIP01-17

Prevention of Bronchopulmonary dysplasia

Day 30 discussion

Neonatology - Paediatric Intensive Care

3.1.44. Padsevonil - EMEA-002466-PIP01-18

Treatment of focal-onset seizures (FOS) in patients with epilepsy / Treatment of FOS in paediatric patients (≥2 to <18 years of age) with epilepsy

Day 30 discussion

Neurology

3.1.45. Pyrimidinyl-aminopyridine dual leucine zipper kinase inhibitor - EMEA-002469-PIP02-18

Treatment of Amyotrophic Lateral Sclerosis

Day 30 discussion

Neurology

3.1.46. Genetically modified Mycobacterium bovis BCG - EMEA-002461-PIP01-18

Non-muscle invasive bladder cancer

Day 30 discussion

Oncology

3.1.47. Larotrectinib - Orphan - EMEA-001971-PIP03-18

Bayer AG; Treatment of malignant neoplasms of the central nervous system / Treatment of paediatric patients with a primary CNS tumour with a Neurotrophic Tyrosine Receptor Kinase (NTRK) gene fusion

Day 30 discussion

Oncology

3.1.48. Marizomib - EMEA-002452-PIP01-18

Treatment of Malignant Glial Tumors / Treatment of patients (pediatric) with diffuse intrinsic pontine glioma (DIPG) who have received radiation therapy

Day 30 discussion

Oncology

3.1.49. Aldesleukin - EMEA-002492-PIP01-18

Treatment of all conditions included in the category of malignant neoplasms (except nervous system, haematopoetic, and lymphoid tissue) / treatment of a relapsed or refractory paediatric malignant solid tumour in paediatric patients less than 18 years old, treatment of patients with unresectable or metastatic melanoma in the age group from 12 to less than 18 years old

Day 30 discussion

Oncology

3.1.50. Zanubrutinib - EMEA-002354-PIP02-18

Treatment of mature B-cell neoplasms excluding lymphoplasmacytic lymphoma (Waldenström's macroglobulinaemia), Treatment of lymphoplasmacytic lymphoma (Waldenström's macroglobulinaemia) / Treatment of primary mediastinal B-cell lymphoma,

Treatment of Burkitt lymphoma, Treatment of diffuse large B-cell lymphoma

Day 30 discussion

Oncology

3.1.51. Empagliflozin - EMEA-000828-PIP06-18

Treatment of chronic kidney disease

Day 30 discussion

Uro-nephrology

3.1.52. Pneumococcal Polyssacharide Serotype 33F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 23F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 22F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 19F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 19A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 18C conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 15B conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 14 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 12F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 11A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 10A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 9V conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 8 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 7F conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 6B conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 6A conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 5 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 4 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 3 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate / Pneumococcal Polyssacharide Serotype 1 conjugated to CRM197 carrier protein and adsorbed on aluminium Phosphate - EMEA-002330-PIP01-18

Disease caused by Streptococcus pneumoniae

Day 30 discussion

Vaccines

3.1.53. Recombinant respiratory syncytial virus fusion (RSV F) glycoprotein - EMEA-001985-PIP01-18

Prevention of respiratory syncytial virus (RSV) disease in infants via maternal immunization

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. Avibactam / ceftazidime - EMEA-C2-001313-PIP01-12-M08

Pfizer Limited; Treatment of Urinary Tract Infections

Day 30 discussion

Infectious Diseases

3.2.2. Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) - EMEA-C1-001715-PIP01-14-M01

Seqirus Netherlands B.V.; Prevention of influenza infection

Day 30 discussion

Vaccines

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Ambrisentan - Orphan - EMEA-000434-PIP01-08-M05

Glaxo Group Limited; Treatment of Pulmonary Arterial Hypertension / Idiopathic (IPAH) and Familial (FPAH) Pulmonary Hypertension; Associated Pulmonary Hypertension (APAH)

Day 30 discussion

Cardiovascular Diseases

3.3.2. Tralokinumab - EMEA-001900-PIP02-17-M02

LEO Pharma A/S; Treatment of Atopic Dermatitis

Day 30 discussion

Dermatology

3.3.3. Alogliptin benzoate (as alogliptin) - EMEA-000496-PIP01-08-M06

Takeda Development Centre Europe Ltd; Type 2 diabetes mellitus (T2DM)

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. Avalglucosidase alfa - Orphan - EMEA-001945-PIP01-16-M01

Genzyme Europe B.V.; ICD-10: E74.0; Glycogen storage disease (Pompe disease) / Long-term use as an enzyme replacement therapy (ERT) for the treatment of patients with a confirmed diagnosis of Pompe disease (acid α-glucosidase deficiency)

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. Tofacitinib - EMEA-000576-PIP03-12-M02

Pfizer Limited; Ulcerative colitis (UC) / Treatment of children and adolescents aged 2 to <18 years of age with moderate to severe ulcerative colitis

Day 30 discussion

Gastroenterology-Hepatology

3.3.6. Ustekinumab - EMEA-000311-PIP04-13-M01

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

Day 30 discussion

Gastroenterology-Hepatology

3.3.7. Crizanlizumab - Orphan - EMEA-002141-PIP01-17-M01

Novartis Europharm Limited; Treatment of sickle cell disease / Prevention of vaso-occlusive crises in patients with sickle cell disease

Day 30 discussion

Haematology-Hemostaseology

3.3.8. Apremilast - EMEA-000715-PIP02-11-M03

Celgene Europe B.V.; Treatment of Juvenile Idiopathic Arthritis (JIA), Treatment of Juvenile Psoriatic Arthritis (JPsA) / Treatment of Juvenile Psoriatic Arthritis (JPsA), NA

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.3.9. Isavuconazonium (sulfate) - Orphan - EMEA-001301-PIP02-12-M03

Basilea Pharmaceutica International Ltd.; Treatment of mucormycosis, Treatment of invasive aspergillosis

Day 30 discussion

Infectious Diseases

3.3.10. EMEA-001838-PIP01-15-M02

Janssen-Cilag International NV; Treatment of respiratory tract disease caused by human respiratory syncytial virus (RSV) Day 30 discussion

Infectious Diseases

3.3.11. Lefamulin - EMEA-002075-PIP01-16-M01

Nabriva Therapeutics AG; Treatment of community-acquired pneumonia

Day 30 discussion

Infectious Diseases

3.3.12. Erenumab - EMEA-001664-PIP02-15-M03

Novartis Europharm Limited; Prevention of migraine headaches / Prophylaxis of migraine

Day 30 discussion

Neurology

3.3.13. Galcanezumab - EMEA-001860-PIP03-16-M02

Eli Lilly and Company Limited; Prevention of migraine headaches

Day 30 discussion

Neurology

3.3.14. Satralizumab - Orphan - EMEA-001625-PIP01-14-M02

CHUGAI PHARMA EUROPE LTD.; Treatment of neuromyelitis optica

Day 30 discussion

Neurology

3.3.15. Lacosamide - EMEA-000402-PIP03-17-M03

UCB Pharma S.A.; Treatment of Generalized Epilepsy and Epilepsy Syndromes: Epilepsy - generalized idiopathic epilepsy and epilepsy syndromes [G40.3] Epilepsy - Other generalized epilepsy and epileptic syndromes [G40.4] / Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures (PGTCS) in paediatric patients with idiopathic generalized epilepsy (IGE)(4 years to <18 years)

Day 30 discussion

Neurology

3.3.16. Peginterferon beta-1a - EMEA-001129-PIP01-11-M03

Biogen Idec Ltd; Multiple Sclerosis / Treatment of relapsing remitting forms of Multiple Sclerosis

Day 30 discussion

Neurology

3.3.17. Acalabrutinib - Orphan - EMEA-001796-PIP03-16-M01

Acerta Pharma, BV; Treatment of mature B cell neoplasms / Treatment of children from 1 to <18 years of age with previously untreated mature B-cell neoplasms (eg, diffuse large B-cell lymphoma [DLBCL], Burkitt lymphoma [BL] and primary mediastinal B-cell lymphoma [PMBCL]). Treatment of children from 1 to <18 years of age with relapsed/refractory mature B-cell neoplasms (eg, diffuse large B-cell lymphoma [DLBCL], Burkitt lymphoma [BL] and primary mediastinal B-cell lymphoma [PMBCL])

Day 30 discussion

Oncology

3.3.18. Dabrafenib mesylate - EMEA-001147-PIP01-11-M06

Novartis Europharm Limited; Treatment of solid malignant tumours (excluding melanoma), Treatment of melanoma / Treatment of paediatric patients with solid malignant tumours containing BRAF V600 mutations, Treatment of adolescent patients with melanoma with a BRAF V600 mutation

Day 30 discussion

Oncology

3.3.19. Carotuximab - Orphan - EMEA-002138-PIP01-17-M01

TRACON Pharma Limited-Charles Theuer; Treatment of soft tissue sarcoma

Day 30 discussion

Oncology

3.3.20. Olaratumab - Orphan - EMEA-001760-PIP01-15-M03

Eli Lilly and Company Limited; Treatment of Soft Tissue Sarcoma, Treatment of Osteosarcoma / Treatment of recurrent rhabdomyosarcoma in children aged from birth to less than 18 years in combination with a standard-of-care chemotherapy regimen, First-line treatment of osteosarcoma in children aged from 5-18 years in combination with a standard-of-care chemotherapy regimen

Day 30 discussion

Oncology

3.3.21. Rituximab - EMEA-000308-PIP01-08-M04

Roche Registration GmbH; Treatment of diffuse large B-cell lymphoma, Treatment of autoimmune arthritis / Treatment of mature B-cell malignancies, that is, diffuse large B-cell lymphoma, Burkitt and Burkitt-like lymphoma/leukaemia. Agreed waiver for all subsets of the paediatric population from birth to less than 18 years of age

Day 30 discussion

Oncology

3.3.22. Trametinib dimethyl sulfoxide - EMEA-001177-PIP01-11-M05

Novartis Europharm Limited; Treatment of solid malignant tumours (excluding melanoma), Treatment of melanoma / Treatment of paediatric patients with solid malignant tumours containing BRAF V600 mutations, Treatment of adolescent patients with melanoma with a BRAF V600 mutation

Day 30 discussion

Oncology

3.3.23. Eltrombopag (eltrombopag olamine) - EMEA-000170-PIP02-10-M03

Novartis Europharm limited; Secondary thrombocytopenia / Treatment of thrombocytopenia secondary to treatment of myeloid or lymphoid malignancies or solid tumours

Day 30 discussion

Oncology / Haematology-Hemostaseology

3.3.24. Autologous cartilage derived cultured chondrocytes - EMEA-001823-PIP01-15-M01

TETEC AG; Treatment of cartilage disorders

Day 30 discussion

Other

3.3.25. Methoxyflurane - EMEA-000334-PIP01-08-M08

Medical Developments UK Ltd; Treatment of acute pain / 1. Self administration to conscious patients with minor trauma and associated pain, under supervision of personnel trained in its use. 2. For the management of acute pain associated with short surgical procedures, such as the change of dressings, dislocations and injections

Day 30 discussion

Pain

3.3.26. Dermatophagoides farinae / dermatophagoides pteronyssinus - EMEA-001258-PIP01-11-M04

ALK-Abelló A/S; Treatment of allergic rhinitis, Treatment of asthma / indicated in house dust mite allergic asthma, indicated in house dust mite allergic rhinitis

Day 30 discussion

Pneumology - Allergology

3.3.27. Chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis - EMEA-001016-PIP01-10-M01

Granzer Regulatory Consulting & Services; Allergic Rhinitis / Allergic Rhinitis, Allergic Rhinoconjunctivitis

Day 30 discussion

Pneumology - Allergology / Oto-rhino-laryngology

3.3.28. Chemically modified extract of grass pollen from Holcus lanatus, Phleum pratense and Poa pratensis - EMEA-001017-PIP01-10-M01

Granzer Regulatory Consulting & Services; Allergic Rhinitis / Allergic Rhinitis, Allergic Rhinoconjunctivitis

Day 30 discussion

Pneumology - Allergology / Oto-rhino-laryngology

3.3.29. Chemically modified extract of trees pollen from Birch and Alder - EMEA-001012-PIP01-10-M01

Granzer Regulatory Consulting & Services; Allergic Rhinitis, Allergic Rhinoconjunctivitis

Day 30 discussion

Pneumology - Allergology / Oto-rhino-laryngology

3.3.30. Chemically modified extract of trees pollen from Birch and Alder - EMEA-001013-PIP01-10-M01

Granzer Regulatory Consulting & Services; Allergic Rhinitis, Allergic Rhinoconjunctivitis

Day 30 discussion

Pneumology - Allergology / Oto-rhino-laryngology

3.3.31. Chemically modified house dust mites allergen extract of Dermatophagoides pteronyssinus and Dermatophagoides farinae - EMEA-001011-PIP01-10-M01

Granzer Regulatory Consulting & Services; Allergic Rhinitis, Allergic Rhinoconjunctivitis

Day 30 discussion

Pneumology - Allergology / Oto-rhino-laryngology

3.3.32. Chemically modified house dust mites allergen extract of Dermatophagoides pteronyssinus and Dermatophagoides farinae - EMEA-001014-PIP01-10-M01

Granzer Regulatory Consulting & Services; Allergic Rhinitis, Allergic Rhinoconjunctivitis

Day 30 discussion

Pneumology - Allergology / Oto-rhino-laryngology

3.3.33. Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily B; Escherichia coli) / Neisseria meningitidis serogroup B recombinant lipoprotein (subfamily A; Escherichia coli) - EMEA-001037-PIP02-11-M05

Pfizer Europe MA EEIG; Invasive meningococcal disease caused by N meningitidis serogroup B.

Day 30 discussion

Vaccines

4. Nominations

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

4.1. List of letters of intent received for submission of applications with start of procedure 29 January 2019 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

No items

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

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

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. Human embryonic stem-cell derived retinal pigment epithelial (hESC-RPE) cells - EMEA-14-2018

Astellas Pharma Europe B.V.; All classes of medicinal products for treatment of age-related macular degeneration and diabetic macular oedema/Treatment of age-related macular

degeneration

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: other retinal dystrophies such as Stargardt 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

7.1.1. Human Papillomavirus Type 6 L1 protein/Human Papillomavirus Type 11 L1 protein/ Human Papillomavirus Type 16 L1 protein/ Human Papillomavirus Type 18 L1 protein/ Human Papillomavirus Type 31 L1 protein/ Human Papillomavirus Type 33 L1 protein/ Human Papillomavirus Type 45 L1 protein/ Human Papillomavirus Type 52 L1 protein/ Human Papillomavirus Type 58 L1 protein - EMEA-000654-PIP01-09-M02

Sanofi Pasteur MSD SNC; Prevention of premalignant genital lesions (cervical, vulvar and vaginal), cervical cancer and external genital warts (condyloma acuminata) causally related to Human Papillomavirus (HPV) types 6, 11, 16, 18, 31, 33, 45, 52, 58

Proposed indication: prevention of head and neck cancers caused by vaccine HPV types

Summary of committee discussion:

The PDCO was of the view that the proposed indication 'prevention of head and neck cancers caused by vaccine HPV types', falls under the scope of the mentioned Decision, as the indication is considered to be covered by the condition 'prevention of infection by human papillomavirus' listed in the Agency Decision.

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 thanked the following leaving members: Jaroslav Sterba and Peter Szitanyi from Czech Republic and Mona Ring Gatke from Denmark, for their contribution to the work of the Paediatric Committee.

It was noted that Jorrit Gerritsen is the new alternate representing Healthcare Professionals replacing Riccardo Riccardi.

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 PDCO members were informed about the final CHMP Opinions on medicinal products with recommended paediatric indications adopted in November 2018. These included Fexinidazole Winthrop (fexidinazole), Ravicti (glycerol phenylbutyrate) and Orkambi (lumacaftor / ivacaftor). New pharmaceutical form for Orkambi (lumacaftor / ivacaftor), granules, in 2 strengths (100/125 mg and 150/188 mg) was approved for paediatric use from 2 to 5 years of age.

The list of procedures with paediatric indications to be evaluated by the CHMP, starting in November 2018, was presented to the PDCO members.

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 identified the products which will require Non-clinical Working Group (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 Formulation Working Group evaluation and discussion.

9.3.3. Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP)

Meeting Summary PCWP Plenary Meeting 25 Sep 2018

Meeting Summary PCWP/HCPWP Joint Meeting 25 Sep 2018

Meeting Summary HCPWP Plenary Meeting 26 Sep 2018

Summary of committee discussion:

The documents were tabled for information.

9.4. Cooperation within the EU regulatory network

9.4.1. CTFG: presentation of CTFG mandate, its activities and potential areas of interaction with PDCO

CTFG vice-Chair: Ann Marie Janson Lang

Summary of committee discussion:

The vice-Chair of the Clinical Trial Facilitation Group (CTFG) presented the role and activities of the CFTG to the Paediatric Committee, followed by a discussion on common interests and potential areas of interaction. PDCO members are asked to propose issues they would like to discuss with the CTFG.
It is suggested to have a preliminary discussion of the proposed issues during the CTFG March 2019 plenary meeting.
Proposals should be sent by mid-January 2019 for discussion and agreement by the PDCO at the January plenary meeting.
An EU training workshop of paediatric clinical assessors from NCAs and ethics committees is planned for 2019, to which PDCO members will be invited to participate.
Finally, PDCO members are asked to recommend EU NTC courses for clinical trial unit assessors.

9.5. Cooperation with International Regulators

No items

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

No items

9.7. PDCO work plan

9.7.1. PDCO work plan 2019 proposal

PDCO member: Dirk Mentzer

Summary of committee discussion:

The Paediatric Committee adopted the PDCO work plan 2019.

9.8. Planning and reporting

No items

10. Any other business

10.1.1. Report from the FDA cluster TC

Summary of committee discussion:

The Committee was informed about the discussions at the Paediatric Cluster teleconference on 4 December 2018.

10.1.2. Feedback on August written procedure

Summary of committee discussion:

The EMA secretariat presented to the PDCO a summary review of the process put in place for facilitating the written procedure held in August 2018 including changes to the

submission timelines for paediatric procedures. The outcome was overall considered successful. Some process improvements were suggested to tackle potential peaks in workload in the remaining meetings of the PDCO.

10.1.3. Announcement of the 4th Accelerate Paediatric Strategy Forum (topic: AML) - Call for expression of Interest of PDCO members

PDCO member: Koenraad Norga

Summary of committee discussion:

The Committee was informed about the organisation of the next Accelerate Paediatric strategy forum on acute myeloid leukaemia.

10.1.4. Update on the future EMA premises in Amsterdam

Summary of committee discussion:

The EMA Secretariat updated the PDCO on the EMA relocation in 2019 to Amsterdam (the Netherlands) and more particularly on the meeting premises in the interim building (SPARK building) in Amsterdam as of March 2019.

11. Breakout sessions

11.1.1. Paediatric oncology

Summary of committee discussion:

The breakout session was cancelled.

11.1.2. Neonatology

Summary of committee discussion:

The breakout session was cancelled.

11.1.3. Inventory

Summary of committee discussion:

The breakout session was cancelled.

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 December 2018 meeting.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Dirk Mentzer	Chair	Germany	No interests declared	
Karl-Heinz Huemer	Member	Austria	No interests declared	
Koenraad Norga	Member (Vice-Chair)	Belgium	No participation in final deliberations and voting on: No participation in discussion, final deliberations and voting on:	Gepotidacin - EMEA-002443-PIP01-18 Gepotidacin - EMEA-002443-PIP02-18 Ambrisentan - Orphan - EMEA-000434-PIP01-08-M05
Karen Van Malderen	Alternate	Belgium	No interests declared	
Dimitar Roussinov	Member	Bulgaria	No restrictions applicable to this meeting	
Suzana Mimica Matanovic	Alternate	Croatia	No interests declared	
Georgios Savva	Member	Cyprus	No interests declared	
Jaroslav Sterba	Member	Czech Republic	No interests declared	
Peter Szitanyi	Alternate	Czech Republic	No interests declared	
Kirstine Moll Harboe	Member	Denmark	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Mona Ring Gatke	Alternate	Denmark	No interests declared	
Jana Lass	Alternate	Estonia	No interests declared	
Ann Marie Totterman	Member	Finland	No interests declared	
Pia Annunen	Alternate	Finland	No participation in discussion, final deliberations and voting on:	BMS-986036 - EMEA-002448-PIP01-18 Nivolumab - EMEA-C2-001407-PIP02-15-M02
Sylvie Benchetrit	Member	France	No interests declared	
Dominique Ploin	Alternate	France	No interests declared	
Sabine Scherer	Member	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	
Alessandro Jenkner	Alternate	Italy	No interests declared	
Dina Apele-Freimane	Member	Latvia	No restrictions applicable to	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
			this meeting	
Sigita Burokiene	Member	Lithuania	No interests declared	
Goda Vaitkeviciene	Alternate	Lithuania	No interests declared	
Carola de Beaufort	Member (CHMP alternate)	Luxembourg	No interests declared	
Maaike van Dartel	Member	Netherlands	No interests declared	
Siri Wang	Member	Norway	No interests declared	
Anette Solli Karlsen	Alternate	Norway	No interests declared	
Marek Migdal	Member	Poland	No interests declared	
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	
Stefan Grosek	Member	Slovenia	No interests declared	
Maria Jesus Fernández Cortizo	Alternate	Spain	No interests declared	
Fernando de Andrés Trelles (via TC)	Member	Spain	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Ninna Gullberg	Member	Sweden	No interests declared	
Eva Agurell	Alternate	Sweden	No interests declared	
Angeliki Siapkara	Member	United Kingdom	No interests declared	
Martina Riegl	Alternate	United Kingdom	No interests declared	
Fernando Cabanas	Member	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	
Johannes Taminiau	Member	Healthcare Professionals' Representative	No interests declared	
Doina Plesca	Alternate	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Günter Karl-Heinz Auerswald	Member	Patients' Organisation Representative	No restrictions applicable to this meeting	
Paola Baiardi	Alternate	Patients' Organisation Representative	No restrictions applicable to this meeting	
Michal Odermarsky	Member	Patients' Organisation Representative	No restrictions applicable to this meeting	
Dimitrios Athanasiou	Member	Patients' Organisation Representative	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Viviana Giannuzzi	Alternate	Patients' Organisation Representative	No restrictions applicable to this meeting	
Ann Marie Janson Lang	Expert - in person*	Sweden	No interests declared	
Shiva Ramroop	Expert - in person*	United Kingdom	No interests declared	
Eleni Gaki	Expert - in person*	United Kingdom	No interests declared	
Susanne Kaul	Expert - via telephone*	Germany	No interests declared	
Homera Fahimeda Binte Ali	Expert - in person*	United Kingdom	No interests declared	
Catriona Elizabeth Baker	Expert - via telephone*	United Kingdom	No interests declared	
Rune Kjeken	Expert - via telephone*	Norway	No restrictions applicable to this meeting	
Bjorg Bolstad	Expert - in person*	Norway	No restrictions applicable to this meeting	
Alexandre Moreau	Expert - in person*	France	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/