24 February 2016
EMA/PDCO/79065/2015
Procedure Management and Committees Support Division

Paediatric Committee (PDCO)

Minutes for the meeting on 27-29 January 2016

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

27 January 2016, 08:30- 19:00, room 3A

28 January 2016, 08:30- 19:00, room 3A

29 January 2016, 08:30- 13:00, room 3A

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.

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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
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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 with amendments.

1.3. Adoption of the minutes

The minutes were adopted with amendments 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. Sulfamethoxazole (CAS#: 723-46-6) / Miconazole (CAS#: 22916-47-8) / Azithromycin [monohydrate (CAS#: 121470-24-4) / dihydrate (CAS#: 117772-70-0)] - EMEA-001769-PIP01-15

Lukács és Társa Gyógyszerkereskedelmi Bt.; Second-Degree Burns / Burn of second degree of ankle and foot, Burn of second degree of trunk, Burn of second degree of wrist and hand, Burn of second degree of hip and lower limb, except ankle and foot, Burn of second degree of shoulder and upper limb, except wrist and hand

Day 120 opinion

Dermatology

Summary of committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee including contributions of external expert(s), the PDCO agrees with the applicant's request for a waiver. The PDCO recommends granting a waiver for Sulfamethoxazole / Miconazole / Azithromycin for all subsets of the paediatric population (0 to 18 years of age) in the condition of treatment of burns. 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.

2.1.2. exenatide - EMEA-001755-PIP01-15

LES LABORATOIRES SERVIER; Treatment of type 2 diabetes mellitus / Treatment of type 2 diabetes mellitus in patients from 10 to less than 18 years old

Day 120 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

Based on the assessment of this application, including clarifications received from the applicant after the D90 discussion and further discussions at the Paediatric Committee including contributions of the NCWG and of the MSSWG, the PDCO confirmed agreement with the applicant's proposal for a PIP in the condition of treatment of type 2 diabetes mellitus. The PIP includes a waiver and a deferral.

2.1.3. romosozumab - EMEA-001075-PIP04-15

Amgen Europe B.V.; Treatment of osteoporosis / Treatment of osteogenesis imperfecta, Treatment of glucocorticoid induced osteoporosis

Day 120 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The PDCO discussed the responses received from the applicant following the D90 discussion

and noted that the majority of the points had been addressed. In conclusion, the PDCO agreed on the PIP for romosozumab in the condition treatment of osteoporosis covering the indications osteogenesis imperfecta and glucocorticoid induced osteoporosis. The PIP includes a waiver. A deferral was also agreed for the PIP.

2.1.4. Rolapitant - EMEA-001768-PIP02-15

TESARO UK Ltd; Prevention of nausea and vomiting

Day 120 opinion

Gastroenterology-Hepatology

Summary of committee discussion:

The PDCO re-discussed the paediatric investigation plan taking into consideration the responses provided after D90 discussion.
All the issues were considered solved.
In conclusion, the PDCO recommended granting a positive opinion for a paediatric investigation plan with a waiver and a deferral.

2.1.5. Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with lentiviral vector that encodes for the human Wiskott Aldrich Syndrome (WAS) cDNA sequence - Orphan - EMEA-001792-PIP01-15

GlaxoSmithKline Trading Services Limited; Wiskott Aldrich Syndrome / Treatment of Wiskott Aldrich Syndrome

Day 120 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

The PDCO discussed again this product and confirmed the conclusions reached at Day 90. Based on the assessment of this application and further discussions at the Paediatric Committee including contributions of external expert(s), the PDCO adopted a positive opinion for this Paediatric Investigation Plan.

2.1.6. Eculizumab - Orphan - EMEA-000876-PIP05-15

Alexion Europe SAS; Treatment of Myasthenia Gravis / Treatment of Refractory Generalised Myasthenia Gravis

Day 120 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

The PDCO re-discussed the plan also taking into consideration the responses provided by the applicant after D90.
In conclusion, the PDCO adopted a positive opinion agreeing on a paediatric investigation plan, a deferral and a waiver.

2.1.7. guselkumab - EMEA-001523-PIP02-14

Janssen Cilag International NV; Treatment of psoriasis / Treatment of severe plaque psoriasis in children ≥6 to <18 years of age who cannot be adequately controlled with topical agents and/or phototherapy

Day 120 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

The applicant followed the PDCO's recommendations. Based on the assessment of this application and further discussions at the Paediatric Committee, including contributions of external expert(s), the PDCO adopted a positive opinion for this Paediatric Investigation Plan.

2.1.8. Human normal immunoglobulin - EMEA-001797-PIP01-15

Octapharma Pharmazeutika Produktionsges.m.b.H; Primary Immunodeficiency Diseases

Day 120 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

The PDCO concluded that all issues have been addressed and resolved satisfactorily.
The PDCO adopted a positive opinion for this PIP including a waiver and a deferral.

2.1.9. (2R,3R,4R,5R)-5-(4-amino-2-oxopyrimidin-1(2H)-yl)-2-(chloromethyl)-4-fluoro-2-((isobutyryloxy)methyl)tetrahydrofuran-3-yl isobutyrate - EMEA-001758-PIP01-15

Alios Biopharma, Inc; Treatment of respiratory tract disease caused by human respiratory syncytial virus (RSV) infection / The treatment of respiratory syncytial virus infection

Day 120 opinion

Infectious Diseases

Summary of committee discussion:

The PDO discussed the applicant's clarifications requested on day 90 and concluded that all remaining issues are satisfactorily resolved. Based on the assessment of this application the PDCO adopted a positive opinion for this PIP including a deferral.

2.1.10. Arimoclomol citrate - Orphan - EMEA-001748-PIP01-15

Orphazyme ApS; Treatment of Niemann-Pick Disease, Type C / Treatment of Niemann-Pick Disease, Type C

Day 120 opinion

Neurology

Summary of committee discussion:

The clarifications provided by the applicant between D90 and D120 were agreed upon. The Paediatric Committee adopted a positive opinion for this PIP.

2.1.11. biotin - EMEA-001712-PIP02-15

MEDDAY SAS; Multiple sclerosis (MS)

Day 120 opinion

Neurology

Summary of committee discussion:

The PDCO confirmed the points discussed at Day 90. Based on the information above, the PDCO agreed that it is appropriate to grant a waiver for biotin for the treatment of multiple sclerosis.

2.1.12. binimetinib - EMEA-001454-PIP03-15

Pierre Fabre Médicament.; Treatment of Melanoma / Binimetinib in combination with encorafenib is indicated for the treatment of patients aged 12 years and older with unresectable or metastatic melanoma harboring BRAF V600 mutations.

Day 120 opinion

Oncology

Summary of committee discussion:

The PDCO re-discussed the application for binimetinib to be used in combination with encorafenib (EMEA-001588-PIP01-13) considering the responses provided by the applicant after the D90 discussion.
All pending issues were considered solved.
In conclusion the PDCO adopted a positive opinion agreeing on a paediatric investigation plan and a deferral for binimetinib to be used in combination with encorafenib in the condition "Treatment of melanoma".
For the paediatric population from birth to less than 12 years of age, the condition "treatment of melanoma" is covered by the EMA decision CW/1/2011.

2.1.13. encorafenib - EMEA-001588-PIP01-13

Pierre Fabre Médicament; Treatment of Melanoma / Encorafenib in combination with binimetinib is indicated for the treatment of patients aged 12 years and older with unresectable or metastatic melanoma harboring BRAF V600 mutations.

Day 120 opinion

Oncology

Summary of committee discussion:

The PDCO re-discussed the application for encorafenib to be used in combination with

binimetinib (EMEA-001454-PIP03-15) considering the responses provided by the applicant after the D90 discussion.
All pending issues were considered solved.
In conclusion, the PDCO adopted a positive opinion agreeing on a paediatric investigation plan for binimetnib to be used in combination with encorafenib in the condition “Treatment of melanoma”.
For the paediatric population from birth to less than 12 years of age the condition “treatment of melanoma” is covered by the EMA decision CW/1/2011.

2.1.14. nivolumab - EMEA-001407-PIP02-15

Bristol-Myers Squibb Pharma EEIG; Treatment of malignant neoplasms of lymphoid tissue, Treatment of malignant neoplasms of the central nervous system / Treatment of paediatric patients with recurrent or progressive high grade primary central nervous system tumours in the age group from 6 months to < 18 years., Treatment of paediatric patients with relapsed or refractory Hodgkin lymphoma in the age group from 5 years to < 18 years.

Day 120 opinion

Oncology

Summary of committee discussion:

The PDCO discussed the application taking into account comments on the draft opinion by the applicant and information on a regulatory interaction with the company. As all issues were resolved, the PDCO agreed a second PIP for nivolumab. The Committee also granted deferrals as indicated in the Opinion as well as waivers.

2.1.15. Gemtuzumab linked to Ozogamicin - Orphan - EMEA-001733-PIP02-15

Pfizer Limited; Treatment of Acute Myeloid Leukaemia / Mylotarg is indicated in combination with liposomal daunorubin/cytarabine or mitoxantrone/cytarabine paediatric induction regimens for the treatment of de novo and secondary Acute Myeloid Leukaemia in children aged 28 days up to 18 years

Day 120 opinion

Oncology / Haematology-Hemostaseology

Summary of committee discussion:

The PDCO continued the discussion of the modified application for agreement of a paediatric investigation plan for gemtuzumab linked to ozogamicin for the treatment of paediatric patients with acute myeloid leukaemia, taking into account comments by the applicant on the draft opinion. Consequently, the PDCO agreed a PIP for gemtuzumab linked to ozogamicin, as detailed in the Opinion, including a waiver and a deferral.

2.1.16. amlodipine / ramipril - EMEA-001871-PIP01-15

Krka, d.d., Novo mesto; Treatment of hypertension

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

The PDCO confirmed the outcome of the D30 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 amlodipine / ramipril in the condition of treatment of hypertension.

2.1.17. Fluoroestradiol (18F) - EMEA-001892-PIP01-15

Florentin Artner; Used for imaging in patients undergoing oncologic diagnostic procedures describing functions or diseases where increased expression of oestrogen receptors by specific tissues is the diagnostic target

Day 60 opinion

Diagnostic

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 fluoroestradiol (18F) in the condition “detection of increased expression of oestrogen receptors in tissues and organs for diagnostic purposes”. 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.

2.1.18. Humanised IgG4 monoclonal antibody against extracellular tau - Orphan - EMEA-001867-PIP01-15

Bristol-Myers Squibb International Corporation; Treatment of progressive supranuclear palsy

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 Humanised IgG4 monoclonal antibody against extracellular tau in the condition of Treatment of progressive supranuclear palsy.
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.

2.1.19. recombinant human monoclonal antibody against growth differentiation factor 8 - EMEA-001859-PIP02-15

Regeneron Pharmaceuticals, Inc; Sporadic inclusion body myositis

Day 60 opinion

Neurology

Summary of committee discussion:

The PDCO discussed this product on 27-29 January 2016.
Based on the assessment of this application and further discussions at the Paediatric Committee including contributions of external expert(s), the PDCO agrees with the applicant's request for a waiver.

2.1.20. Testosterone - EMEA-001873-PIP01-15

Allergan Pharmaceuticals Ireland; Treatment of dry eye disease

Day 60 opinion

Ophthalmology

Summary of committee discussion:

A positive opinion was adopted granting a waiver for Testosterone for the treatment of dry eye disease.

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. velaglucerase alfa - EMEA-C-000556-PIP01-09-M02

Shire Pharmaceuticals Ireland Limited; Treatment of Gaucher Disease, Types 1 and 3

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The PDCO adopted an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0157/2012) of 25 July 2012.

2.2.2. Ozenoxacin - EMEA-C-000981-PIP01-10-M04

Ferrer Internacional, S.A.; Treatment of impetigo

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

The Applicant responses to the 2 issues were presented. Upon reconsideration, the PDCO adopted an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0167/2014).

2.2.3. tenofovir disoproxil fumarate / emtricitabine - EMEA-C1-001091-PIP02-15

Gilead Sciences International Ltd.; Treatment of Human Immunodeficieny (HIV-1) infection

Day 30 opinion

Infectious Diseases

Summary of committee discussion:

The applicant has been compliant with the agreed PIP, so far. The interim compliance check is positive.

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. recombinant 10 kD culture filtrate protein / Recombinant dimer of 6 kD early secretory antigenic target - EMEA-001156-PIP01-11-M06

Statens Serum Institut; Diagnosis of tuberculosis / To diagnose individuals suspected to be infected with Mycobacterium tuberculosis from 28 days of age

Day 60 opinion

Diagnostic

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/0171/2014 of 9 July 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.2. Evolocumab - EMEA-001268-PIP01-12-M02

Amgen Europe B.V.; Treatment of mixed dyslipidaemia, Treatment of elevated cholesterol / , Heterozygous Familial Hypercholesterolaemia (HeFH) and Homozygous Familial Hypercholesterolaemia (HoFH) after Prior Lipid-Lowering Therapy in paediatric subjects aged 10 years and above.

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

The PDCO confirmed the conclusions reached for this product at Day 30.
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/0071/2015 of 1/4/2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.3. macitentan - Orphan - EMEA-001032-PIP01-10-M02

Actelion Registration Ltd.; Treatment of Idiopathic Pulmonary Fibrosis, Treatment of Pulmonary Arterial Hypertension, Treatment of Systemic Sclerosis / N.A., Treatment of Pulmonary Arterial Hypertension

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0087/2012 of 25 May 2012).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.4. dabigatran etexilate - EMEA-000081-PIP01-07-M08

Boehringer Ingelheim International GmbH; Treatment of thromboembolic events, Prevention of thomboembolic events / Treatment of venous thromboembolic events in paediatric patients (secondary venous thrombotic event prevention)

Day 60 opinion

Cardiovascular Diseases / Haematology-Hemostaseology

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted. The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0241/2014 of 29 September 2014). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.5. dupilumab - EMEA-001501-PIP01-13-M02

Regeneron Pharmaceuticals, Inc; Atopic Dermatitis / Atopic Dermatitis

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/0122/2015 of 5 June 2015). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.6. Bupropion Hydrochloride / Naltrexone Hydrochloride - EMEA-001373-PIP01-12-M01

Orexigen Therapeutics Ireland Limited; Treatment of obesity / Treatment of obesity

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The PDCO adopted a positive opinion on the modifications of the agreed PIP requested by the applicant with an additional minor modification. The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.7. Dapagliflozin - EMEA-000694-PIP02-14-M01

AstraZeneca AB; Type 1 Diabetes Mellitus / As an adjunct to insulin treatment to improve glycaemic control in adults with type 1 diabetes mellitus when insulin alone does not provide adequate control

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 as stated above.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0064/2015 of 01/04/2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.8. denosumab - EMEA-000145-PIP02-12-M01

Amgen Europe B.V.; Treatment of Osteoporosis / Treatment of osteogenesis imperfecta, Treatment of glucocortcoid induced osteoporosis

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 and the additional information provided by the applicant following D30 discussion, 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/0086/2013 of 29/4/2013). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.9. saxagliptin - EMEA-000200-PIP01-08-M06

AstraZeneca AB; E11 Type 2 Diabetes / Treatment of Type 2 Diabetes

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, with some alterations.
The PDCO adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0061/2013 of 26 March 2013). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.10. Tolvaptan - EMEA-001231-PIP02-13-M02

Otsuka Pharmaceutical Europe Ltd.; Polycystic Kidney Disease (PKD), Dilutional hyponatraemia / Treatment of chronic (>48 hours) dilutional hyponatraemia resistant to fluid restriction (i.e., euvolemic and hypervolemic hyponatremia) associated with heart failure, cirrhosis or SIADH., Treatment of progression of ADPKD, Treatment of progression of ARPKD

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The applicant clarified all outstanding issues following Day 30.
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/0336/2014 of 22 December 2014). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.11. ferric maltol - EMEA-001195-PIP01-11-M01

Iron Therapeutics (UK) Ltd.; Iron deficiency anaemia (IDA) / Treatment of Iron deficiency anaemia (IDA)

Day 60 opinion

Haematology-Hemostaseology

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0228/2013 of 23 September 2013).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.12. Trenonacog alfa - EMEA-000661-PIP01-09-M07

Cangene Europe Limited; Hereditary Factor IX Deficiency (Haemophilia B) / Replacement therapy or prophylaxis in patients with hereditary Factor IX Deficiency/ Haemophilia B

Day 60 opinion

Haematology-Hemostaseology

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0038/2014 of 5 March 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.13. rituximab - EMEA-000308-PIP02-11-M01

Roche Registration Limited; Granulomatosis with polyangiitis (Wegener's) and microscopic polyangiitis; ANCA associated vasculidities / Treatment of granulomatosis with polyangiitis (Wegener's), Treatment of microscopic polyangiitis

Day 60 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

The PDCO discussed the modification request for the PIP agreed for rituximab for treatment of polyangiitis, taking into account comments on the draft opinion 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 some of 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.

2.3.14. Aztreonam - Orphan - EMEA-000827-PIP01-09-M04

Gilead Sciences International Limited; E84.0 Cystic Fibrosis with pulmonary manifestations / Treatment of initial Pseudomonas aeruginosa pulmonary infection/ colonisation in patients

with Cystic Fibrosis., Treatment of chronic Pseudomonas aeruginosa pulmonary infection/ colonisation in patients with Cystic Fibrosis.

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/0124/2013 of 28 May 2013).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.15. dalbavancin - EMEA-000016-PIP01-07-M05

Durata Therapeutics International B.V; skin and soft tissue skin infections

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 responses received by the applicant after discussion at D30 as well as further clarifications received following additional points raised by the Rapporteur, the PDCO considered that the proposed changes could be accepted and suggested some additional ones - that were included in the opinion - in order to clarify the wording in agreement with the applicant.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0138/2015 of 10 July 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.16. Meropenem - EMEA-000898-PIP01-10-M02

NeoMero Consortium; Bacterial sepsis, Bacterial meningitis / Treatment of bacterial meningitis in neonates and infants below 3 months of age, Treatment of bacterial sepsis in neonates and infants below 3 months of age

Day 60 opinion

Neonatology - Paediatric Intensive Care / Infectious Diseases

Summary of committee discussion:

The PDCO adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision P/0159/2015.
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.17. Rufinamide - Orphan - EMEA-000709-PIP01-09-M04

Eisai Limited; Lennox-Gastaut Syndrome

Day 60 opinion

Neurology

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that 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/0263/2015 of 30 October 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.18. Tasimelteon - Orphan - EMEA-001531-PIP01-13-M02

Vanda Pharmaceuticals Ltd.; ICD9 - 327.34 Circadian rhythm sleep disorder, free-running type / Non-24-Hour Sleep-Wake Disorder (Non-24) in the totally blind

Day 60 opinion

Neurology

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0123/2015 of 05 June 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.19. midostaurin - Orphan - EMEA-000780-PIP01-09-M02

Novartis Europharm Ltd; C92.0 Acute myeloid leukaemia, C94.3 Mast cell leukaemia, C96.2 Malignant mastocytosis / Treatment of paediatric patients with FLT3 mutated AML, newly diagnosed or in first relapse, A waiver is in place for this condition.

Day 60 opinion

Oncology

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, and the confirmation from the applicant that no change to the agreed indication in the PIP was intended, 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/0296/2014 of 07/11/2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.20. pazopanib - EMEA-000601-PIP01-09-M03

Novartis Europharm Limited; Ewing sarcoma family of tumours, Rhabdomyosarcoma, Non-rhabdomyosarcoma soft tissue sarcoma / Treatment of pediatric patients with rhabdomyosarcoma, Treatment of pediatric patients with Ewing sarcoma family of tumours, Treatment of pediatric patients with non-rhabdomyosarcoma soft tissue sarcoma

Day 60 opinion

Oncology / Uro-nephrology

Summary of committee discussion:

The PDCO discussed again this modification.
The PDCO examined the answers the applicant provided to the questions the Committee asked at Day 30 and noted that they were satisfactory.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP.
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.21. Human Thrombin / Human Fibrinogen - EMEA-001149-PIP01-11-M03

Omrix Biopharmaceuticals N.V.; Treatment of cerebrospinal fluid leakage resulting from a surgical procedure. Treatment of haemorrhage resulting from a surgical procedure. / EVICEL is indicated for suture line sealing in dura mater closure. EVARREST is indicated for supportive treatment in surgery where standard surgical techniques are insufficient, for improvement of haemostasis. EVICEL is indicated for supportive treatment in surgery where standard surgical techniques are insufficient, for improvement of haemostasis.

Day 60 opinion

Other

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0171/2015 of 07 August 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.22. zoledronic acid - EMEA-000057-PIP01-07-M06

Novartis Europharm Limited; Osteoporosis / Glucocorticoid-induced osteoporosis

Day 60 opinion

Other

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed change could not be accepted. The PDCO therefore adopted a negative Opinion on the modification of the agreed

PIP as set in the Agency's latest decision.

2.3.23. Tapentadol - EMEA-000325-PIP01-08-M04

Grünenthal GmbH; Chronic pain / Treatment of chronic pain

Day 60 opinion

Pain

Summary of committee discussion:

The PDCO discussed the applicant's clarifications requested by the committee on Day 30. 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/0095/2014 of 7 April 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.24. Tapentadol - EMEA-000485-PIP01-08-M04

Grünenthal GmbH; Chronic pain / Treatment of chronic pain

Day 60 opinion

Pain

Summary of committee discussion:

The PDCO discussed the applicant's clarifications requested by the committee on Day 30. 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/0096/2014 of 7 April 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.
With this modification this PIP is closed and is superseded by PIP [P/48/2009 issued 24 March 2009] and all its subsequent modifications.

2.3.25. Tapentadol - EMEA-000486-PIP01-08-M04

Grünenthal GmbH; Chronic pain / Treatment of chronic pain

Day 60 opinion

Pain

Summary of committee discussion:

The PDCO discussed the applicant's clarifications requested by the Committee on Day 30. 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/0097/2014 of 7 April 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.
With this modification this PIP is closed and is superseded by PIP [P/48/2009 issued 24 March 2009] and all its subsequent modifications.

2.3.26. Naloxone (hydrochloride) - EMEA-001567-PIP01-13-M02

Develco Pharma GmbH; Opioid-induced constipation / Treatment of opioid-induced constipation

Day 60 opinion

Pain / 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/0219/2015 of 2 October 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.27. Basmisanil - EMEA-001506-PIP02-14-M01

Roche Registration Ltd; Treatment of Down syndrome / Treatment of intellectual disability associated with Down syndrome

Day 60 opinion

Psychiatry

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that 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/0075/2015 of 01 April 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.28. Cariprazine hydrochloride - EMEA-001652-PIP01-14-M01

Gedeon Richter Plc.; F20 Schizophrenia

Day 60 opinion

Psychiatry

Summary of committee discussion:

The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0156/2015 of 10 July 2015).

The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.29. Etelcalcetide - EMEA-001554-PIP01-13-M01

Amgen Europe B.V.; Hyperparathyroid disorders / Hyperparathyroidism Secondary

Day 60 opinion

Uro-nephrology

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/0259/2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.4. Opinions on Re-examinations

No items.

2.5. Finalisation and adoption of opinions

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. certolizumab pegol - EMEA-001071-PIP03-14

Treatment of psoriasis / treatment of severe chronic plaque psoriasis

Day 90 discussion

Dermatology

3.1.2. Recombinant Human alpha-galactosidase A - EMEA-001828-PIP01-15

Treatment of Fabry disease

Day 90 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.3. Human normal immunoglobulin for subcutaneous administration - EMEA-001853-PIP01-15

Treatment of primary immunodeficiency

Day 90 discussion

Immunology-Rheumatology-Transplantation

3.1.4. Humanised monoclonal antibody against myostatin - Orphan - EMEA-001763-PIP01-15

Pfizer Limited; Duchenne Muscular Dystrophy

Day 90 discussion

Neurology

3.1.5. Octenidine dihydrochloride - EMEA-001514-PIP01-13

Treatment of upper respiratory tract infections / Treatment of sore-throat due to infectious pharyngitis

Day 90 discussion

Oto-rhino-laryngology

3.1.6. Ketamine / Sufentanil - EMEA-001739-PIP01-14

ICD10: R52 Pain, unspecified

Day 90 discussion

Pain

3.1.7. Tetracaine hydrochloride / Oxymetazoline hydrochloride - EMEA-001764-PIP03-15 (Opinion adopted at Day 60)

Anesthesia

Day 60 discussion

Anaesthesiology

Summary of committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee including clarifications received from the applicant following D30 discussion, the PDCO agreed with the applicant's request for a PIP in the condition topical anaesthesia for a nasal spray containing tetracaine (hydrochloride) / oxymetazoline (hydrochloride) together with a waiver.

3.1.8. Ularitide acetate - EMEA-001863-PIP01-15

Treatment of acute heart failure

Day 60 discussion

Cardiovascular Diseases

3.1.9. White soft paraffin / Liquid paraffin - EMEA-001789-PIP02-15

Prevention of atopic dermatitis / Prevention of atopic dermatitis in neonates and infants at risk to develop the disease

Day 60 discussion

Dermatology

3.1.10. Recombinant Fusion Protein Linking Coagulation Factor VIIa with Albumin - Orphan - EMEA-001886-PIP01-15

CSL Behring GmbH; Treatment of congenital Haemophilia A or B

Day 60 discussion

Haematology-Hemostaseology

3.1.11. Recombinant Fusion Protein Linking Coagulation Factor VIIa with Albumin - Orphan - EMEA-001886-PIP02-15

CSL Behring GmbH; Treatment of congenital Factor VII Deficiency

Day 60 discussion

Haematology-Hemostaseology

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

Treatment of Duchenne Muscular Dystrophy / Treatment of Duchenne Muscular Dystrophy in patients aged ≥6 months to <18 years

Day 60 discussion

Neurology

3.1.13. copanlisib - EMEA-001757-PIP02-15

Treatment of all conditions included in the category of malignant neoplasms (except hematopoietic and lymphoid tissue)., Treatment of mature B-cell neoplasms / , Treatment of children with neuroblastoma, Ewing's sarcoma, osteosarcoma or rhabdomyosarcoma who failed one or more prior lines of therapy.

Day 60 discussion

Oncology

3.1.14. Carfilzomib - Orphan - EMEA-001806-PIP02-15

Amgen Europe B.V.; Treatment of acute lymphoblastic leukemia / Treatment of pediatric patients (≥ 28 days to ≤ 18 years of age, and young adults ≤ 21 years at the time of their initial diagnosis) with early first relapse (< 36 months from initial diagnosis), multiple relapses, or refractory ALL, with or without extramedullary disease

Day 60 discussion

Oncology / Haematology-Hemostaseology

3.1.15. bempedoic acid - EMEA-001872-PIP01-15

Primary Hypercholesterolemia / Treatment of heterozygous familial hypercholesterolaemia

Day 60 discussion

Other / Cardiovascular Diseases

3.1.16. Levamisole (hydrochloride) - Orphan - EMEA-001885-PIP01-15 (Opinion adopted at Day 30)

ACE Pharmaceuticals BV; Glomerulonephritis and Nephrotic syndrome / Treatment of steroid sensitive nephrotic syndrome

Day 60 discussion

Uro-nephrology

Summary of committee discussion:

The PDCO confirmed the outcome of the Day 30 discussion. The committee agreed with the proposed PIP for the treatment of glomerulonephritis and nephrotic syndrome. Therefore, the PDCO adopted a positive opinion on this PIP including a waiver.

3.1.17. Pandemic influenza vaccine (H5N1) (surface antigen, inactivated, adjuvanted) - EMEA-001830-PIP01-15

Prevention of influenza / Prophylaxis of influenza caused by Pandemic strain (as example A(H5N1v) is used)

Day 60 discussion

Vaccines

3.1.18. EMEA-001868-PIP01-15

Treatment of Persistent Pulmonary Hypertension of the Newborn [PPHN], Treatment of Pulmonary Arterial Hypertension (PAH), Treatment of Pulmonary Veno-Occlusive Disease and Pulmonary Capillary Hemangiomatosis [PVOD/PCH] / , Treatment of PAH in pediatric patients

aged 1 to <18 years of age

Day 30 discussion

Cardiovascular Diseases

3.1.19. Finasteride - EMEA-001878-PIP01-15

Treatment of androgenetic alopecia

Day 30 discussion

Dermatology

3.1.20. 2-hydroxypropyl-ß-cyclodextrin - Orphan - EMEA-001866-PIP01-15

Vtesse Europe Ltd; Treatment of Niemann-Pick disease, type C

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.21. Perindopril arginine / Atorvastatin - EMEA-001876-PIP01-15

Treatment of cardiovascular diseases, Treatment of ischaemic coronary artery disorders, Treatment of hypertension, Treatment of elevated cholesterol

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases

3.1.22. Synthetic double-stranded siRNA oligonucleotide directed against antithrombin mRNA and covalently linked to a ligand containing three N-acetylgalactosamine residues - Orphan - EMEA-001855-PIP01-15

Alnylam UK Limited; Treatment of Haemophilia B, Treatment of Haemophilia A / ALN-AT3SC is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in children aged ≥1 year with severe haemophilia A, including patients who express neutralizing antibodies to exogenous factor VIII substitution, ALN-AT3SC is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in children aged ≥1 year with severe haemophilia B, including patients who express neutralizing antibodies to exogenous factor IX substitution

Day 30 discussion

Haematology-Hemostaseology

3.1.23. Eculizumab - Orphan - EMEA-000876-PIP06-15

Alexion Europe SAS; Prevention of graft rejection following solid organ transplantation / Prevention of acute antibody-mediated rejection in sensitized recipients after kidney transplantation

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.1.24. Recombinant human monoclonal antibody to GM-CSF - EMEA-001882-PIP01-15

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis) / Treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 1 year of age and older, Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.1.25. Immunoglobulin G2, anti-(human α-calcitonin gene-related peptide/β-calcitonin gene-related peptide) - EMEA-001877-PIP01-15

Migraine / Prophylaxis of headache in children aged 6 to 18 years with episodic and chronic migraine

Day 30 discussion

Neurology

3.1.26. acalabrutinib - EMEA-001796-PIP02-15

Treatment of lymphoplasmacytic lymphoma, Treatment of mantle cell lymphoma

Day 30 discussion

Oncology

3.1.27. pidilizumab - EMEA-001891-PIP01-15

Treatment of Diffuse Large B-Cell Lymphoma

Day 30 discussion

Oncology / Haematology-Hemostaseology

3.1.28. andexanet alfa - EMEA-001902-PIP01-15

Prevention of factor Xa inhibitor associated haemorrhage, Treatment of factor Xa inhibitor associatedhaemorrhage / (as above), For the reversal of anticoagulation due to direct and indirect factor Xa inhibitors in patients experiencing an acute major bleeding event or requiring urgent surgery.

Day 30 discussion

Other

3.1.29. Gallium68 chloride (Ga68Cl3) - EMEA-001842-PIP02-15

This medicinal product is not intended for direct use in patients. Visualisation of function and/or specific organs or lesions in the body, depending on the carrier molecule used.

Day 30 discussion

Other

3.1.30. Recombinant, CHO cell expressed, fully human IgG1, kappa light chain, monoclonal antibody - Orphan - EMEA-001864-PIP01-15

Dyax Corp.; Hereditary angioedema / Treatment of hereditary angioedema

Day 30 discussion

Other

3.1.31. Birch pollen extract (Betula verrucosa) - EMEA-001879-PIP01-15

J30.1 Allergic rhinitis due to pollen / Treatment of tree pollen allergic rhinitis and/or conjunctivitis

Day 30 discussion

Pneumology - Allergology

3.1.32. Levocetirizine dihydrochloride / Montelukast sodium - EMEA-001908-PIP01-15

Treatment of asthma

Day 30 discussion

Pneumology - Allergology

3.1.33. Ragweed pollen extract (Ambrosia artemisiifolia) - EMEA-001881-PIP01-15

Treatment of allergic rhinitis and/or conjunctivitis / treatment of ragweed pollen allergic rhinitis and/or conjunctivitis

Day 30 discussion

Pneumology – Allergology

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. Canakinumab - EMEA-C-000060-PIP04-14-M01

Novartis Europharm Ltd.; Treatment of hyperimmunoglobulin D syndrome

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.2.2. Canakinumab - EMEA-C-000060-PIP05-14-M01

Novartis Europharm Ltd.; Treatment of tumour necrosis factor receptor associated periodic syndrome

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.2.3. Human normal immunoglobulin - EMEA-C-000830-PIP02-10-M02 (Opinion adopted at Day 30)

Bio Products Laboratory Limited; Treatment of idiopathic thrombocytopenic purpura as model for immunomodulation

Day 30 discussion

Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology

Summary of committee discussion:

The PDCO adopted an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0295/2015) of 03 December 2015.

3.2.4. Everolimus - EMEA-C-000019-PIP02-07-M05 (Opinion adopted at Day 30)

Novartis Europharm Limited; Subependymal Giant Cell Astrocytoma

Day 30 discussion

Neurology

Summary of committee discussion:

The PDCO discussed the request for an opinion on compliance, taking into account previous procedures to verify compliance.
The PDCO adopted an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (see A.1).

3.2.5. Recombinant Human TriPeptidyl Peptidase 1 (rhTPP1) - EMEA-C1-001362-PIP01-12-M02

BioMarin International Limited; Treatment of Neuronal Ceroid Lipofuscinosis Type 2 (CLN2)

Day 30 discussion

Neurology

3.2.6. Bevacizumab - EMEA-C-000056-PIP01-07-M02

F.Hoffmann-La Roche Ltd; Treatment of non-rhabdomyosarcoma soft tissue sarcoma

Day 30 discussion

Oncology

3.2.7. mirabegron - EMEA-C1-000597-PIP02-10-M04

Astellas Pharma Europe B.V.; Treatment of Idiopathic overactive bladder

Day 30 discussion

Uro-nephrology

3.2.8. mirabegron - EMEA-C1-000597-PIP03-15-M01

Astellas Pharma Europe B.V.; Treatment of neurogenic detrusor overactivity

Day 30 discussion

Uro-nephrology

3.2.9. Japanese-encephalitis virus, inactivated (attenuated strain SA14-14-2 grown in vero cells) - EMEA-C-000559-PIP01-09-M03

Valneva Austria GmbH; Prevention of Japanese encephalitis

Day 30 discussion

Vaccines

3.2.10. Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily A) / Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily B) - EMEA-C1-001037-PIP02-11-M03

Pfizer Ltd.; Prevention of invasive meningococcal disease caused by N. meningitidis serogroup B

Day 30 discussion

Vaccines

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Alipogene Tiparvovec - Orphan - EMEA-000292-PIP01-08-M02

uniQure biopharma B.V.; Hyperchylomicronaemia / Glybera is indicated for patients aged 2 or above diagnosed with familial lipoprotein lipase deficiency (LPLD) and suffering from severe or multiple pancreatitis attacks despite dietary fat restrictions. The diagnosis of LPLD has to be confirmed by genetic testing. The indication is restricted to patients with detectable levels of LPL protein.

Day 30 discussion

Cardiovascular Diseases

3.3.2. Alirocumab - EMEA-001169-PIP01-11-M01

Sanofi-aventis Recherche & développement; Treatment of elevated cholesterol / Treatment of heterozygous and homozygous familial hypercholesterolemia

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.3. Pitavastatin - EMEA-000054-PIP01-07-M04

Kowa Pharmaceutical Europe Company Ltd; Endocrine, nutritional and metabolic diseases - Metabolic disorders - Disorders of lipoprotein metabolism and other lipidaemias E78 / Treatment of high-risk hyperlipidaemia (excluding homozygous familial hypercholesterolaemia) in children and adolescents who are not controlled on diet

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.4. Pitavastatin - EMEA-000300-PIP01-08-M04

Kowa Pharmaceutical Europe Company Ltd; Endocrine, nutritional and metabolic diseases - Metabolic disorders - Disorders of lipoprotein metabolism and other lipidaemias E78 / Treatment of high-risk hyperlipidaemia (excluding homozygous familial hypercholesterolaemia) in children and adolescents who are not controlled on diet

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. Heterologous Human Adult Liver-derived Progenitor Cells (HHAPLC) - Orphan - EMEA-001155-PIP01-11-M03

Promethera Biosciences; Urea Cycle Disorders, Crigler-Najjar Syndrome / Treatment of inborn errors of liver metabolism

Day 30 discussion

Gastroenterology-Hepatology

3.3.6. Coagulation Factor VIIa (Recombinant) - EMEA-001203-PIP02-14-M01

LFB SA; Treatment of congenital coagulation disorders, Treatment of acquired haemophilia / Treatment of bleeding and prevention of bleeding in those undergoing surgery or invasive procedures in patients with haemophilia A or B with inhibitors to Factors VIII or IX, Treatment of bleeding and prevention of bleeding in those undergoing surgery or invasive procedures in patients with acquired haemophilia

Day 30 discussion

Haematology-Hemostaseology

3.3.7. ixekizumab - EMEA-001050-PIP01-10-M01

Eli Lilly & Company Limited; Treatment of psoriasis vulgaris, Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis) / Treatment of moderate to severe chronic plaque psoriasis in paediatric patients from the age of 6 years who are not adequately controlled by topical therapies., Treatment of JIA (including polyarticular arthritis, extended oligoarticular arthritis, sJIA without active systemic features, and ERA including JoAS and JPsA) in paediatric patients from the age of 2 years and for the treatment of sJIA with active systemic features in paediatric patients from the age of 1 year

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.3.8. Adalimumab - EMEA-000366-PIP05-12-M01

AbbVie Limited; Non-infectious uveitis

Day 30 discussion

Immunology-Rheumatology-Transplantation / Ophthalmology / Dermatology / Gastroenterology-Hepatology

3.3.9. boceprevir - EMEA-000583-PIP01-09-M07

Merck Sharp & Dohme Ltd; Treatment of chronic viral hepatitis C / Treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alpha and ribavirin, in children and adolescents from 3 years to less than 18 years of age with compensated liver disease who are previously untreated or who have failed previous therapy.

Day 30 discussion

Infectious Diseases

3.3.10. Fidaxomicin - EMEA-000636-PIP01-09-M04

Astellas Pharma Europe B.V.; Treatment of enterocolitis caused by clostridium difficile / Treatment of Clostridium difficile infections (CDI) also known as C. difficile-associated diarrhoea (CDAD)

Day 30 discussion

Infectious Diseases

3.3.11. Olesoxime - Orphan - EMEA-001414-PIP01-12-M01

Roche Registration Limited; Spinal Muscular Atrophy

Day 30 discussion

Neurology

3.3.12. Talimogene laherparepvec - EMEA-001251-PIP01-11-M01

Amgen Europe B.V.; Treatment of melanoma in adults / Treatment of solid malignant non-CNS tumours

Day 30 discussion

Oncology

3.3.13. Tapentadol - EMEA-000018-PIP01-07-M10

Grünenthal GmbH; Acute pain / Treatment of acute pain

Day 30 discussion

Pain

3.3.14. Tapentadol - EMEA-000494-PIP01-08-M09

Grünenthal GmbH; Acute pain / Treatment of acute pain

Day 30 discussion

Pain

3.3.15. Tapentadol - EMEA-000495-PIP01-08-M09

Grünenthal GmbH; Acute pain / Treatment of acute pain

Day 30 discussion

Pain

3.3.16. mometasone furoate / indacaterol acetate (dose expressed as free base) - EMEA-001217-PIP01-11-M02

NOVARTIS EUROPHARM LTD.; Treatment of asthma

Day 30 discussion

Pneumology - Allergology

3.3.17. tralokinumab - EMEA-000782-PIP01-09-M03

MedImmune Ltd; Asthma / Treatment of adults and adolescents whose asthma is inadequately controlled with medium or high-dose inhaled corticosteroids (ICS) and at least one additional controller medication

Day 30 discussion

Pneumology - Allergology

3.3.18. Loxapine - EMEA-001115-PIP01-10-M04 (Opinion adopted at Day 30)

Ferrer Internacional, S.A.; Bipolar Disorder, Schizophrenia / For rapid control of agitation in patients with schizopherenia, For rapid control of agitation in patients with schizophrenia

Day 30 discussion

Psychiatry

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, and taking the above points into account, the PDCO adopted a positive opinion on the modification of the agreed PIP. All other key elements of the PIP remain unchanged.
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

3.3.19. potassium hydrogen carbonate / potassium citrate monohydrated - EMEA-001357-PIP01-12-M01

Advicenne Pharma; Treatment of renal tubular acidosis

Day 30 discussion

Uro-nephrology

3.3.20. Everolimus - Orphan - EMEA-000019-PIP08-12-M02

Novartis Europharm Limited; Tuberous Sclerosis Complex (TSC) / Treatment of refractory epilepsy associated with tuberous sclerosis complex (TSC)

Day 30 discussion

Uro-nephrology / Neurology

4.

4. Nominations

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

4.1. List of letters of intent received for submission of applications with start of procedure April 2016 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

4.3.1. Nomination of PDCO members for 10 year report for creation of review group

Summary of committee discussion:

A review group for the 10 year report was created.

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.

Note: Products proposed for presentation / discussion during the PDCO plenary are flagged in the Annex A. The briefing packages for SAWP procedures are included in column 'S' of the table.

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. Relugolix - EMEA-52-2015

Takeda Development Centre Europe Ltd.; Classes of androgen receptor modulator, of oestrogen receptor modulator, of growth and sex hormone as well as their releasing or inhibiting factors, and of sex hormonemetabolism modulator medicinal products for treatment of breast malignant neoplasms,prostate malignant neoplasms and neuroendocrine malignant neoplasms/ Treatment of hormone-sensitive advanced prostate cancer

Summary of committee discussion:

The applicability of the class waiver as referred to in the Agency's Decision CW/0001/2015 to the planned therapeutic indication was confirmed.
Other potential paediatric interest of this medicine suggested by PDCO: non-oncological gynaecology conditions.

6.1.2. Brolucizumab - EMEA-53-2015

Alcon Laboratories (UK) Ltd; Treatment of age-related macular degeneration/ Treatment of neovascular (wet) age-related macular degeneration in adults

Summary of committee discussion:

The applicability of the class waiver as referred to in the Agency's Decision CW/1/2011 to the planned therapeutic indication was confirmed.
Other potential paediatric interest of this medicine suggested by PDCO: treatment of retinopathy of prematurity.

Note: in case of removal from the list of class waivers listed in the Agency's Decision CW/1/2011, the requirements set out in Article 7 and 8 of Regulation (EC) No 1901/2006 of the Agency's Decision CW/0001/2015 shall apply after 36 months from the date of the removal from the list of class waivers.

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. linagliptin (base) - EMEA-000498-PIP01-08

Boehringer Ingelheim International GmbH

Summary of committee discussion:

The PDCO was of the view that the proposed indication "treatment of type 2 diabetes mellitus to improve glycaemic control in adults as monotherapy or in combination therapy" falls under the

scope of the Decision, as the indication is considered to be covered by the condition “treatment of type 2 diabetes mellitus” listed in the Agency Decision.

7.1.2. linagliptin/metformin - EMEA-000699-PIP01-09

Boehringer Ingelheim International GmbH

Summary of committee discussion:

The PDCO was of the view that the proposed indication “treatment of type 2 diabetes mellitus as adjunct to diet and exercise or in combination therapy”, falls under the scope of the Decision, as the indication is considered to be covered by the condition “diabetes type 2” listed in the Agency Decision.

8. Annual reports on deferrals

8.1.1. Alogliptin benzoate - EMEA-000496-PIP01-08-M04

Takeda Global Research and Development Centre (Europe) Ltd.

Difficulties progressing the PIP? No

Summary of committee discussion:

The Committee noted the report.

8.1.2. clevidipine butyrate - EMEA-000282-PIP01-08-M02

The Medicines Company

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The Committee noted the report.

A modification of the agreed PIP will be necessary at a later stage.

8.1.3. Dextran, 3 [(2-aminoethyl)thio]propyl 17-carboxy-10,13,16-tris(carboxymethyl)-8-oxo-4-thia-7,10,13,16-tetraazaheptadec-1-yl 3-[[2-[[1-imino-2-(D-mannopyranosylthio)ethyl]amino]ethyl]thio]propyl ether - EMEA-001255-PIP01-11

Navidea Biopharmaceuticals Limited

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The Committee noted the report.

8.1.4. Lu AA21004 - EMEA-000455-PIP02-10-M03

H. Lundbeck A/S

Difficulties progressing the PIP? No

Summary of committee discussion:

The Committee noted the report.

8.1.5. Macitentan - EMEA-001032-PIP01-10-M01

Actelion Registration Ltd

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO was informed that the PIP was no longer feasible. However, a PIP modification procedure was already ongoing.

8.1.6. Mirabegron - EMEA-000597-PIP03-M01

Astellas Pharma Europe B.V.

Difficulties progressing the PIP? No

Summary of committee discussion:

The Committee noted the report.

8.1.7. Mirabegron - EMEA-000597-PIP02-10-M04

Astellas Pharma Europe B.V.

Difficulties progressing the PIP? No

Summary of committee discussion:

The Committee noted the report.

8.1.8. Nonacog alfa (recombinant coagulation factor IX) - EMEA-001139-PIP01-11-M01

BAXTER Innovations GmbH

Difficulties progressing the PIP? No

Summary of committee discussion:

The Committee noted the report.

8.1.9. raltegravir - EMEA-000279-PIP01-08-M04

Merck Sharp & Dohme (Europe), Inc.

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The Committee noted the report.

8.1.10. rilpivirine (as hydrochloride) / emtricitabine / tenofovir disoproxil (as fumarate) - EMEA-000774-PIP01-09-M02

Gilead Sciences International Limited

Difficulties progressing the PIP? No

Summary of committee discussion:

The Committee noted the report.

8.1.11. Solifenacin (succinate) - EMEA-000573-PIP02-13-M03

Astellas Pharma Europe B.V.

Difficulties progressing the PIP? No

Summary of committee discussion:

The Committee noted the report.

8.1.12. Ticagrelor - EMEA-000480-PIP01-08-M08

AstraZeneca AB

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report. A modification of the agreed PIP has already been concluded.

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. Deferrals in paediatric-only development

PDCO member: Karl-Heinz Huemer

Summary of committee discussion:

The PDCO members and the EMA secretariat discussed the regulatory aspects regarding deferrals of completion of PIP paediatric studies that are expected to be included in the assessment of the risk-benefit balance at the time of marketing authorisation, particularly in the context of a (possible) conditional marketing authorisation of a medicinal product.

9.1.2. Procedure of assignment of PDCO expert for centralised procedures of relevance (including Art. 46 procedures)

Summary of committee discussion:

The PDCO members confirmed their interest to be involved, as consulting experts, when requested by the CHMP Rapporteur in the context of CHMP P46 Procedures (submission of paediatric studies for authorised products, under Art. 46 of the Paediatric Regulation). The EMA Secretariat will manage the assignment of resources and the sharing of information as appropriate.

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 3 products, Iblias, Kovaltry and Vaxelis, for which the CHMP adopted positive opinions recommending paediatric indications during their meeting in December 2015.

9.2.2. Reflection paper on extrapolation of efficacy and safety in paediatric medicine development

Summary of committee discussion:

The draft reflection paper was presented to PDCO; comments are expected by end of February 2016 for an adoption at PDCO in March.

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

9.3.1. Non-clinical Working Group: D30 Products identified

PDCO member: Jacqueline Carleer

Summary of committee discussion:

Documents tabled for information.

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Summary of committee discussion:

Documents tabled for information.

9.4. Cooperation within the EU regulatory network

None

9.5. Cooperation with International Regulators

None

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

None

9.7. PDCO work plan

9.7.1. PDCO Work Plan 2016

Summary of committee discussion:

The PDCO adopted its Work Plan 2016 which will be published on the external EMA website.

9.8. Planning and reporting

9.8.1. Report on the 'Data Gathering Initiative'

Summary of committee discussion:

Postponed to PDCO February 2016 meeting.

9.9. PDCO ORGAM

9.9.1. PDCO ORGAM Agenda for 13 January 2016

Summary of committee discussion:

Document tabled for information.

9.9.2. PDCO ORGAM Minutes for 2 December 2015

Summary of committee discussion:

The PDCO noted the adopted minutes of the PDCO ORGAM December 2015 meeting.

10. Any other business

None.

11. Breakout sessions

11.1.1. Paediatric oncology

Summary of committee discussion:

The participants reflected on the recent public meetings on the status and progress for children with a malignant disease.

11.1.2. Neonatology

Summary of committee discussion:

The group met shortly in the margins of the meeting to discuss input on neonatal issues for external and internal activities.

11.1.3. Inventory

Summary of committee discussion:

The participants discussed the medicines proposed for the respiratory inventory.

11.1.4. Deferrals in paediatric-only development

Summary of committee discussion:

The PDCO members and the EMA secretariat discussed the regulatory aspects regarding deferrals of completion of PIP paediatric studies that are expected to be included in the assessment of the risk-benefit balance at the time of marketing authorisation, particularly in the context of a possible conditional marketing authorisation of a medicinal product.

Although clarification was provided for cases in the context of a possible conditional marketing authorisation of a medicinal product, some PDCO members highlighted the need for further clarification regarding deferrals of completion of PIP paediatric studies outside this context, for PIPs covering paediatric only development in a single population subset.

11.1.5. Ethics

Summary of committee discussion:

The participants prepared comments for a draft revised guidance.

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 27-29 January 2016 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	
Christoph Male	Alternate	Austria	No participation in final deliberations and voting	EMEA-001886-PIP 01-15 EMEA-001886-PIP 02-15 EMEA-001902-PIP 01-15 EMEA-001855-PIP 01-15 EMEA-001203-PIP 02-14-M01
Koenraad Norga	Member (Vice-Chair)	Belgium	To be replaced for discussions, final deliberations and voting when chairing the meeting	EMEA-001792-PIP 01-15 EMEA-001882-PIP 01-15 EMEA-001749-PIP 01-15
Jacqueline Carleer	Alternate	Belgium	No restrictions applicable to this meeting	
Dimitar Roussinov	Member	Bulgaria	No restrictions applicable to this meeting	
Suzana Mimica Matanovic	Alternate	Croatia	No participation in discussions, final deliberations and voting	EMEA-000308-PIP 02-11-M01 EMEA-001506-PIP 02-14-M01 EMEA-001414-PIP 01-12-M01 EMEA-C-000056-PIP01-07-M02
Jaroslav Sterba	Member	Czech Republic	No interests declared	
Marianne Orholm	Member	Denmark	No interests declared	
Marta Granström	Alternate	Denmark	No interests declared	
Jana Lass	Alternate	Estonia	No interests declared	
Maija Pihlajamaki	Alternate	Finland	No interests declared	
Sylvie Benchetrit	Member	France	No interests declared	
Immanuel Barth	Member	Germany	No interests declared	
Sabine Scherer	Alternate	Germany	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Grigorios Melas	Member	Greece	No interests declared	
Ágnes Gyurasics	Member (CHMP member)	Hungary	No interests declared	
Brian Aylward	Member	Ireland	No interests declared	
Francesca Rocchi	Alternate	Italy	No restrictions applicable to this meeting	
Dina Apele-Freimane	Member	Latvia	No interests declared	
Kristine Supe	Alternate	Latvia	No interests declared	
Carola de Beaufort	Member (CHMP alternate)	Luxembourg	No restrictions applicable to this meeting	
Herbert Lenicker	Alternate	Malta	No interests declared	
Hendrik van den Berg	Member	Netherlands	No interests declared	
Siri Wang	Member	Norway	No interests declared	
Marek Migdal	Member	Poland	No restrictions applicable to this meeting	
Jolanta Witkowska-Ozogowska	Alternate	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	
Stefan Grosek	Member	Slovenia	No interests declared	
Fernando de Andrés Trelles	Member	Spain	No interests declared	
Maria Jesús Fernández Cortizo	Alternate	Spain	No interests declared	
Ninna Gullberg	Member	Sweden	No interests declared	
Angeliki Siapkara	Member	United Kingdom	No interests declared	
Martina Riegl	Alternate	United Kingdom	No interests declared	
Riccardo Riccardi	Member	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Paolo Paolucci	Alternate	Healthcare Professionals' Representative	No interests declared	
Johannes Taminiau	Member	Healthcare Professionals' Representative	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Paola Baiardi	Alternate	Patients' Organisation Representative	No interests declared	
Tsvetana Schyns-Liharska	Member	Patients' Organisation Representative	No restrictions applicable to this meeting	
Kerry Leeson-Beevers	Alternate	Patients' Organisation Representative	No restrictions applicable to this meeting	
Eva Agurell	Expert - in person*	Sweden	No restrictions applicable to this meeting	
A representative from the European Commission attended the meeting				
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/