24 January 2017
EMA/PDCO/860428/2016
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Minutes for the meeting on 13-16 December 2016

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

13 December 2016, 14:00 - 17:00, room 3E

14 December 2016, 08:30 - 19:00, room 3E

15 December 2016, 08:30 - 19:00, room 3E

16 December 2016, 08:30 - 13:00, room 3E

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regard to intended therapeutic indications or procedure scopes listed against products, it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. Additional details on some of these procedures will be published in the PDCO Committee meeting reports (after the PDCO Opinion is adopted), and on the Opinions and decisions on paediatric investigation plans webpage (after the EMA Decision is issued).

Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Table of contents

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

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

Day 120 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The PDCO adopted a positive opinion for 2-hydroxypropyl-ß-cyclodextrin (HP-ß-CD) for all subsets of the paediatric population (0 to 18 years of age) in the condition of Treatment of Niemann-Pick disease, type C, agreeing on a PIP and a deferral.

2.1.2. A phosphorothioate oligonucleotide targeted to apolipoprotein C-III - Orphan - EMEA-001915-PIP01-15

Ionis Pharmaceuticals; Familial Chylomicronemia Syndrome

Day 120 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The PDCO re-discussed this product on 16 December 2016.
The Committee considered the answers provided after Day 90 and was pleased that the applicant agreed to start paediatric studies earlier than previously planned and agreed with other requests from the PDCO.
The Committee adopted a positive opinion at day 120.

2.1.3. pegvaliase - Orphan - EMEA-001951-PIP01-16

BioMarin International Limited; For the treatment of hyperphenylalaninaemia / For the treatment of hyperphenylalaninaemia in paediatric patients of all ages with phenylketonuria

Day 120 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The Paediatric Committee adopted a positive opinion on the agreement of a PIP and a deferral.

2.1.4. Autologous CD34+ cells transduced with lentiviral vector encoding the human beta-globin gene - Orphan - EMEA-001933-PIP01-16

Fondazione Telethon; Beta-thalassemia major and intermedia / Treatment of Beta thalassemia

Day 120 opinion

Haematology-Hemostaseology

Summary of committee discussion:

The Paediatric Committee adopted a positive opinion on a PIP and a waiver for Autologous CD34+ cells transduced with lentiviral vector encoding the human beta-globin gene, in the condition of Treatment of beta-thalassemia.

2.1.5. vadadustat - EMEA-001944-PIP01-16

Akebia Therapeutics, Inc.; Anaemia secondary to chronic kidney disease / Treatment of anaemia secondary to chronic kidney disease

Day 120 opinion

Haematology-Hemostaseology

Summary of committee discussion:

The PDCO re-discussed this product on 16 December 2016.
The Committee considered the answers provided after Day 90 and was pleased that the applicant agreed to start paediatric studies earlier than previously planned.
The Committee adopted a positive opinion at day 120.

2.1.6. abatacept - EMEA-000118-PIP03-15

Bristol-Myers Squibb Pharma EEIG; Treatment of childhood-onset SLE / Treatment of childhood-onset lupus nephritis caused by childhood-onset SLE with abatacept in combination with MMF or CY, and CS in pediatric patients 5 years of age and older who have had an insufficient response to MMF or CY, and CS.

Day 120 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

Following receipt of responses from the applicant addressing some additional points raised by the PDCO at D90 at their December 2016 meeting the PDCO adopted a positive opinion for abatacept EMEA-000118-PIP03-15 with the condition Treatment of systemic lupus erythematosus. The PIP includes a waiver and a deferral.

2.1.7. Ciprofloxacin Hydrochloride - EMEA-001563-PIP02-15

Aradigm Limited; Treatment of cystic fibrosis related bronchiectasis associated with P. aeruginosa infection, Treatment of non-cystic fibrosis related bronchiectasis associated with P. aeruginosa infection (NCFBEPA+)

Day 120 opinion

Infectious Diseases

Summary of committee discussion:

The PDCO's view expressed at day 90 was re-discussed and endorsed. The committee also discussed and supported the applicant's additional clarifications. Therefore, based on the assessment of this application, the PDCO adopted a positive opinion.

2.1.8. Anti-(human calcitonin gene-related peptide receptor) human monoclonal antibody - EMEA-001664-PIP02-15

Amgen Europe B.V.; Migraine headaches / Prophylaxis of migraine

Day 120 opinion

Neurology

Summary of committee discussion:

Following responses received by the applicant addressing some additional points raised by the PDCO at D90 the PDCO adopted a positive opinion for EMEA-001664-PIP02-15 for Anti-(human calcitonin gene-related peptide receptor) human monoclonal antibody (AMG 334) with a waiver and a deferral.

2.1.9. Esketamine (hydrochloride) - EMEA-001428-PIP03-15

Janssen-Cilag International NV; Major Depressive Disorder (MDD)

Day 120 opinion

Psychiatry

Summary of committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO endorses the modified PIP. A positive opinion has been adopted.

2.1.10. Fc- and CDR-modified humanized monoclonal antibody against C5 - Orphan - EMEA-001943-PIP01-16

Alexion Europe SAS; Atypical Haemolytic Uremic Syndrome / Treatment of atypical Haemolytic Uremic Syndrome

Day 120 opinion

Uro-nephrology / Haematology-Hemostaseology

Summary of committee discussion:

The PDCO adopted a positive opinion for Fc- and CDR-modified humanized monoclonal antibody against C5 on the agreement of a PIP and a deferral for all subsets of the paediatric population (0 to 18 years of age) in the condition of treatment of atypical Haemolytic Uremic Syndrome.

2.1.11. Varicella-zoster virus (inactivated) - EMEA-001073-PIP02-14

Merck Sharp & Dohme (Europe), Inc; Prevention of Varicella Zoster Virus disease / Prevention of HZ in immunocompromised patients from 1 to less than 18 years of age

Day 120 opinion

Vaccines

Summary of committee discussion:

The PDCO re-discussed the application for Varicella-zoster virus (VZV) inactivated vaccine taking into account the applicant's responses of the clarifications requested after D90 and the comments received by the applicant on the draft opinion.
In conclusion, the PDCO recommended the granting of a paediatric investigation plan for Varicella-zoster virus vaccine (inactivated), and a deferral for the condition 'prevention of Varicella Zoster Virus disease' including a waiver.

2.1.12. Apolipoprotein A-1 (ApoA-1) - EMEA-002040-PIP01-16

CSL Behring GmbH; Treatment of Acute Myocardial Infarction

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO agrees with the applicant's proposed condition of treatment of acute myocardial infarction. The PDCO recommends granting a waiver for Apolipoprotein A-1 (ApoA-1) in this condition.
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. There might be an interest in developing this product for the treatment of coronary artery disease/ coronary atherosclerosis, with a potential interest in children with rare disorders of lipid metabolism, such as homozygous familial hypercholesterolaemia.
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. Candesartan cilexetil / Amlodipine besylate / Hydrochlorothiazide - EMEA-002024-PIP01-16

Midas Pharma GmbH; Treatment of essential hypertension (ICD9: 401, ICD10: I10)

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

The PDCO's view expressed at day 30 was re-discussed and endorsed.
Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO agrees with the applicant's request for a waiver. The PDCO adopted a positive opinion granting a waiver for Candesartan cilexetil / Amlodipine besylate / Hydrochlorothiazide for all subsets of the paediatric population (0 to 18 years of age) in the condition of treatment of essential hypertension.

2.1.14. (2-Hydroxyethyl)trimethylammonium 3-[2-fluoro-5-(2,3-difluoro-6-methoxybenzyloxy)-4-methoxyphenyl]-2,4-dioxo-1,2,3,4-tetrahydrothieno[3,4-d]pyrimidine-5-carboxylate - EMEA-002039-PIP01-16

ObsEva Ireland Limited; Treatment of uterine leiomyoma (fibroids), Treatment of endometriosis / Treatment of uterine fibroids, Treatment of endometriosis

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

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 (2-Hydroxyethyl)trimethylammonium 3-[2-fluoro-5-(2,3-difluoro-6-methoxybenzyloxy)-4-methoxyphenyl]-2,4-dioxo-1,2,3,4-tetrahydrothieno[3,4-d]pyrimidine-5-carboxylate for all subsets of the paediatric population (0 to 18 years of age) in the condition of Treatment of uterine leiomyoma (fibroids), Treatment of endometriosis.

2.1.15. Doxorubicin hydrochloride - Orphan - EMEA-002043-PIP01-16

ONXEO; Treatment of hepatocellular carcinoma / Treatment of hepatocellular carcinoma

Day 60 opinion

Oncology

Summary of committee discussion:

EMEA-002043-PIP01-16 product-specific waiver requested for the treatment of hepatocelullar carcinoma. Clarifications requested to the applicant at D30 provided, full-waiver considered acceptable.

2.1.16. mirvetuximab soravtansine - Orphan - EMEA-001921-PIP01-16

ImmunoGen Europe Limited; For the treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours), For the treatment of peritoneal carcinoma, For the treatment of fallopian tube carcinoma (excluding rhabdomyosarcoma and germ cell tumours)

Day 60 opinion

Oncology

Summary of committee discussion:

EMEA-001921-PIP01-16 product-specific waiver requested for mirvetuximab soravtansine, a folate receptor alpha (FRα)-targeting antibody-drug conjugate, for the conditions 'treatment of ovarian carcinoma', 'Fallopian tube carcinoma' and 'Peritoneal carcinoma'. Clarifications requested to the applicant at D30 provided, full- waiver considered acceptable.

2.1.17. (1S, 3S, 4R)-4-[(3aS, 4R, 5S,7aS)-4-(aminomethyl)-7a-methyl-1-methylidene-octahydro-1H-inden-5-yl]-3-(hydroxymethyl)-4-methylcyclohexan-1-ol; acetic acid salt - EMEA-002062-PIP01-16

Aquinox Pharmaceuticals (Canada) Inc.; Interstitial Cystitis/Bladder Pain Syndrome

Day 60 opinion

Uro-nephrology

Summary of committee discussion:

The PDCO confirmed its position from day 30 and agreed with the applicant's waiver request for (1S, 3S, 4R)-4-[(3aS, 4R, 5S,7aS)-4-(aminomethyl)-7a-methyl-1-methylidene-octahydro-1H-inden-5-yl]-3-(hydroxymethyl)-4-methylcyclohexan-1-ol (acetic acid salt) for the treatment of interstitial 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 (1S, 3S, 4R)-4-[(3aS, 4R, 5S,7aS)-4-(aminomethyl)-7a-methyl-1-methylidene-octahydro-1H-inden-5-yl]-3-(hydroxymethyl)-4-methylcyclohexan-1-ol (acetic acid salt) for all subsets of the paediatric population (0 to 18 years of age) in the condition of interstitial cystitis.

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. Catridecacog - EMEA-C-000185-PIP01-08-M05

Novo Nordisk A/S; Treatment of congenital factor XIII A-subunit deficiency

Day 60 opinion

Haematology-Hemostaseology

Summary of committee discussion:

The PDCO took note of the preceding procedures and reports on partially completed compliance (EMEA-C1-000185-PIP01-08 and EMEA-C2-000185-PIP01-08-M05).
The PDCO adopted on 16 December 2016 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0001/2013) of 11/01/2013.

2.2.2. Fibrinogen (human plasma-derived) - EMEA-C-000457-PIP02-10-M02

LFB Biotechnologies; Treatment of congenital fibrinogen deficiency

Day 60 opinion

Haematology-Hemostaseology

Summary of committee discussion:

The PDCO took note of preceding procedures and reports on partially completed compliance (EMEA-C1-000457-PIP02-10-M02). The PDCO adopted on 16-Dec-2016 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0136/2014) of 11 June 2014.

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

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

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

Following the Day 30 discussion, the applicant has provided an updated report.
The PDCO took note of preceding procedures and reports on partially completed compliance

(EMEA-C1-001091-PIP02-15).
The PDCO adopted on 16 December 2016 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0294/2015) of 3 December 2015.

2.2.4. natalizumab - EMEA-C-001095-PIP02-12

Biogen Idec Ltd; Treatment of Multiple Sclerosis

Day 60 opinion

Neurology

Summary of committee discussion:

The completed studies were checked for compliance The PDCO adopted on 16 December 2016 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0252/2012) of 19 October 2012.

2.2.5. Dinutuximab - EMEA-C-001285-PIP01-12-M02

United Therapeutics Europe Limited; Treatment of Neuroblastoma

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO took note of the preceding procedure and report on partially completed compliance (EMEA-C1-001285-PIP01-12-M01).
The PDCO adopted on 16 December 2016 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0215/2016) of 12/08/2016.

2.2.6. zanamivir - EMEA-C1-001318-PIP01-12-M01

GlaxoSmithKline Trading Services Limited; Prevention of Influenza

Day 30 opinion

Infectious Diseases

Summary of committee discussion:

The PDCO discussed the completed study and considered that this is compliant with the latest Agency's Decision (P/0094/2015) of 08 May 2015.
The PDCO finalised on 16/12/2016 this partially completed compliance procedure and confirmed the compliance of all those studies contained in the agreed paediatric investigation plan that were to be completed until this date.

2.2.7. Blinatumomab - EMEA-C2-000574-PIP02-12-M01

Amgen Europe B.V.; Treatment of Acute Lymphoblastic Leukaemia

Day 30 opinion

Oncology

Summary of committee discussion:

The PDCO discussed the completed study(ies) and the initiated study(ies) and considered that these are compliant with the latest Agency's Decision (P/0014/2016) of 29 January 2016.
The PDCO finalised on 16 December 2016 this partially completed compliance procedure and confirmed the compliance of all those studies contained in the agreed paediatric investigation plan that were to be completed until this date.

2.2.8. Ivacaftor N-(2,4-di-tert-butyl-5-hydroxyphenyl)-4-oxo-1,4-dihydroquinoline-3-carboxamide / Lumacaftor 3 [6 ({[1 (2,2-difluoro 1,3-benzodioxol-5-yl)cyclopropyl]carbonyl}amino)-3 methylpyridin-2-yl]benzoic acid - EMEA-C3-001582-PIP01-13-M04

Vertex Pharmaceuticals (Europe) Limited; Treatment of cystic fibrosis

Day 30 opinion

Other

Summary of committee discussion:

The completed studies were checked for compliance.
Compliance with the following studies had been previously confirmed in the partial compliance procedures EMEA-C1-001582-PIP01-13 (compliance report EMA/604209/2014) and EMEA-C2-001582-PIP01-13 (compliance report EMA/515971/2016) :
In conclusion, the PDCO finalised on 16 December 2016 this partially completed compliance procedure and confirmed the compliance of all those studies contained in the agreed paediatric investigation plan that were to be completed until this date.

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. edoxaban tosilate - EMEA-000788-PIP02-11-M05

Daiichi Sankyo Europe GmbH; 82 Other venous embolism and thrombosis, I74 Arterial embolism and thrombosis, I80 Phlebitis and thrombophlebitis / Prevention of arterial thromboembolism in paediatric cardiac patients at risk of thrombotic events, Acute treatment & secondary prevention of symptomatic recurrent venous thrombotic events (VTE) in paediatric patients at risk

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that some of the proposed changes could be accepted. As discussed at Day 30, some modifications were deemed unacceptable.

The PDCO adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0302/2015 of 21 December 2015). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.2. Terbinafine hydrochloride - EMEA-001259-PIP02-13-M01

Polichem SA; Treatment of onychomycosis / Treatment of onychomycosis

Day 60 opinion

Dermatology

Summary of committee discussion:

The applicant provided the requested clarifications. The applicant confirmed that the changes proposed in this request for modification of the agreed PIP have already been implemented, before starting the trial. Based on the review of the rationale submitted by the applicant 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/0144/2013 of 3 July 2013). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.3. Idursulfase - EMEA-000294-PIP02-12-M01

Shire Human Genetic Therapies AB; ICD10 E76.1: / Treatment of Mucopolysaccharidosis II (Hunter Syndrome)

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant 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/0194/2013 of 29 August 2013).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.4. Potassium chloride / Sodium chloride / Citric acid (as citric acid anhydrous) / Sodium citrate / Simeticone / Sodium sulfate (as sodium sulfate anhydrous) / Macrogol 4000 - EMEA-001356-PIP02-12-M01

Alfa Wassermann S.p.A.; bowel cleansing prior to clinical procedures

Day 60 opinion

Gastroenterology-Hepatology

Summary of committee discussion:

The PDCO confirmed the outcome of the Day 30 discussion
Based on the review of the rationale submitted by the applicant 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/0051/2014 of 07 March 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.5. Eltrombopag - EMEA-000170-PIP03-13-M02

Novartis Europharm Limited; Bone Marrow Depression and Hypoplastic Anaemia / Treatment of cytopenias in paediatric patients with severe aplastic anaemia who are no receiving hematopoietic stem cell transplant

Day 60 opinion

Haematology-Hemostaseology

Summary of committee discussion:

The PDCO finalised on 14 December 2016 the discussion of the request for modification for eltrombopag for treatment of children with severe aplastic anaemia (SAA), taking into account the supplementary information provided by the applicant.
Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision. The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.6. Methoxy polyethylene glycol- epoetin beta - EMEA-000172-PIP01-07-M02

Roche Registration Limited; Anaemia associated with chronic kidney disease

Day 60 opinion

Haematology-Hemostaseology

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes 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; the key elements of the plan remain unchanged.

2.3.7. belatacept - EMEA-000157-PIP01-07-M03

Bristol-Myers Squibb Pharma EEIG; Prevention of rejection of transplanted kidney / in combination with corticosteroids and a mycophenolic acid (MPA), is indicated for prophylaxis of graft rejection in pediatric patients at least 12 years of age and with a stable renal transplant for at least 6 months, who convert to a CNI-free maintenance immunosuppressive regimen.

Day 60 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant 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/0080/2015 of 10/04/2015).

2.3.8. 4-amino-1-[5-chloro-2,5-dideoxy-2-fluoro-3-O-(2-methylpropanoyl)-4-[[(2-methylpropanoyl)oxy]methyl]-a-L-lyxofuranosyl]-2(1H)-pyrimidinone - EMEA-001758-PIP01-15-M01

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

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

In conclusion, based on the review of the rationale submitted by the applicant 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/0081/2016 of 18 March 2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.9. bedaquiline (fumarate) - Orphan - EMEA-000912-PIP01-10-M03

Janssen-Cilag International NV; Treatment of multi-drug resistant tuberculosis / Treatment of multi-drug resistant tuberculosis

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant 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/0065/2015 of 01 April 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.10. elbasvir / grazoprevir - EMEA-001604-PIP01-13-M02

Merck Sharp & Dohme (Europe), Inc.; treatment of chronic Hepatitis C infection / Treatment of chronic hepatitis C genotype 1, 4, and 6 infection with the combination regimen 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

Peg-Interferon/Interferon therapy with ribavirin with or without cirrhosis

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

Following the Day 30 discussion the applicant has revised their proposal.
Therefore, based on the review of the rationale submitted by the applicant 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/0314/2015 of 21 December 2015).
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-M01

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

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant 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/0030/2016 of 11/12/2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.12. Tenofovir Alafenamide / Emtricitabine - EMEA-001577-PIP02-14-M01

Gilead Sciences International Ltd.; Treatment of human immunodeficiency virus (HIV-1) infection / indicated for the treatment of HIV-1 infection

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

The applicant has provided satisfactory clarifications for the issues raised at Day 30.
Thus, based on the review of the rationale submitted by the applicant 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/0032/2015 of 16 February 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.13. Nanobody directed towards the fusion protein of human respiratory syncytial virus - EMEA-001553-PIP01-13-M01

Ablynx NV; Lower respiratory tract disease caused by RSV / Treatment of RSV lower respiratory tract infection

Day 60 opinion

Neonatology - Paediatric Intensive Care

Summary of committee discussion:

Overall, the applicant has provided satisfactory additional clarifications or justifications on the points highlighted in the draft opinion.
In conclusion, based on the review of the rationale submitted by the applicant 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/0246/2014 of 29 September 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.14. Bumetanide - EMEA-001303-PIP01-12-M01

Neurochlore; Autism Spectrum Disorder / Treatment of AutiSm Spectrum Disorder

Day 60 opinion

Neurology

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes 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; the key elements of the plan remain unchanged.

2.3.15. Humanized anti-IL-6 receptor (IL-6R) monoclonal antibody - Orphan - EMEA-001625-PIP01-14-M01

CHUGAI PHARMA EUROPE LTD.; neuromyelitis optica

Day 60 opinion

Neurology

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that most of 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/0154/2015 of 10 July 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.16. Ocrelizumab - EMEA-000310-PIP03-10-M02

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

Day 60 opinion

Neurology

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant 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/0143/2014 of 13 June 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.17. Idelalisib - EMEA-001350-PIP02-13-M03

Gilead Sciences International Ltd; Treatment of mature B-cell neoplasm / Treatment of children from 1 year to less than 18 years of age with a relapsed or refractory diffuse large B-cell lymphoma (DLBCL) or mediastinal B-cell lymphoma (MBCL)

Day 60 opinion

Oncology

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant 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.

2.3.18. ipilimumab - EMEA-000117-PIP02-10-M07

Bristol-Myers Squibb Pharma EEIG; Treatment of melanoma / Treatment of pre-treated and naive patients with advanced metastatic melanoma

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO discussed on 14 December 2016 the modification requested for the second PIP for ipilimumab, targeting to extend an indication for treatment of melanoma to the paediatric population. The Committee took into account comments by the applicant on a draft Opinion.
Based on the review of the rationale submitted by the applicant 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.

2.3.19. midostaurin - Orphan - EMEA-000780-PIP01-09-M03

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, A waiver is in place for this condition.

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO re-discussed the requested modification in view of the responses provided by the applicant after the D30 discussion.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0039/2016 of 19 February 2016).

2.3.20. nivolumab - EMEA-001407-PIP02-15-M01

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 relapsed or refractory Hodgkin lymphoma in the age group from 5 years to < 18 years., Treatment of paediatric patients with a relapsed or refractory non-Hodgkin lymphoma in the age group from 6 months to less than 18 years old., Treatment of paediatric patients from 6 months to less than 18 years of age with a recurrent or progressive high-grade glioma.

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO discussed on 15 December 2016 the request to modify the agreed PIP , taking into account the supplementary information provided by the applicant largely addressing the issues flagged in the day 30 summary as well as comments on drafts of the Opinion. Based on the review of the rationale submitted by the applicant 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.

2.3.21. paclitaxel - EMEA-001308-PIP01-12-M01

Celgene Europe Limited; Treatment of Solid malignant tumours / Treatment of a paediatric solid malignant tumour

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO discussed on 14 December 2016 the request to modify the PIP agreed for paclitaxel, taking into account the supplementary information provided. The Committee agreed to all requested changes.
Based on the review of the rationale submitted by the applicant 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.

2.3.22. ranibizumab - EMEA-000527-PIP04-13-M01

Novartis Europharm Limited; retinopathy of prematurity / Treatment of patients with retinopathy of prematurity

Day 60 opinion

Ophthalmology

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant 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.

2.3.23. Patiromer sorbitex calcium - EMEA-001720-PIP01-14-M01

Vifor Fresenius Medical Care Renal Pharma France; Hyperkalaemia

Day 60 opinion

Other

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant 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/0235/2015 of).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.24. CONCENTRATE OF PROTEOLYTIC ENZYMES ENRICHED IN BROMELAIN - Orphan - EMEA-000142-PIP02-09-M05

MediWound Germany GmbH; Treatment of burns of external body surfaces / Removal of eschar in deep partial and/or full thickness burns

Day 60 opinion

Other / Dermatology

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant 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/0072/2014 of 1 April 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.25. budesonide - EMEA-001087-PIP02-12-M03

Vectura Limited; Treatment of asthma

Day 60 opinion

Pneumology - Allergology

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/0212/2016 of 12 August 2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.26. Dupilumab - EMEA-001501-PIP02-13-M02

sanofi-aventis recherche & développement; Asthma

Day 60 opinion

Pneumology - Allergology

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0160/2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.27. Formoterol fumarate dihydrate / Beclometasone dipropionate - EMEA-000548-PIP01-09-M06

Chiesi Farmaceutici S.p.A.; COPD, Asthma / Maintenance therapy of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate: - patients not adequately controlled with inhaled corticosteroids and 'as needed' inhaled short-acting beta2-agonist or - patients already adequately controlled on both inhaled corticosteroids and long-acting beta2-agonists.

Day 60 opinion

Pneumology - Allergology

Summary of committee discussion:

After the Day 30 discussion of the PDCO, the applicant provided further justifications. Other requested modifications were accepted. Based on the review of the rationale submitted by

the applicant 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/0291/2013 of 29 November 2013). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.28. Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily B; Escherichia coli) / Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily A; Escherichia coli) - EMEA-001037-PIP02-11-M04

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

Day 60 opinion

Vaccines

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, including the applicant's additional justifications, 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/0304/2015 of 21/12/2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.4. Opinions on Re-examinations

2.4.1. methoxyflurane - EMEA-000334-PIP01-08-M05

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

Pain

Summary of committee discussion:

The PDCO re-discussed the application including the comments from the Coordinator and the new Rapporteur and Peer Reviewer.

The PDCO recommends that the applicant elaborates a robust solution before initiating the study and submits it for approval in a subsequent modification procedure, for full certainty.

The opinion has therefore been revised accordingly.

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. Gadolinium - EMEA-001949-PIP01-16

Detection and visualisation for areas with disruption of blodd brain barrier and/or abnormal vascularity for diagnostic purposes

Day 90 discussion

Diagnostic

3.1.2. Recombinant human alpha-glucosidase conjugated with multiple copies of synthetic bismannose-6-phosphate-tetra-mannose glycan - Orphan - EMEA-001945-PIP01-16

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

Day 90 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.3. Somapacitan - EMEA-001469-PIP01-13

Growth Hormone Deficiency

Day 90 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.4. Testosterone - EMEA-001529-PIP02-14

Male hypogonadism

Day 90 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.5. Autologous CD34+ hematopoietic stem cells transduced ex vivo with EFS lentiviral vector encoding for the human ADA gene - Orphan - EMEA-001974-PIP01-16

Pr Bobby Gaspar; Severe combined immunodeficiency disorder due to adenosine deaminase deficiency [ADA-SCID] / Treatment of severe combined immunodeficiency disorder due to adenosine deaminase deficiency [ADA-SCID]

Day 90 discussion

Immunology-Rheumatology-Transplantation

3.1.6. Filgotinib - EMEA-001619-PIP02-15

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis, and juvenile idiopathic arthritis) / Treatment of juvenile idiopathic arthritis

Day 90 discussion

Immunology-Rheumatology-Transplantation

3.1.7. T-lymphocytes enriched leukocyte preparation depleted ex vivo of host host-alloreactive T cells using photodynamic treatment - Orphan - EMEA-001980-PIP01-16

Kiadis Pharma Netherlands B.V.; Adjunctive treatment in haematopoietic stem cell transplantation for a malignant disease / Adjunctive treatment to a haploidentical haematopoietic stem cell transplantation with CD34+ selected cells, in patients with a haematological malignancy, for the reduction of morbidity (i.e. incidences and severity of graft versus host disease) and mortality due to infection and relapse.

Day 90 discussion

Immunology-Rheumatology-Transplantation / Oncology

3.1.8. Lamivudine (3TC) / Dolutegravir (DTG) - EMEA-001940-PIP01-16

Treatment of human immunodeficiency virus (HIV-1) infection / Treatment of human immunodeficiency virus (HIV-1) infection

Day 90 discussion

Infectious Diseases

3.1.9. EMEA-001918-PIP01-15

ICD10 F84: Treatment of autism spectrum disorder

Day 90 discussion

Neurology

3.1.10. avelumab (recombinant human monoclonal IgG1 antibody directed against Programmed Death Ligand-1 (anti-PD-L1) - Orphan - EMEA-001849-PIP02-15

Merck KGaA; Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours, haematopoietic and lymphoid tissue neoplasms)

Day 90 discussion

Oncology

3.1.11. tadalafil / ambrisentan - EMEA-002030-PIP01-16 - adopted at day 60

Glaxo Group Limited; Pulmonary Arterial Hypertension

Day 60 adoption

Cardiovascular Diseases

Summary of committee discussion:

Based on the assessment of this application, the discussion at D30 and further discussions

at the Paediatric Committee the PDCO agrees recommends granting a waiver for tadalafil / ambrisentan for all subsets of the paediatric population (0 to 18 years of age) in the condition of Pulmonary Arterial Hypertension.
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.

3.1.12. Ligelizumab - EMEA-001811-PIP02-15

Treatment of chronic spontaneous urticaria / Treatment of chronic spontaneous urticaria

Day 60 discussion

Dermatology

3.1.13. Empagliflozin - EMEA-000828-PIP04-16

Treatment of type 1 diabetes mellitus

Day 60 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.14. Synthetic double-stranded siRNA oligonucleotide directed against hydroxyacid oxidase 1 mRNA that is covalently linked to a ligand containing three N-acetylgalactosamine residues - Orphan - EMEA-002079-PIP01-16

Alnylam UK Limited; Treatment of Primary Hyperoxaluria Type 1 / Treatment of Primary Hyperoxaluria Type 1

Day 60 discussion

Gastroenterology-Hepatology

3.1.15. Plasminogen (human) - Orphan - EMEA-002044-PIP01-16

ProMetic BioTherapeutics Ltd; Plasminogen deficiency

Day 60 discussion

Haematology-Hemostaseology

3.1.16. anifrolumab - EMEA-001435-PIP02-16

Lupus nephritis, Systemic lupus erythematosis

Day 60 discussion

Immunology-Rheumatology-Transplantation

3.1.17. EMEA-001989-PIP01-16

Staphylococcal skin infection / Treatment of acute bacterial skin and skin structure

infections (ABSSSI) due to staphylococcus sensitive or resistant to meticillin

Day 60 discussion

Infectious Diseases

3.1.18. (human immunoglobulin G1 monoclonal antibody directed against a unique, functionally conserved epitope on the influenza A haemagglutinin protein) - EMEA-001924-PIP01-15

Influenza A (ICD10 code: J09) / Treatment of influenza A

Day 60 discussion

Infectious Diseases

3.1.19. Polihexanide (PHMB) - Orphan - EMEA-002053-PIP01-16

Società Industria Farmaceutica Italiana (S.I.F.I.) SpA; ICD10: B.60.1 Keratitis and keratoconjunctivitis (interstitial) in acanthamoebiasis

Day 60 discussion

Ophthalmology

3.1.20. Vosoritide - Orphan - EMEA-002033-PIP01-16

BioMarin International Limited; Treatment of achondroplasia / Treatment of achondroplasia

Day 60 discussion

Other

3.1.21. Formoterol Fumarate / Glycopyrronium Bromide / Budesonide - EMEA-002063-PIP01-16

Asthma / For the regular treatment of asthma in children 6 to 11 years of age where use of a triple combination medicinal product (ICS, LAMA and LABA) is appropriate: • patients not adequately controlled with ICS and another controller such as a LABA or LAMA

Day 60 discussion

Pneumology - Allergology

3.1.22. Ezetimibe / Atorvastatin Calcium trihydrate - EMEA-002047-PIP01-16

Dyslipidaemia

Day 30 discussion

Cardiovascular Diseases

3.1.23. Crisaborole - EMEA-002065-PIP01-16

Mild to moderate atopic dermatitis

Day 30 discussion

Dermatology

3.1.24. lebrikizumab - EMEA-001053-PIP03-16

Treatment of atopic dermatitis

Day 30 discussion

Dermatology

3.1.25. (2S)-2-{[(2R)-2-[({[3,3-dibutyl-7-(methylthio)-1,1-dioxido-5-phenyl-2,3,4,5-tetrahydro-1,2,5-benzothiadiazepin-8-l]oxy}acetyl)amino]-2-(4-hydroxyphenyl)acetyl]amino}butanoic acid - Orphan - EMEA-002054-PIP01-16

Albireo AB; Treatment of Progressive Familial Intrahepatic Cholestasis

Day 30 discussion

Gastroenterology-Hepatology

3.1.26. EMEA-001868-PIP02-16

K70.1 Alcoholic hepatitis

Day 30 discussion

Gastroenterology-Hepatology

3.1.27. Fc- and CDR-modified humanised monoclonal antibody against C5 - Orphan - EMEA-002077-PIP01-16

Alexion Europe SAS; Paroxysmal Nocturnal Haemoglobinuria / Treatment of Paroxysmal Nocturnal Haemoglobinuria

Day 30 discussion

Haematology-Hemostaseology

3.1.28. EMEA-001741-PIP03-16

Treatment of Crohn's Disease

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.1.29. riociguat - Orphan - EMEA-000718-PIP02-16

Bayer Pharma AG; M34.9 Treatment of Systemic Sclerosis / Treatment of Diffuse Cutaneous Systemic Sclerosis (dcSSc)

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.1.30. EMEA-002057-PIP01-16

Post ischemic stroke recovery / Treatment of ischemic stroke to improve recovery

Day 30 discussion

Neurology

3.1.31. Deutetrabenazine - EMEA-002052-PIP01-16

Treatment of tics associated with Tourette syndrome

Day 30 discussion

Neurology

3.1.32. Recombinant human arylsulfatase A (rhASA) - Orphan - EMEA-002050-PIP01-16

Shire Pharmaceuticals Ireland Limited; Treatment of metachromatic leukodystrophy (MLD) / Treatment of metachromatic leukodystrophy (MLD)

Day 30 discussion

Neurology

3.1.33. (S)-N-(5-((R)-2-(2,5-difluorophenyl)pyrrolidin-1-yl)pyrazolo[1,5-a]pyrimidin-3-yl)-3-hydroxypyrrolidine-1-carboxamide hydrogen sulfate - Orphan - EMEA-001971-PIP02-16

Loxo Oncology, Inc.; Treatment of solid tumours / The treatment of adults, adolescents and children (> 1 month of age) with advanced solid tumours harbouring an NTRK fusion, as established prior to initiation of therapy.

Day 30 discussion

Oncology

3.1.34. Allogeneic Epstein-Barr virus specific cytotoxic T lymphocytes - Orphan - EMEA-002025-PIP02-16

Atara Biotherapeutics, Inc.; Treatment of Epstein-Barr virus associated post-transplant lymphoproliferative disorder / Treatment of allogeneic haematopoietic cell transplant (alloHCT) patients with Epstein-Barr virus associated Post Transplant Lymphoproliferative Disease (EBV-PTLD) who have failed prior therapy with rituximab

Day 30 discussion

Oncology

3.1.35. alpelisib - EMEA-002016-PIP02-16

Treatment of breast cancer

Day 30 discussion

Oncology

3.1.36. EMEA-002003-PIP02-16

Treatment of chronic lymphocytic leukaemia

Day 30 discussion

Oncology

3.1.37. gilteritinib (as fumarate) - EMEA-002064-PIP01-16

Treatment of acute myeloid leukemia / Treatment of FLT3/ITD positive acute myeloid leukemia

Day 30 discussion

Oncology / Haematology-Hemostaseology

3.1.38. Venetoclax - Orphan - EMEA-002018-PIP02-16

AbbVie Ltd; Treatment of haematopoietic and lymphoid malignant neoplasms, Treatment of solid tumour malignant neoplasms / As monotherapy, or in combination with chemotherapy, for the treatment of relapsed or refractory NHL patients < 18 years of age, who have progressed following autologous stem cell transplantation or who are ineligible for transplantation, As monotherapy or in combination for the treatment of patients with relapsed or refractory neuroblastoma < 18 years of age, As monotherapy, or in combination with chemotherapy, for the treatment of relapsed or refractory ALL in the third line setting in patients < 18 years of age, As monotherapy, or in combination with chemotherapy, for the treatment of relapsed or refractory AML in patients < 18 years of age

Day 30 discussion

Oncology / Haematology-Hemostaseology

3.1.39. Fluocinolone Acetonide - Orphan - EMEA-000801-PIP03-16

CAMPHARM Limited; Chronic non-infectious uveitis affecting the posterior segment of the eye

Day 30 discussion

Ophthalmology

3.1.40. EMEA-002082-PIP01-16

Treatment of cystic fibrosis / indicated to improve lung function and reduce pulmonary exacerbations for patients in all age groups with cystic fibrosis in conjunction with standard therapies.

Day 30 discussion

Pneumology - Allergology

3.1.41. Nintedanib - Orphan - EMEA-001006-PIP04-16

Boehringer Ingelheim International GmbH; Treatment of Progressive Fibrosing Interstitial

Lung Disease (PF-ILD)

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. rivaroxaban - EMEA-C3-000430-PIP01-08-M09

Bayer Pharma AG; Treatment of thromboembolic events

Day 30 discussion

Cardiovascular Diseases

3.2.2. Cobicistat / elvitegravir / tenofovir disoproxil / emtricitabine - EMEA-C-000970-PIP01-10-M01 – adopted at D30

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

Day 30 discussion

Infectious Diseases

Summary of committee discussion:

The PDCO adopted on 16 December 2016 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0309/2016) of 4 November 2016.

3.2.3. Melatonin - EMEA-C-000440-PIP02-11-M04

RAD Neurim Pharmaceuticals EEC Ltd; Treatment of insomnia

Day 30 discussion

Neurology

3.2.4. Human recombinant IgGI monoclonal antibody targeting fibroblast growth factor 23 (FGF23) - EMEA-C1-001659-PIP01-15-M01 – adopted at Day 30

Ultragenyx Pharmacetical Inc.; X-linked Hypophosphatemia

Day 30 opinion

Other

Summary of committee discussion:

The PDCO discussed the ongoing study and considered that it is compliant with the latest Agency's Decision (P/0265/2016) of 05 October 2016.
The PDCO finalised on the 16th of December 2016 this partially completed compliance

procedure and confirmed the compliance of all those studies contained in the agreed paediatric investigation plan that were to be completed until this date.

3.2.5. Solifenacin (succinate) - EMEA-C-000573-PIP02-13-M03 – adopted at D30

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

Day 30 discussion

Uro-nephrology

Summary of committee discussion:

The PDCO took note of preceding procedures and reports on partially completed compliance EMEA-C1-000573-PIP02-13-M02.
The PDCO adopted on 16 December 2016 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0115/2015) of 05 June 2015.

3.2.6. Pneumococcal polysaccharide serotype 6B conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 23F conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 1 conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 18C conjugated to tetanus toxoid / Pneumococcal polysaccharide serotype 19F conjugated to diphtheria toxoid / Pneumococcal polysaccharide serotype 7F conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 9V conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 14 conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 4 conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 5 conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein - EMEA-C-000673-PIP01-09-M09

GlaxoSmithKline Biologicals S.A.; Prevention of acute otitis media caused by non-typeable Haemophilus influenzae

Day 30 discussion

Vaccines

3.2.7. Purified Pertussis Toxoid (PT) / Hepatitis B Surface Antigen, recombinant (HBsAg) / Purified Filamentous Haemagglutinin (FHA) / Inactivated Type 2 Poliovirus (MEF-1) / Haemophilus influenzae type b polysaccharide conjugated to tetanus protein / Inactivated Type 3 Poliovirus (Saukett) / Purified Diphtheria Toxoid / Inactivated Type 1 Poliovirus (Mahoney) / Purified Tetanus Toxoid - EMEA-C-001201-PIP01-11-M02

Sanofi Pasteur; Prevention of infections caused by Corynebacterium diphtheriae, Clostridium tetani, Bordetella pertussis, poliovirus types 1, 2 and 3, prevention against invasive infections caused by Haemophilus influenzae type b and infection caused by hepatitis B virus

Day 30 adoption

Vaccines

Summary of committee discussion:

The PDCO discussed the compliance request on 15 December 2016.
PDCO concluded that all studies could be considered compliant.

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Vericiguat - EMEA-001636-PIP01-14-M01

Bayer Pharma AG; Treatment of left ventricular failure / Treatment of chronic left ventricular failure with reduced ejection fraction in paediatric patients with dilated cardiomyopathies

Day 30 discussion

Cardiovascular Diseases

3.3.2. dupilumab - EMEA-001501-PIP01-13-M04

Regeneron Pharmaceuticals, Inc; Atopic Dermatitis / Atopic Dermatitis

Day 30 discussion

Dermatology

3.3.3. tofacitinib - EMEA-000576-PIP02-11-M04

Pfizer Limited; Treatment of psoriasis / Treatment of severe plaque psoriasis

Day 30 discussion

Dermatology

3.3.4. saxagliptin - EMEA-000200-PIP01-08-M07

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

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. Tofacitinib - EMEA-000576-PIP01-09-M06

Pfizer Limited; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis) / Juvenile idiopathic arthritis

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.3.6. Treosulfan - Orphan - EMEA-000883-PIP01-10-M03

medac Gesellschaft für klinische Spezialpräparate mbH; Conditioning treatment prior to haematopoietic progenitor cell transplantation / Conditioning treatment prior to haematopoietic progenitor cell transplantation

Day 30 discussion

Immunology-Rheumatology-Transplantation / Oncology

3.3.7. Anidulafungin - EMEA-000469-PIP01-08-M07

Pfizer Limited; Treatment of invasive candidiasis

Day 30 discussion

Infectious Diseases

3.3.8. avibactam / ceftazidime - EMEA-001313-PIP01-12-M05

AstraZeneca AB; Treatment of bacterial infections / For the treatment of complicated urinary tract infections, For the treatment hospital acquired pneumonia, For the treatment of complicated intra-abdominal infections, For the treatment of Gram-negative bacterial infections

Day 30 discussion

Infectious Diseases

3.3.9. Cobicistat - EMEA-000969-PIP01-10-M04

Gilead Sciences International Ltd.; Treatment of human immunodeficiency virus type-1 (HIV-1) infection. / Treatment of human immunodeficiency virus type-1 (HIV-1) infection - pharmacoenhancer for use in combination with antiretroviral agents.

Day 30 discussion

Infectious Diseases

3.3.10. dasabuvir sodium monohydrate - EMEA-001439-PIP01-13-M01

Abbvie Ltd; Treatment of chronic hepatitis C / Treatment of children and adolescents from >= 3 years to less than 18 years of age with chronic HCV infection with compensated cirrhosis or without compensated cirrhosis in combination with ombitasvir, paritaprevir and ritonavir

Day 30 discussion

Infectious Diseases

3.3.11. Fidaxomicin - EMEA-000636-PIP01-09-M05

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

3.3.12. ledipasvir / sofosbuvir - EMEA-001411-PIP01-12-M04

Gilead Sciences International Ltd.; Treatment of chronic hepatitis C / Treatment of chronic hepatitis C

Day 30 discussion

Infectious Diseases

3.3.13. ritonavir / paritaprevir / ombitasvir - EMEA-001440-PIP01-13-M01

Abbvie Ltd; Treatment of chronic hepatitis C / Treatment of children and adolescents from >= 3 years to < 18 years of age with chronic HCV infection with compensated cirrhosis or without compensated cirrhosis in combination with other medicinal products

Day 30 discussion

Infectious Diseases

3.3.14. tazobactam / ceftolozane - EMEA-001142-PIP01-11-M02

Merck Sharp & Dohme (Europe), Inc.; treatment of abdominal and gastrointestinal infections, treatment of urinary tract infections / Treatment of complicated urinary tract infections (cUTI), Treatment of complicated intra-abdominal infections (cIAI)

Day 30 discussion

Infectious Diseases

3.3.15. Brivaracetam - Orphan - EMEA-000332-PIP01-08-M11

UCB Pharma S.A.; treatment of paediatric epilepsy syndromes, Treatment of epilepsy with partial onset seizures, Treatment of neonatal seizures / Treatment of neonatal seizures with adjunctive administration of brivaracetam, Treatment of paediatric patients with partial onset seizures, treatment of refractory paediatric epilepsy syndromes with adjunctive administration of brivaracetam

Day 30 discussion

Neurology

3.3.16. Fingolimod hydrochloride - EMEA-000087-PIP01-07-M05

Novartis Europharm Limited; Multiple Sclerosis / Multiple Sclerosis

Day 30 discussion

Neurology

3.3.17. lacosamide - EMEA-000402-PIP02-11-M03

UCB Pharma S.A.; Treatment of Epilepsy - Partial-onset seizures [G40.0 - G40.1 - G40.2], 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 partial-onset seizures with or without secondary generalization in pediatric patients with epilepsy (birth to <16 years), Monotherapy in the treatment of partial-onset seizures with or without secondary generalization in pediatric patients (1 month to <18 years), Adjunctive therapy in the treatment of primary generalized tonic-clonic seizures (PGTCS) in pediatric patients with idiopathic generalized epilepsy (IGE)(4 years to <18 years), Adjunctive therapy in the treatment of epileptic syndromes associated with generalized seizures in pediatric patients with epilepsy birth to <18 years (specific epileptic syndrome(s) to be based on future clinical development further to exploratory study results)

Day 30 discussion

Neurology

3.3.18. cobimetinib - EMEA-001425-PIP01-13-M02

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

Day 30 discussion

Oncology

3.3.19. Sirolimus - Orphan - EMEA-001416-PIP01-12-M01

Santen Incorporated; Treatment of chronic non-infectious uveitis

Day 30 discussion

Ophthalmology

3.3.20. tafluprost - EMEA-001187-PIP01-11-M04

Santen Oy; Glaucoma (ICD: H40) / Tafluprost preservative-free is indicated for the treatment of elevated intraocular pressure in paediatric patients 1 month post-natal to less than 18 years of age.

Day 30 discussion

Ophthalmology

3.3.21. conestat alfa - EMEA-000367-PIP01-08-M06

Pharming Group N.V.; D84.1 Defects in the complement system C1 esterase inhibitor (C1-INH) deficiency / treatment of acute attacks of angioedema associated with hereditary

C1 esterase inhibitor deficiency

Day 30 discussion

Other

3.3.22. mepolizumab - Orphan - EMEA-000069-PIP02-10-M07

GSK Trading Services Limited; treatment of asthma / add-on treatment for severe refractory eosinophilic asthma

Day 30 discussion

Pneumology - Allergology

3.3.23. mirabegron - EMEA-000597-PIP03-15-M03

Astellas Pharma Europe B.V.; Treatment of neurogenic detrusor overactivity / Treatment of detrusor overactivity in children and adolescents with neurogenic bladder dysfunction

Day 30 discussion

Uro-nephrology

3.3.24. Influenza virus surface antigens - A/turkey/Turkey/1/05 (H5N1)-like strain (NIBRG-23) - EMEA-000599-PIP01-09-M05

Seqirus S.r.l.; Prevention of influenza / Active immunization against H5N1 subtype of Influenza A virus

Day 30 discussion

Vaccines

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 21 February 2017 for Nomination of Rapporteur and Peer reviewer

Summary of committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

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

Summary of committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

4.3. Nominations for other activities

Summary of committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

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

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

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. EMEA-33-2016

Sanofi-aventis groupe; Treatment of primary and secondary osteoarthrosis/ Improvement in pain and function in patients with moderate to severe pain due to osteoarthritis of the knee who have failed to respond adequately to conservative non-pharmacologic therapy or simple analgesics (e.g. acetaminophen)

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 not confirmed since the mechanism of action of the medicinal product is not directly targeting osteoarthrosis, but the pain associated with osteoarthrosis.

Other potential paediatric interests of this medicine suggested by PDCO: painful joint conditions such as post-traumatic or osteochondritis dissecans lesions, oligoarthritis in juvenile idiopathic arthritis, bone cancer pain.

6.1.2. (nanoparticle-drug conjugate (NDC) composed of 20(S)-camptothecin conjugated to a linear, cyclodextrin polyethylene glycol-based copolymer) - EMEA-34-2016, EMEA-35-2016, EMEA-36-2016

Viadoc Business Solutions Limited; Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumors)- Treatment of Fallopian tube carcinoma (excluding rhabdomyosarcoma and germ cell tumors)- Treatment of peritoneal carcinoma (excluding blastomas and sarcomas)/ Treatment of patients with platinum-resistant ovarian carcinoma, fallopian tube carcinoma or primary peritoneal cancer.

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

advanced paediatric solid tumours (e.g. neuroblastoma, rhabdomyosarcoma).

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.

6.1.3. Beta-site-APP-Cleaving Enzyme inhibitor - EMEA-37-2016

Novartis Europharm Limited; Treatment of Alzheimer's Disease/ Treatment of Alzheimer's Disease

Summary of Committee discussion:

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

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

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. Alirocumab - EMEA-001169-PIP01-11-M02

Sanofi-aventis Recherche & Developpement; Treatment of elevated cholesterol / Proposed adult indication: To reduce the risk of cardiovascular events in adult patients with a history of an acute coronary syndrome and elevated LDL cholesterol

Summary of Committee discussion:

The inclusion of the new indication within the scope of the Agency Decision P/0102/2016 was confirmed.

8. Annual reports on deferrals

Note: The annual reports on deferrals to be noted by the members of the PDCO are flagged in the Annex B.

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. Rapporteur and peer reviewer comments on Summary Reports

PDCO Chair: Dirk Mentzer

Summary of Committee discussion:

9.1.2. Granting deferrals for initiation/completion of measures in PIPs

PDCO Chair: Dirk Mentzer

Summary of Committee discussion:

A proposal for systematic approach on granting deferrals for initiation/completion of measures in PIPs will be developed in 2017.

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 5 medicinal products, Afstyla, Vemlidy, Caprelsa, Humira and Nimenrix for which the CHMP adopted a positive opinion recommending paediatric indication during their meeting in November 2016.

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:

The chair of the Non-clinical Working Group identified the products which will require Non-clinical Working Group evaluation and discussion.

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Summary of Committee discussion:

The chair of the Formulation Working Group identified the products which will require Formulation Working Group evaluation and discussion.

9.3.3. Patients and Consumers Working Party (PCWP) Workplan 2017

Summary of Committee discussion:

The committee adopted the work plan.

9.3.4. Healthcare Professionals Working Party (HCPWP) Workplan 2017

Summary of Committee discussion:

The committee adopted the work plan.

9.3.5. Agenda of the Training session for patients and consumers interested in EMA activities held on 29 Nov 2016

Summary of Committee discussion:

Document tabled for information

9.3.6. Agenda of the PCWP meeting with all eligible organisations held on 30 November 2016

Summary of Committee discussion:

Document tabled for information

9.3.7. Report of the PCPWP/ HCPWP workshop on social media held on 19 September 2016

Summary of Committee discussion:

Document tabled for information

9.4. Cooperation within the EU regulatory network

9.4.1. EMA and PDCO during the public consultation phase of 2017 Commission Report on the Paediatric Regulation

PDCO member: Koenraad Norga

Summary of Committee discussion:

The PDCO noted the update.

9.4.2. PDCO advice to the European Commission on priority areas for research in paediatrics - Horizon 2020 strategy

PDCO member: Tsveta Schyns

Summary of Committee discussion:

The Committee discussed and agreed on some areas of paediatric research that may be suggested for the future call of Horizon 2020. A dedicated letter containing these suggestions was adopted.

9.5. Cooperation with International Regulators

9.5.1. Report on the progress of the update of the EMA/FDA strategic document on Gaucher disease

PDCO member: Sylvie Benchetrit

Summary of Committee discussion:

PDCO noted the report.

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 2017

Summary of Committee discussion:

The Committee discussed the latest version of the PDCO work plan 2017. Few changes in identified resources for specific activities were suggested. The revised version will be

distributed for adoption at the PDCO January 2017 meeting.

9.8. Planning and reporting

9.8.1. Business Pipeline Report for the human scientific committees. - Forecast for 2017

Summary of Committee discussion:

Document tabled for information.

10. Any other business

10.1.1. Flow of documents from PDCO members to EMA

Summary of Committee discussion:

The PDCO noted the presentation.

10.1.2. Updated policy on handling interests for scientific committees' members and experts

Summary of Committee discussion:

PDCO members were informed on the updated policy on the handling of competing interests of scientific committees' members and experts, which becomes applicable as from 01 December 2016 (policy 0044). The update stems from an annual review of the Agency's independence policies and alignment with the policy on the handling of competing interests for Management Board members. Committee members impacted by the updated policy were contacted by EMA as necessary.

11. Breakout sessions

11.1.1. Paediatric oncology

Summary of Committee discussion:

The participants prepared product-specific discussions and reflected on forthcoming public meetings.

11.1.2. Neonatology

Summary of Committee discussion:

The participants discussed product-related topics as well as topics related to the International Neonatal Consortium (BPD, organizational and scientific issues). Furthermore, there were discussions regarding the organization of a planned revision of the neonatal guideline.

11.1.3. Inventory

Summary of Committee discussion:

The group met on the margins of the PDCO to progress on the discussions on how to improve the methodology for drafting inventories of paediatric needs. A new approach is being considered.

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 13-16 December 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	
Johanna Wernsperger *via TC*	Alternate	Austria	No interests declared	
Koenraad Norga	Member (Vice-Chair)	Belgium	When chairing the meeting: To be replaced for discussions, final deliberations and voting When not chairing the meeting: No participation in final deliberations and voting	EMEA-002030-PIP01-16 EMEA-C1-001318-PIP01-12-M01 EMEA-C-000673-PIP01-09-M09
Jacqueline Carleer	Alternate	Belgium	No interests declared	
Dimitar Roussinov	Member	Bulgaria	No restrictions applicable to this meeting	
Adriana Andrić	Member	Croatia	No interests declared	
Suzana Mimica Matanovic	Alternate	Croatia	No participation in discussions, final deliberations and voting	EMEA-000172-PIP01-07-M02 EMEA-001053-PIP03-16 EMEA-001918-PIP01-15 EMEA-000310-PIP03-10-M02 EMEA-001425-PIP01-13-M02
Jaroslav Sterba	Member	Czech Republic	No interests declared	
Peter Szitanyi	Alternate	Czech Republic	No interests declared	
Marianne Orholm	Member	Denmark	No interests	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
			declared	
Marta Granström	Alternate	Denmark	No interests declared	
Irja Lutsar	Member	Estonia	No interests declared	
Ann Marie Kaukonen	Member	Finland	No interests declared	
Maija Pihlajamaki	Alternate	Finland	No interests declared	
Sylvie Benchetrit	Member	France	No interests declared	
Sabine Scherer	Member	Germany	No interests declared	
Immanuel Barth	Alternate	Germany	No interests declared	
Eleni Katsomiti	Member	Greece	No interests declared	
Ágnes Gyurasics	Member (CHMP member)	Hungary	No interests declared	
Brian Aylward	Member	Ireland	No interests declared	
Dina Apele-Freimane	Member	Latvia	No interests declared	
Carola de Beaufort	Member (CHMP alternate)	Luxembourg	No restrictions applicable to this meeting	
Maaike van Dartel	Member	Netherlands	No interests declared	
Siri Wang	Member	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	
Stefan Grosek	Member	Slovenia	No interests declared	
Fernando de Andrés Trelles *via TC*	Member	Spain	No interests declared	
Maria Jesús Fernández Cortizo	Alternate	Spain	No interests declared	
Ninna Gullberg	Member	Sweden	No interests declared	
Eva Agurell	Alternate	Sweden	No restrictions applicable to this meeting	
Angeliki Siapkara	Member	United Kingdom	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Martina Riegl	Alternate	United Kingdom	No interests declared	
Riccardo Riccardi	Member	Healthcare Professionals' Representative	No participation in final deliberations and voting	EMEA-001425-PIP01-13-M02 EMEA-001945-PIP01-16
Jorrit Gerritsen	Alternate	Healthcare Professionals' Representative	No interests declared	
Johannes Taminiau	Member	Healthcare Professionals' Representative	No interests declared	
Doina Plesca	Alternate	Healthcare Professionals' Representative	No participation in discussions, final deliberations and voting	EMEA-002082-PIP01-16
Günther Auerswald	Member	Patients' Organisation Representative	No restrictions applicable to this meeting	
Paola Baiardi	Alternate	Patients' Organisation Representative	No interests declared	
Tsvetana Schyns-Liharska	Member	Patients' Organisation Representative	No restrictions applicable to this meeting	
Sara Homer	Expert - in person*	United Kingdom	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/