21 March 2017
EMA/PDCO/123280/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Draft minutes for the meeting on 21-24 February 2017

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

21 February 2017, 14:00 - 18:00, room 3A

22 February 2017, 08:30 - 19:00, room 3A

23 February 2017, 08:30 - 19:00, room 3A

24 February 2017, 08:30 - 13:00, room 3A

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).

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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 of the January PDCO plenary meeting 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. Macimorelin - EMEA-001988-PIP01-16

Aeterna Zentaris GmbH; Growth hormone deficiency / Diagnosis of growth hormone deficiency

Day 120 opinion

Endocrinology-Gynaecology-Fertility-Metabolism / Diagnostic

Summary of committee discussion:

The PDCO adopted a positive opinion for PIP1988 (macimorelin, an oral growth hormone

secretagogue which stimulates the pituitary to release growth hormone, for the diagnosis of growth hormone deficiency) during its plenary on 24 February 2017.

2.1.2. Human fibrinogen concentrate - EMEA-001931-PIP01-16

Biotest AG; Treatment of congenital fibrinogen deficiency

Day 120 opinion

Haematology-Hemostaseology

Summary of committee discussion:

The PDCO deemed the applicant's responses to the outstanding issues from the day 90 discussion acceptable.

2.1.3. Entolimod - Orphan - EMEA-002020-PIP01-16

Cleveland BioLabs Inc; Treatment of acute Radiation Syndrome / Entolimod is indicated for reducing the risk of death following exposure to potentially lethal irradiation occurring as the results of a radiation disaster

Day 120 opinion

Other

Summary of committee discussion:

The applicant provided several responses to the issues raised at Day 90 by the PDCO. The Committee therefore adopted a positive opinion.

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

Esperion Therapeutics, Inc.; Treatment of primary hypercholesterolemia / Treatment of heterozygous familial hypercholesterolaemia

Day 120 opinion

Other / Cardiovascular Diseases

Summary of committee discussion:

The PDCO deemed the applicant's responses to the outstanding issues from the day 90 discussion acceptable.

The PDCO adopted a positive opinion for PIP1872 (bempedoic acid, which inhibits ATP citrate lyase (ACL)- an enzyme involved in fatty acid and cholesterol synthesis, for the treatment of elevated cholesterol) during its plenary on 24 February 2017.

2.1.5. olodaterol hydrochloride - EMEA-001965-PIP01-16

Boehringer Ingelheim International GmbH; Treatment of cystic fibrosis

Day 120 opinion

Pneumology - Allergology

Summary of committee discussion:

The PDCO's views expressed at day 90 were re-discussed and endorsed. The committee also discussed the applicant's clarifications and considered them acceptable.
Based on the assessment of this application and further discussions the PDCO adopted a positive opinion for olodaterol hydrochloride in the condition of treatment of cystic fibrosis.

2.1.6. Baclofen - EMEA-001549-PIP02-14

Ethypharm; Alcohol use disorders (DSM-5) / Reduction of alcohol consumption as a second line treatment after psychosocial intervention, in 15-17 years adolescents with alcohol use disorders according to DSM 5

Day 120 opinion

Psychiatry

Summary of committee discussion:

The PDCO confirmed the views expressed at D90, and concluded that the product is unlikely to provide significant benefit compared to existing treatments. Consequently, the PDCO could not agree with the proposed paediatric investigation plan, and granted by consensus a product-specific waiver ex officio for all paediatric age groups, in the condition "Treatment of alcohol dependence".

2.1.7. rVSVΔG-ZEBOV-GP - EMEA-001786-PIP01-15

Merck Sharp & Dohme (Europe) Inc.; Prevention of Ebola disease

Day 120 opinion

Vaccines

Summary of committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO agreed at their February 2017 meeting a PIP rVSV-ZEBOV-GP for the condition of Prevention of Ebola disease.

2.1.8. Acetylsalicylic acid / Prasugrel HCl - EMEA-002071-PIP01-16

Daiichi Sankyo Europe GmbH; Prevention of atherosclerosis, thrombosis and thromboembolic events

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

The PDCO's views expressed at day 30 were 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 Prasugrel HCl / Acetylsalicylic acid for all subsets of the paediatric population (0 to 18 years of age) in the condition of Prevention of thromboembolic events.

2.1.9. Amlodipine / Candesartan - EMEA-002090-PIP01-16

ERREKAPPA EUROTERAPICI S.p.A.; Treatment of hypertension

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 request for a waiver.
The PDCO recommends granting a waiver for amlodipine / candesartan for all subsets of the paediatric population (0 to 18 years of age) in the condition of Treatment of hypertension.

2.1.10. Amlodipine / Perindopril - EMEA-002091-PIP01-16

CIPROS S.r.l.; Treatment of hypertension

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

The PDCO confirmed the Day 30 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 Perindopril / Amlodipine for all subsets of the paediatric population (0 to 18 years of age) in the condition of treatment of hypertension.

2.1.11. Tobramycin - Orphan - EMEA-000184-PIP03-16

Novartis Europharm Limited; Treatment of Pseudomonas aeruginosa pulmonary colonisation in patients with bronchiectasis

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

The PDCO's views expressed at day 30 were 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 Tobramycin inhalation powder, hard capsule, for all subsets of the paediatric population (0 to 18 years of age) in the condition "treatment of Pseudomonas aeruginosa pulmonary colonisation in patients with bronchiectasis".

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. Brexpiprazole - EMEA-C2-001185-PIP01-11-M03

Otsuka Pharmaceutical Europe Ltd.; Treatment of Schizophrenia

Day 0 letter

Psychiatry

Summary of committee discussion:

The PDCO discussed the completed study and considered that it is compliant with the latest Agency's Decision.
The PDCO finalised on 24 February 2017 this partially completed compliance procedure.

2.2.2. ipilimumab - EMEA-C-000117-PIP02-10-M07

Bristol-Myers Squibb Pharma EEIG; Treatment of melanoma

Day 30 opinion

Oncology

Summary of committee discussion:

The completed studies were checked for compliance.
The PDCO adopted on 24 February 2017 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0003/2017) of 12 January 2017.

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Evolocumab - EMEA-001268-PIP01-12-M04

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 therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0235/2016 of 09 September 2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.2. Trifarotene - EMEA-001492-PIP01-13-M01

GALDERMA R&D; Treatment of acne vulgaris

Day 60 opinion

Dermatology

Summary of committee discussion:

The applicant provided further justifications and corroborated their requests prior to the Day 60 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/0231/2014 of 05/09/2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.3. Recombinant human N-acetylglucosaminidase (rhNAGLU) - Orphan - EMEA-001653-PIP01-14-M02

Alexion Europe SAS; Treatment of Mucopolysaccharidosis IIIB (Sanfilippo B)

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted. The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0082/2015 of 10 April 2015). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.4. ferric maltol - EMEA-001195-PIP01-11-M02

Shield TX (UK) Limited; Treatment for 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/0069/2016 of 18/03/2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.5. ustekinumab - EMEA-000311-PIP03-11-M02

Janssen-Cilag International NV; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondyloarthritis, PsA and juvenile idiopathic arthritis [JIA]) / Treatment of juvenile idiopathic arthritis (jPsA and ERA)

Day 60 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted. The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0292/2012 of 18 December 2012). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.6. rituximab - EMEA-000308-PIP01-08-M03

Roche Registration Limited; Treatment of diffuse large B-cell lymphoma, Treatment of autoimmune arthritis / Treatment of mature B-cell malignancies, that is, diffuse large B-cell lymphoma, Burkitt and Burkitt-like lymphoma/leukaemia

Day 60 opinion

Immunology-Rheumatology-Transplantation / Oncology

Summary of committee discussion:

The PDCO's view expressed at Day 30 was endorsed.
Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0017/2013 of 18/01/2013).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.7. letermovir - Orphan - EMEA-001631-PIP01-14-M02

Merck Sharp & Dohme (Europe), Inc.; Prevention of cytomegalovirus infection / Prevention of CMV viremia and/or disease in at-risk patients having undergone an allogeneic HSCT or SOT

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 therefore 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/0155/2015 of 10 July 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.8. Oseltamivir phosphate - EMEA-000365-PIP01-08-M08

Roche Registration Limited; Treatment and prevention of influenza / Treatment and prevention of influenza in healthy and immunocompromised patients from 0 to less than 18 years of ages.

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/0267/2015 of 27 November 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.9. posaconazole - EMEA-000468-PIP02-12-M03

Merck Sharp & Dohme (Europe), Inc.; Prevention of invasive fungal infections, Treatment of invasive fungal infections / For treatment of invasive fungal infections in the following paediatric patients: -Invasive aspergillosis in patients with disease that is refractroy to amphotericin B or itraconazole or in patients who are intolerant of these medicinal products;, Treatment of invasive aspergillosis, -Patients receiving remission-induction chemotherapy for acute myelogenous leukemia (AML) or myelodysplastic syndromes (MDS) expected to result in prolonged neutropenia and who are at high risk of developing invasive fungal infections; - Hematopoietic stem cell transplant (HSCT) recipients who are undergoing high-dose immunosuppressive therapy for graft versus host disease and who are at high risk of developing invasive fungal infections.

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

The PDCO re-discussed and endorsed its views expressed 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/0141/2015 of 10 July 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.10. telaprevir - EMEA-000196-PIP01-08-M04

Janssen-Cilag International NV; Treatment of chronic viral hepatitis C

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/0225/2014 of 5 September 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.11. Oritavancin diphosphate - EMEA-001270-PIP01-12-M01

The Medicines Company; Treatment of acute bacterial skin and skin structure infections

Day 60 opinion

Infectious Diseases / 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/0056/2013 of 25 March 2013).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.12. Bivalent anti-human myostatin adnectin recombinant human IgG1-Fc fusion protein - EMEA-001793-PIP01-15-M01

Bristol-Myers Squibb International Corporation; Treatment of Duchenne Muscular Dystrophy / Treatment of Duchenne Muscular Dystrophy in patients from 2 to less than 18 years of age

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 adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0250/2016 of 09 September 2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.13. Siponimod hemifumarate - EMEA-000716-PIP01-09-M02

Novartis Europharm Limited; Multiple Sclerosis / Treatment of children/adolescent patients (10-18 years old) with relapsing forms of multiple sclerosis

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/0015/2014 of 22 January 2014). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.14. HSV-1/ICP34.5-/ICP47-/hGM-CSF - EMEA-001251-PIP01-11-M03

Amgen Europe B.V.; Treatment of solid malignant non-CNS tumours

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 (P/0353/2016 of 09-December 2016). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.15. ibrutinib - Orphan - EMEA-001397-PIP03-14-M02

Janssen-Cilag International N.V.; Treatment of mature B-cell neoplasm / Treatment of children from 1 year to less than 18 years of age with newly-diagnosed and relapsed/refractory mature B-cell lymphoma, that is, diffuse large B-cell lymphoma or Burkitt and Burkitt-like lymphoma.

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO discussed on 24 February the request for modification of the agreed PIP for ibrutinib for treatment of mature B-cell lymphoma in paediatric patients, 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.

2.3.16. Lenvatinib - Orphan - EMEA-001119-PIP02-12-M03

Eisai Europe Ltd; Treatment of papillary thyroid carcinoma, Treatment of Osteosarcoma, Treatment of follicular thyroid carcinoma / Treatment of refractory or relapsed

osteosarcoma in children and adolescents, Treatment of progressive, radioiodine-refractory differentiated thyroid cancer in children and adolescents

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 (P/0282/2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.17. Regorafenib - EMEA-001178-PIP01-11-M03

Bayer Pharma; Treatment of all conditions contained in the category of malignant neoplasms (except haematopoietic and lymphoid tissue) / Treatment of paediatric patients with a solid malignant tumour(s) integrated with anti-cancer therapy

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO discussed the responses received from the applicant to the issues raised at D30.
The PDCO adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0190/2016 of 15/7/2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.18. ivacaftor / lumacaftor - EMEA-001582-PIP01-13-M05

Vertex Pharmaceuticals (Europe) Limited; Treatment of cystic fibrosis

Day 60 opinion

Other

Summary of committee discussion:

The PDCO re-discussed and endorsed the views expressed at day 30.
Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that some but not all proposed changes could be accepted and adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0220/2016 of 26/08/2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.4. Opinions on Re-examinations

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

Roche Registration Limited; Treatment of anaemia associated with chronic kidney disease

Day 30 opinion

Haematology-Hemostaseology

Summary of committee discussion:

In conclusion the PDCO established that the negative opinion refusing the proposed changes was justified and correct on the basis of the then available information, and expressed their agreement with the concept of the proposed changes in light of the new information but requested further adjustments.
A final opinion maintaining the previous, negative opinion has thus been adopted.

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. EMEA-001983-PIP01-16

Monitoring of renal function

Day 90 discussion

Diagnostic / Uro-nephrology

3.1.2. avacopan - Orphan - EMEA-002023-PIP01-16

ChemoCentryx, Ltd.; Treatment of ANCA-associated vasculitis

Day 90 discussion

Immunology-Rheumatology-Transplantation

3.1.3. Tetrofosmin - Orphan - EMEA-002019-PIP02-16

proACTINA SA; Diagnosis of malignant Glioma

Day 60 discussion

Diagnostic

3.1.4. Levoglutamide - Orphan - EMEA-001996-PIP02-16

Emmaus Medical Europe Ltd.; Sickle cell disease / Levoglutamide is indicated for the prevention of sickle cell crises in adults, adolescents and children older than 5 years suffering from Sickle Cell Disease

Day 60 discussion

Haematology-Hemostaseology

3.1.5. Recombinant human monoclonal antibody to GM-CSF . - EMEA-001882-PIP02-16

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 60 discussion

Immunology-Rheumatology-Transplantation

3.1.6. Iclaprim mesylate - EMEA-000345-PIP02-16

Treatment of acute bacterial skin and skin structure infections caused by susceptible strains of Gram-positive bacteria

Day 60 discussion

Infectious Diseases

3.1.7. Lefamulin - EMEA-002075-PIP01-16

Treatment of community-acquired pneumonia

Day 60 discussion

Infectious Diseases

3.1.8. EMEA-002070-PIP01-16

Treatment of spinal muscular atrophy

Day 60 discussion

Neurology

3.1.9. fenfluramine hydrochloride - Orphan - EMEA-001990-PIP01-16

Zogenix International Ltd; The adjunctive treatment of seizures in paediatric patients at least 2 years of age with Dravet Syndrome

Day 60 discussion

Neurology

3.1.10. Autologous CD3+ T Cells Expressing CD19 Chimeric Antigen Receptor - EMEA-001994-PIP01-16

Treatment of B-cell non-Hodgkin's lymphoma, Treatment of B-cell acute lymphoblastic leukemia / Treatment of pediatric patients with relapsed or refractory B-cell acute lymphoblastic leukemia, Treatment of pediatric patients with relapsed or refractory diffuse large B-cell lymphoma, Burkitt lymphoma, and primary mediastinal large B-cell lymphoma

Day 60 discussion

Oncology

3.1.11. Autologous CD4+ and CD8+ T cells Expressing a CD19-Specific Chimeric Antigen Receptor - EMEA-001995-PIP01-16

Treatment of B-cell non-Hodgkin's lymphoma, Treatment of B-cell acute lymphoblastic leukemia / Treatment of pediatric patients with relapsed or refractory B-cell acute lymphoblastic leukemia, Treatment of pediatric patients with relapsed or refractory diffuse large B-cell lymphoma, Burkitt lymphoma, and primary mediastinal large B-cell lymphoma

Day 60 discussion

Oncology

3.1.12. Enasidenib - Orphan - EMEA-001798-PIP02-16

Celgene Europe Ltd; Treatment of Acute Myeloid Leukaemia / Treatment of patients aged 2 to 21 years old with relapsed or refractory IDH2- mutated AML after at least 2 prior induction attempts.

Day 60 discussion

Oncology

3.1.13. Entospletinib - EMEA-002058-PIP01-16

Treatment of Acute myeloid leukemia / Treatment of Acute myeloid leukemia

Day 60 discussion

Oncology

3.1.14. epacadostat EMEA-002072-PIP01-16

Treatment of melanoma / Melanoma >12years - <18 years

Day 60 discussion

Oncology

3.1.15. Ramucirumab - EMEA-002074-PIP01-16

Treatment of soft tissue sarcoma, Treatment of intestinal malignant neoplasm, Treatment of gastric cancer and gastro-oesophageal junction adenocarcinoma, Treatment of liver cancer, Treatment of urinary tract malignant neoplasm, Treatment of lung malignant neoplasm, Treatment of synovial sarcoma and / or desmoplastic small round cell tumour

Day 60 discussion

Oncology

3.1.16. ruxolitinib phosphate - EMEA-000901-PIP03-16

Treatment of acute graft versus host disease / Steroid refractory (SR) acute (a) Graft vs Host Disease (GvHD) after allogeneic hematopoietic stem cell transplantation (alloSCT)

Day 60 discussion

Oncology

3.1.17. Vadastuximab Talirine - Orphan - EMEA-002013-PIP01-16

Seattle Genetics UK, Limited; Treatment of Acute Myeloid Leukaemia / Treatment of relapsed or refractory AML

Day 60 discussion

Oncology

3.1.18. Angiotensin II - EMEA-001912-PIP02-16

Treatment of catecholamine-resistant hypotension associated with distributive shock

Day 60 discussion

Other

3.1.19. Ketamine hydrochloride / Sufentanil citrate - EMEA-001739-PIP02-16

Treatment of pain, unspecified

Day 60 discussion

Pain

3.1.20. Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) - EMEA-002068-PIP01-16

Prevention of influenza

Day 60 discussion

Vaccines

3.1.21. Chloroprocaine Hydrochloride - EMEA-000639-PIP03-16

Treatment of peripheral nerve block (local anesthesia by perineural injection)

Day 30 discussion

Anaesthesiology

3.1.22. Indapamide / Ramipril - EMEA-002081-PIP01-16

Treatment of hypertension ICD10 I10-I15 / Treatment of hypertension as substitution therapy in adults whose blood pressure is adequately controlled by the use of ramipril and indapamide with the individual products given concurrently at the same dose level as in the combination, but as separate medicinal products. Treatment of hypertension in adults whose blood pressure is not adequately controlled by the use of ramipril monotherapy and for whom the use of the second medicinal product is an optimal therapeutic procedure

Day 30 discussion

Cardiovascular Diseases

3.1.23. Recombinant modified human growth hormone - Orphan - EMEA-001152-PIP02-16

Richardson Associates Regulatory Affairs Ltd; Treatment of growth hormone deficiency / Treatment of children with growth failure due to inadequate secretion of endogenous growth hormone

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.24. Selonsertib - EMEA-001868-PIP03-16

Treatment of Non-Alcoholic Steatohepatitis (NASH) with moderate to severe fibrosis (F2-F4) in paediatric subjects, 8 to < 18 years of age

Day 30 discussion

Gastroenterology-Hepatology

3.1.25. Human normal immunoglobulin - EMEA-002084-PIP01-16

Treatment of Primary Immunodeficiency Diseases

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.1.26. Human Normal Immunoglobulin for Intravenous Administration (IVIg) - EMEA-002092-PIP01-16

Treatment of primary immunodeficiency (PID), Treatment of idiopathic thrombocytopenic purpura (ITP) / Primary immunodeficiency syndromes with impaired antibody production, Primary immune thrombocytopenia (ITP), in patients at high risk of bleeding or prior to surgery to correct the platelet count

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.1.27. Influenza virus surface antigens (haemagglutinin) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin) of strain A (H1N1) / Influenza virus surface antigens (haemagglutinin) of strain B (Victoria lineage) - EMEA-002027-PIP01-16

Prevention of Influenza infection

Day 30 discussion

Infectious Diseases

3.1.28. maribavir - Orphan - EMEA-000353-PIP02-16

Shire Pharmaceuticals Ireland Limited; Treatment of CMV infection / Treatment of CMV infection in transplant patients who are ≥2 to <18 years of age

Day 30 discussion

Infectious Diseases

3.1.29. allopregnanolone - EMEA-002051-PIP01-16

Treatment of Super Refractory Status Epilepticus

Day 30 discussion

Neurology

3.1.30. GIVINOSTAT - Orphan - EMEA-000551-PIP03-16

Italfarmaco S.p.A.; Treatment of Duchenne Muscular Dystrophy (DMD) / Treatment of Duchenne Muscular Dystrophy (DMD)

Day 30 discussion

Neurology

3.1.31. Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta chimeric antigen receptor - Orphan - EMEA-001862-PIP01-15

Kite Pharma EU B.V.; Treatment of B-precursor Acute Lymphoblastic Leukaemia (ALL)

Day 30 discussion

Oncology

3.1.32. Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta chimeric antigen receptor - Orphan - EMEA-002010-PIP01-16

Kite Pharma EU B.V.; Treatment of primary mediastinal B cell lymphoma (PMBCL), Treatment of follicular lymphoma (FL), Treatment of diffuse large B cell lymphoma (DLBCL)

Day 30 discussion

Oncology

3.1.33. erdafitinib - EMEA-002042-PIP01-16

Treatment of Ureter and Bladder Carcinoma

Day 30 discussion

Oncology

3.1.34. Small interfering RNA targeting human TRPV1 - EMEA-002061-PIP01-16

Treatment of dry eye disease

Day 30 discussion

Ophthalmology

3.1.35. Brimapitide - Orphan - EMEA-001926-PIP02-16

Auris Medical Ltd.; Treatment of Idiopathic Sudden Sensorineural Hearing Loss (ISSNHL)

Day 30 discussion

Oto-rhino-laryngology

3.1.36. gpASIT+TM - EMEA-001815-PIP02-16

Treatment of grass pollen induced seasonal allergic rhinoconjunctivitis (SAR)

Day 30 discussion

Pneumology - Allergology

3.1.37. ivacaftor / tezacaftor - EMEA-002086-PIP01-16

Treatment of Cystic Fibrosis

Day 30 discussion

Pneumology - Allergology

3.1.38. mepolizumab - Orphan - EMEA-000069-PIP05-16

GSK Trading Services Limited; Treatment of nasal polyposis / NUCALA is indicated for the add-on maintenance treatment of adult patients with severe bilateral nasal polyposis who have had prior nasal polyp surgery

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. darbepoetin alfa - EMEA-C-000329-PIP02-09-M05

Amgen Ltd.; Treatment of anaemia due to chronic disorders

Day 30 discussion

Oncology / Uro-nephrology

3.2.2. 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-C4-001582-PIP01-13-M04

Vertex Pharmaceuticals (Europe) Limited; Treatment of cystic fibrosis

Day 30 letter

Other

Summary of committee discussion:

The completed studies were checked for compliance
In conclusion, the PDCO finalised on 24 February 2017 this fourth partially completed compliance procedure and confirmed the compliance of all those studies contained in the agreed paediatric investigation plan (P/0220/2016 of 26 August 2016) that were to be completed until this date.

3.2.3. Beclometasone dipropionate / Formoterol fumarate dihydrate - EMEA-C5-000548-PIP01-09-M06

Chiesi Farmaceutici S.p.A.; Treatment of asthma

Day 30 letter

Pneumology - Allergology

Summary of committee discussion:

The PDCO discussed the completed studies, and considered that these are compliant with the latest Agency's Decision (P/0001/2017) of 05 January 2017. The PDCO finalised on 24-Feb-2017 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.

3.2.4. Eravacycline - EMEA-C1-001555-PIP01-13-M02

Tetraphase Pharmaceuticals, Inc.; Treatment of urinary tract infection

Day 30 letter

Infectious Diseases

Summary of committee discussion:

The PDCO discussed the completed studies and considered that these are compliant with the latest Agency's Decision (P/0336/2016) of 02 December 2016.
The PDCO finalised on 24/02/2017 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.

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Dopamine hydrochloride - EMEA-001105-PIP01-10-M03

BrePco Biopharma Limited; Treatment of vascular hypotensive disorders / Treatment of hypotension in neonates including the extremely low gestational age newborn. Treatment of hypotension in infants and children

Day 30 discussion

Cardiovascular Diseases

3.3.2. 3-[[5-chloro-1-[3-(methylsulfonyl)propyl]-1H-indol-2-yl]methyl]-1-(2,2,2-trifluoroethyl)-1,3-dihydro-2H-imidazo[4,5-c]pyridine-2-one - EMEA-001838-PIP01-15-M01

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

Day 30 discussion

Infectious Diseases

3.3.3. doravirine - EMEA-001676-PIP01-14-M01

Merck Sharp & Dohme (Europe), Inc.; Treatment of human immunodeficiency virus-1 (HIV-1) infection / Antiretroviral therapy, in combination with other antiretroviral agents, for the

treatment of HIV-1 infection in children aged from birth to 18 years

Day 30 discussion

Infectious Diseases

3.3.4. tenofovir disoproxil fumarate / lamivudine / doravirine - EMEA-001695-PIP01-14-M01

Merck Sharp & Dohme (Europe), Inc.; Treatment of human immunodeficiency virus-1 (HIV-1) infection / Antiretroviral combination therapy, for the treatment of HIV-1 infection in adults and children aged 2 to 18 years

Day 30 discussion

Infectious Diseases

3.3.5. ponatinib - Orphan - EMEA-001186-PIP01-11-M01

Incyte Biosciences UK Ltd.; Treatment of chronic myeloid leukaemia, Philadelphia chromosome positive acute lymphoblastic leukaemia / Paediatric population with Chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant or intolerant to at least one prior BCR-ABL TKI therapy; or who have the T315I mutation. Paediatric population with Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) who are resistant or intolerant to at least one prior BCR-ABL TKI therapy; or who have the T315I mutation

Day 30 discussion

Oncology

3.3.6. Febuxostat - EMEA-001417-PIP01-12-M02

Menarini International Operations Luxembourg S.A.; Prevention/treatment of hyperuricemia / Prevention or treatment of hyperuricemia in patients at intermediate or high risk of Tumor Lysis Syndrome (TLS) affected by hematologic malignancies

Day 30 discussion

Other / Oncology

3.3.7. Tapentadol - EMEA-000018-PIP01-07-M13

Grünenthal GmbH; Acute pain / Treatment of acute pain

Day 30 discussion

Pain

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 25 April 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

4.3.1. Call for a PDCO representative to be Co-Chair of a new Working Group on clinical trial preparedness

Summary of committee discussion:

EMA presented at the PDCO plans for the creation of a temporary, ad-hoc working group of the EnprEMA to discuss clinical trial preparedness focusing on how to tackle feasibility issues in the conduction of paediatric clinical trials. This is an initiative which follows previous discussion at the EnprEMA annual meeting as well as the latest EMA/EFGCP/DIA annual meeting in October 2016. The group will meet virtually in 2017 to agree on a mandate, scope of the work and deliverables; it will be composed by members of the EnprEMA including industry and will be Co-chaired by one representative of the networks and by one PDCO member. A call for participation and for being a Co-Chair of the group was launched. The PDCO will be kept updated of any progress.

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. Atezolizumab (EMEA-001638-PIP01-14-M01) - EMEA-42-2016

Roche Registration Limited; Treatment of multiple myeloma/ Atezolizumab in combination with daratumumab for the treatment of patients with relapsed/refractory multiple myeloma (MM) who have received at least three prior lines of therapy, including a proteasome inhibitor (PI) and an immunomodulatory drug (IMiD), or who are double refractory to a PI and an IMiD; Atezolizumab in combination with daratumumab, and an IMiD in previously untreated MM patients

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 indications was confirmed.

Other potential paediatric interests of this medicine suggested by PDCO: PIP for 'Treatment of all conditions included in the category of malignant neoplasms (except central nervous system tumours, haematopoietic and lymphoid tissue neoplasms)'.

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.

6.1.2. Axalimogene filolisbac - EMEA-01-2017

Advaxis Inc; Treatment of cervix and corpus uteri carcinoma/ Treatment of persistent or recurrent squamous or non-squamous cell carcinoma of the cervix in women of 18 years of age and older who progress beyond first-line chemotherapy

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 interests of this medicine suggested by PDCO: none at this stage.

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. (anti-vascular endothelial growth factor)- EMEA-02-2017

PanOptica, Inc; All classes of medicinal products for treatment of age-related macular degeneration and diabetic macular oedema/ Treatment of neovascular age-related macular degeneration

Summary of committee discussion:

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

Other potential paediatric interests of this medicine suggested by PDCO: retinopathy of the premature.

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

None

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. Committee meeting dates 2019-2021

Summary of committee discussion:

The PDCO adopted the plenary meeting dates for years 2019-2021.

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 presented the list of procedures with paediatric indications to be evaluated by the CHMP starting in January 2017.

The members were also informed about 1 medicinal product, Jylamvo for which the CHMP adopted a positive opinion recommending paediatric indications during their meeting in January 2017.

9.2.2. Joint CHMP-PDCO session

Summary of committee discussion:

The first joint CHMP/PDCO session took place.

9.2.3. Sodium-glucose co-transporter 2 (SGLT2) inhibitors: Canaglifozin – INVOKANA (CAP); canagliflozin, metformin – VOKANAMET (CAP); dapaglifozin – EDISTRIDE (CAP), FORXIGA (CAP); dapaglifozin, metformin – XIGDUO (CAP), EBYMECT (CAP); empaglifozin – JARDIANCE (CAP); empaglifozin, metformin – SYNJARDY (CAP) - EMEA/H/A-20/1442

Applicant: Janssen-Cilag International N.V. (Invokana, Vokanamet); AstraZeneca AB (Edistride, Forxiga, Xigduo, Ebymect); Boehringer Ingelheim International GmbH (Jardiance; Synjardy)

Scope: Review of the benefit-risk balance of sodium-glucose co-transporter-2 (SGLT2) inhibitors following notification by the European Commission of a referral under Article 20 of Regulation (EC) No 726/2004, based on pharmacovigilance data

Summary of committee discussion:

The PDCO was informed about the conclusions by the PRAC and CHMP.

9.2.4. Human coagulation (plasma-derived) factor VIII: human coagulation factor VIII (antihemophilic factor A) (NAP); human coagulation factor VIII (inhibitor bypassing fraction) (NAP); human coagulation factor VIII, human von Willebrand factor - VONCENTO (CAP) Recombinant factor VIII: antihemophilic factor (recombinant) (NAP); moroctocog alfa – REFACTO AF (CAP) octocog alfa – ADVATE (CAP), HELIXATE NEXGEN (CAP), IBLIAS (CAP), KOGENATE (CAP), KOVALTRY (CAP) - EMEA/H/A-31/1448

Applicant: Baxter AG (Advate), Bayer Pharma AG (Helixate Nexgen, Iblias, Kogenate, Kovaltry), CSL Behring GmbH (Voncento), Pfizer Limited (Refacto AF), various

Scope: Review of the benefit-risk balance of factor VIII following notification by Germany of a referral under Article 31 of Directive 2001/83/EC, based on pharmacovigilance data

Summary of committee discussion:

The PDCO was informed about the preliminary conclusions by the PRAC.

9.2.5. Fluoroquinolones for systemic and inhalation use: ciprofloxacin (NAP); enoxacin (NAP); flumequin (NAP); levofloxacin – QUINSAIR (CAP), NAP; lomefloxacin (NAP); moxifloxacin (NAP); norfloxacin (NAP); ofloxacin (NAP); pefloxacin (NAP); prulifloxacin (NAP); rufloxacin (NAP) Quinolones for systemic and inhalation use: cinoxacin (NAP); nalidixic acid (NAP); pipemidic acid (NAP)

Applicant: Raptor Pharmaceuticals Europe BV (Quinsair), various

Scope: Review of the benefit-risk balance following notification by Germany of a referral under Article 31 of Directive 2001/83/EC, based on pharmacovigilance data

Summary of committee discussion:

The PDCO was informed about the start of the referral procedure.

9.2.6. Selexipag - UPTRAVI (CAP)

Applicant: Actelion Registration Ltd.

Summary of committee discussion:

The committee was informed that the EMA/PRAC is reviewing the safety of Uptravi (selexipag)

9.2.7. Potential harmonisation referral of morphine after Art. 45 WS / HU

Summary of committee discussion:

The PDCO members were informed about the status of potential harmonisation referral of morphine. The CMDh is collecting data on authorised products from NCAs, discussion at the CMDh level will continue once all the data are compiled.

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.

9.4. Cooperation within the EU regulatory network

9.4.1. The 2017 Commission Report on the Paediatric Regulation

Summary of committee discussion:

The European Commission representative presented to the PDCO the next steps with regard to the publication of the 2017 EC report on the paediatric regulation.

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. Preliminary discussion of PDCO on the scope of inventories

PDCO member: Karl-Heinz Huemer

Summary of committee discussion:

The work done with the inventories in the past together with a proposal for a new methodology to draft an inventory based on a list of conditions occurring in children was presented at the plenary. A pilot project was proposed in order to test the new methodology and will be presented to the Committee in the next few months.

9.8. Planning and reporting

None

10. Any other business

10.1.1. Survey to committee members on the service provided by the Scientific Committees Service

Summary of committee discussion:

The PDCO noted the presentation. The support by the Scientific Committee Secretariat was acknowledged.

10.1.2. Results on the first 18 months of the 'Early Paediatric Interaction Meeting'

Summary of committee discussion:

The data on the first 18 months of the Early Paediatric Interaction Meeting were considered and discussed.

10.1.3. Results of juvenile animal studies (JAS) and impact on anti-cancer medicine development and use in children

PDCO member: Jacqueline Carleer

Summary of committee discussion:

The PDCO adopted the project report 'Results of juvenile animal studies (JAS) and impact on anti-cancer medicine development and use in children'.

11. Breakout sessions

11.1.1. Paediatric oncology

Summary of committee discussion:

The participants discussed the forthcoming multistakeholder strategy forum meeting and the addendum on paediatric oncology.

11.1.2. Neonatology

Summary of committee discussion:

The participants discussed organisational issues and upcoming scientific meetings in the field.

12. List of participants

List of participants including any restrictions with respect to involvement of members/alternates/ experts following evaluation of declared interests for the 21 – 24 February 2017 meeting.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Dirk Mentzer	Chair	Germany	No interests declared	
Karl-Heinz Huemer	Member	Austria	No interests declared	
Koenraad Norga	Member (Vice-Chair)	Belgium	No participation in final deliberations and voting on:	EMEA-001882-PIP02-16 EMEA-000069-PIP05-16
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 discussion, final deliberations and voting on:	EMEA-002070-PIP01-16 EMEA-000308-PIP01-08-M03 EMEA-000365-PIP01-08-M08 EMEA-000172-PIP01-07-M02 EMEA-42-2016
Georgios Savva	Member	Cyprus	No interests declared	
Jaroslav Sterba	Member	Czech Republic	No interests declared	
Peter Szitanyi	Alternate	Czech Republic	No interests declared	
Marianne Orholm	Member	Denmark	No interests declared	
Marta Granström	Alternate	Denmark	No interests declared	
Irja Lutsar	Member	Estonia	No interests declared	
Ann Marie Kaukonen	Member	Finland	No interests declared	
Sylvie Benchetrit	Member	France	No interests declared	
Dominique Ploin	Alternate	France	No interests declared	
Sabine Scherer	Member	Germany	No interests declared	
Immanuel Barth	Alternate	Germany	No interests declared	
Eleni Katsomiti	Member	Greece	No interests	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
			declared	
Ágnes Gyurasics	Member (CHMP member)	Hungary	No interests declared	
Brian Aylward	Member	Ireland	No interests declared	
Alessandro Jenkner	Alternate	Italy	No interests declared	
Dina Apele-Freimane	Member	Latvia	No interests declared	
Carola de Beaufort	Member (CHMP alternate)	Luxembourg	No interests declared	
Herbert Lenicker	Alternate	Malta	No interests declared	
Maaike van Dartel	Member	Netherlands	No interests declared	
Siri Wang	Member	Norway	No interests declared	
Ine Skottheim Rusten	Alternate	Norway	No interests declared	
Marek Migdal	Member	Poland	No interests declared	
Helena Fonseca	Member	Portugal	No interests declared	
Hugo Tavares	Alternate	Portugal	No interests declared	
Dana Gabriela Marin	Member (CHMP alternate)	Romania	No interests declared	
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 participation in discussion, final deliberations and voting on:	
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 restrictions applicable to this meeting	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Günther Auerswald	Member	Patients' Organisation Representative	No restrictions applicable to this meeting	
Paola Baiardi	Alternate	Patients' Organisation Representative	No participation in final deliberations and voting on:	EMEA-001882-PIP02-16 EMEA-000069-PIP05-16
Tsvetana Schyns-Liharska	Member	Patients' Organisation Representative	No restrictions applicable to this meeting	
Flora Musuamba Tshinanu	Expert - via telephone*	Belgium	No interests declared	
Nuria Prieto	Expert - via telephone*	Spain	No interests declared	
Juliana Min	Expert - in person*	United Kingdom	No interests declared	
Sara Homer	Expert - in person*	United Kingdom	No interests declared	
Joan Deckers	Observer	Medicines Evaluation Board - Netherlands	No interests declared	
Stan van Belkum	Observer	Medicines Evaluation Board - Netherlands	No interests declared	
Hoebert Sybe Hiemstra	Observer	Medicines Evaluation Board - Netherlands	No interests declared	
Gertruda Knol	Observer	Medicines Evaluation Board - Netherlands	No interests declared	
Peter Salomons	Observer	Medicines Evaluation Board - Netherlands	No interests declared	
Karen van der Velden	Observer	Medicines Evaluation Board - Netherlands	No restrictions applicable to this meeting	
Fons Wesseling	Observer	Medicines Evaluation Board - Netherlands	No interests declared	
Diederick Slijkerman	Observer	Medicines Evaluation Board - Netherlands	No interests declared	
Representative from the European Commission participated in the meeting				
Meeting run with support from relevant EMA staff				

* Experts were only evaluated against the product(s) they have been invited to talk about.

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/