16 May 2017
EMA/PDCO/246316/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Minutes for the meeting on 18-21 April 2017

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

18 April 2017, 14:00- 19:00, room 2F

19 April 2017, 08:30- 19:00, room 2F

20 April 2017, 08:30- 19:00, room 2F

21 April 2017, 08:30- 13:00, room 2F

Disclaimers

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

Of note, this set of minutes is a working document primarily designed for PDCO members and the work the Committee undertakes.

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

Note on access to documents

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

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1. Introductions

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

In accordance with the Agency's policy on handling of declarations of interests of scientific committees' members and experts, based on the declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced the restricted involvement of some meeting participants in upcoming discussions as included in the pre-meeting list of participants and restrictions.

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

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 23 or more members were present in the room). All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

1.2. Adoption of agenda

The agenda was adopted with amendments.

1.3. Adoption of the minutes

The minutes of the March 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. Expanded donor-derived allogenic T cells transduced with the retroviral vector expressing the transgenes for inducible caspase9 and the truncated CD19 selectable marker - Orphan - EMEA-001869-PIP01-15

Bellicum Pharma Ltd.; Treatment in haematopoietic stem cell transplantation / Treatment of immunodeficiency after mismatched, related, allogeneic transplantation in paediatric

patients with malignant and non-malignant disorders amenable to haematopoietic stem cell transplantation

Day 120 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

The PDCO discussed this procedure at Day 120 at the April 2017 meeting.
The Committee confirmed all the points discussed at Day 90
The PDCO adopted a positive Opinion at Day 120.

2.1.2. Rimiducid - Orphan - EMEA-001870-PIP01-15

Bellicum Pharma Ltd.; Treatment of Graft Versus Host Disease (ICD 279.50) / Treatment of graft versus host disease (GvHD) in paediatric patients who have received a mismatched, related, allogeneic haematopoietic stem cell transplantation together with rivogenlecleucel (expanded T lymphocytes transduced with a retroviral vector containing inducible caspase 9 and truncated CD19)

Day 120 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

The PDCO discussed this procedure at Day 120 at the April 2017 plenary.
The Committee confirmed all the points discussed at Day 90. The PDCO also assessed the answers provided to the questions raised at Day 90
The PDCO adopted a positive Opinion at Day 120.

2.1.3. Pimodivir - EMEA-001975-PIP01-16

Janssen-Cilag International NV; Treatment of influenza

Day 120 opinion

Infectious Diseases

Summary of committee discussion:

The PDCO re-discussed the application for pimodivir taking into account the clarifications provided by the applicant after the D90 discussion.

In conclusion the PDCO recommended granting a paediatric investigation plan for the entire paediatric population from birth to less than 18 years of age for pimodivir and a deferral

2.1.4. Cannabidiol - Orphan - EMEA-001964-PIP01-16

GW Research Ltd; Treatment of seizures associated with Tuberous Sclerosis Complex (TSC), Treatment of seizures associated with Dravet Syndrome (DS), Treatment of seizures associated with Infantile Spasms (IS), Treatment of seizures associated with Lennox-Gastaut Syndrome (LGS)

Day 120 opinion

Neurology

Summary of committee discussion:

The Committee reviewed and re-discussed the application including the new information received after Day 90 A positive opinion endorsing the PIP has therefore been adopted.

2.1.5. 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 120 opinion

Ophthalmology

Summary of committee discussion:

The PDCO discussed this application on D120. In line with the discussion on D90 and the applicant's response , the PDCO has granted a waiver for the entire paediatric population on own motion for the treatment of acanthamoeba keratitis on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

2.1.6. Ezetimibe / Rosuvastatin (calcium) - EMEA-002118-PIP01-17

Neopharmed Gentili S.r.l; Treatment of hypercholesterolaemia

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, the PDCO agrees with the applicant's request for a waiver. The PDCO recommends granting a waiver for Rosuvastatin (calcium) / Ezetimibe for all subsets of the paediatric population (0 to 18 years of age) in the condition of "Treatment of hypercholesterolaemia" on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

2.1.7. Nimodipine - Orphan - EMEA-002097-PIP01-16

Edge Therapeutics, Inc.; Treatment of aneurysmal subarchnoidal haemorrhage

Day 60 opinion

Neurology

Summary of committee discussion:

Based on the assessment of this application and further discussions at the Paediatric

Committee, the PDCO agrees with the applicant's request for a waiver. The PDCO recommends granting a waiver for Nimodipine for all subsets of the paediatric population (0 to 18 years of age) in the condition of Treatment of aneurysmal subarchnoidal haemorrhage.
The PDCO emphasises that the granting of a waiver for the condition mentioned above should not prevent the applicant from considering a development in the paediatric population in indications where there is a paediatric need. In principle according to the Paediatric Regulation, incentives for the development for use in the paediatric population are available even if a waiver has been granted in another condition.

2.1.8. Malic acid / Zinc sulphate / Sodium acetate / Potassium chloride / Magnesium sulphate / Sodium glycerophosphate / Calcium chloride / Glucose / Valine / Tyrosine / Tryptophan / Threonine / Serine / Proline / Phenylalanine / Methionine / Lysine acetate / Leucine / Isoleucin / Histidine / Glycine / Arginine / Alanine / Acetyl-cysteine / Fish oil / Olive oil / Medium-chain triglycerides / Soybean oil - EMEA-002067-PIP02-17

Fresenius Kabi AB; Need for parenteral nutrition

Day 60 opinion

Nutrition

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 Glycine / Lysine acetate / Tryptophan / Tyrosine / Glucose / Sodium glycerophosphate / Phenylalanine / Serine / Threonine / Calcium chloride / Magnesium sulphate / Acetyl-cysteine / Zinc sulphate / Malic acid / Potassium chloride / Alanine / Medium-chain triglycerides / Olive oil / Fish oil / Sodium acetate / Soybean oil / Arginine / Histidine / Isoleucin / Leucine / Methionine / Proline / Valine for all subsets of the paediatric population (0 to 18 years of age) in the condition of Parenteral nutrition.
The PDCO emphasises that the granting of a waiver for the condition mentioned above should not prevent the applicant from considering a development in the paediatric population in indications where there is a paediatric need. In principle according to the Paediatric Regulation, incentives for the development for use in the paediatric population are available even if a waiver has been granted in another condition.

2.1.9. Buprenorphine hydrochloride - EMEA-002099-PIP01-16

Titan Pharmaceuticals Inc.; Treatment of opioid dependence

Day 60 opinion

Psychiatry

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 Buprenorphine hydrochloride for all subsets of the paediatric population (0 to 18 years of age) in the condition of Treatment of opioid

dependence.
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. oxymetazoline hydrochloride / Tetracaine hydrochloride - EMEA-C-001764-PIP03-15

St. Renatus, LLC; Local anesthesia

Day 60 opinion

Anaesthesiology

Summary of committee discussion:

The completed studies were checked for compliance
The PDCO adopted on 21 April 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/0082/2016) of 18 March 2016.

2.2.2. voretigene neparvovec - EMEA-C-001684-PIP01-14

Spark Therapeutics Inc.; Treatment of genetic congenital retinal disorders

Day 60 opinion

Ophthalmology

Summary of committee discussion:

The completed study was checked for compliance.
The PDCO adopted on 21 April 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/0221/2015) of 02 October 2015.

2.2.3. dasatinib (as monohydrate) - EMEA-C4-000567-PIP01-09-M04

Bristol-Myers Squibb Pharma EEIG; Treatment of Philadelphia chromosome (BCR-ABL translocation)-positive chronic myeloid leukaemia

Day 30 letter

Oncology

Summary of committee discussion:

The completed studies were checked for compliance

The PDCO discussed the completed studies, , and considered that these are compliant with the latest Agency's Decision (P/0118/2013) of 02 May 2013.
The PDCO finalised on 21 April 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.

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Split influenza virus, inactivated containing antigens equivalent to the B-like strain Victoria lineage) / Split influenza virus, inactivated containing antigens equivalent to the B-like strain (B/Yamagata lineage) / Split influenza virus, inactivated containing antigens equivalent to the A/H3N2-like strain / Split influenza virus, inactivated containing antigens equivalent to the A/H1N1-like strain - EMEA-001254-PIP01-11-M02

Sanofi Pasteur; Prevention of influenza infection

Day 30 opinion

Vaccines

Summary of committee discussion:

The PDCO discussed this modification on 20 April 2017.
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/0249/2015 of 30/10/2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.2. Enalapril maleate - EMEA-001706-PIP01-14-M01

Ethicare GmbH; Treatment of Heart Failure

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

The PDCO discussed the additional information received after Day 30 and concluded that the proposed modifications are acceptable.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP.
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.3. rivaroxaban - EMEA-000430-PIP01-08-M10

Bayer Pharma AG; Treatment of thromboembolic events, Prevention of thromboembolic events, Treatment (secondary prevention) of venous thromboembolism

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

The PDCO concerns expressed at day 30 were discussed

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/0126/2016 of 20/05/16).

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

2.3.4. Apremilast - EMEA-000715-PIP03-11-M04

Celgene Europe Limited; Psoriasis in children

Day 60 opinion

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 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/0300/2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.5. Rubidium Rb-82 Chloride - EMEA-000882-PIP03-11-M03

Jubilant DraxImage Inc.; Visualization of myocardial perfusion for diagnostic purposes / Rubidium Chloride[82Rb] Injection is a radiopharmaceutical to be used in PET imaging for the assessment of myocardial perfusion abnormalities

Day 60 opinion

Diagnostic

Summary of committee discussion:

The PDCO reviewed the additional information and concluded that the proposed modifications can be accepted.
A positive opinion endorsing the proposed modifications was adopted. The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.6. Telbivudine - EMEA-000065-PIP01-07-M05

Novartis Europharm Limited; Treatment of chronic hepatitis B / Treatment of children and adolescents from 2 to below 18 years of age with compensated HBeAg-positive or HBeAg-negative chronic hepatitis B

Day 60 opinion

Gastroenterology-Hepatology

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO 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/0006/2014 of 22 January 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.7. vedolizumab - EMEA-000645-PIP01-09-M05

Takeda Pharma A/S; Ulcerative colitis, Crohn's disease

Day 60 opinion

Gastroenterology-Hepatology

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO 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/0247/2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.8. turoctocog alfa pegol - Orphan - EMEA-001174-PIP02-12-M02

Novo Nordisk A/S; ICD10 - D66 - Hereditary factor VIII deficiency

Day 60 opinion

Haematology-Hemostaseology

Summary of committee discussion:

The committee confirmed the main conclusions from the Day 30 discussion.
Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.

The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0284/2014 of 28/10/14).

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

2.3.9. Sirukumab - EMEA-001043-PIP01-10-M03

Janssen-Cilag International NV; Children:Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondyloarthritis, psoriatic arthritis and juvenile idiopathic arthritis)

(ICD: M08), Adults: Rheumatoid Arthritis (ICD: M05) / N.A., Treatment of juvenile idiopathic arthritis

Day 60 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

The PDCO's view expressed at D30 was re-discussed and endorsed.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0020/2016 of 29/01/2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.10. Isavuconazonium (sulfate) - Orphan - EMEA-001301-PIP02-12-M01

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

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

The PDCO re-discussed this procedure at the April 2017 plenary.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision P/0135/2013 of 14 June 2013).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.11. Laquinimod - EMEA-000972-PIP01-10-M05

Teva GmbH; Multiple Sclerosis (MS) / Treatment of relapsing remitting multiple sclerosis

Day 60 opinion

Neurology

Summary of committee discussion:

The PDCO reviewed and endorsed the preliminary conclusion reached at Day 30 and adopted an opinion recommending a product-specific waiver. The new PDCO Opinion granting the waiver supersedes the previous PDCO Opinion, the PIP requirements laid out there are no longer applicable.

2.3.12. olaratumab - Orphan - EMEA-001760-PIP01-15-M02

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

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO re-discussed the modification request on 19 April 2017 also taking into account the applicant's comments on the draft Opinion. The view expressed at D30 was endorsed and 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/0299/2016 of 04/11/2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.13. Human recombinant IgG1 monoclonal antibody targeting fibroblast growth factor 23 (FGF23) - Orphan - EMEA-001659-PIP01-15-M02

Ultragenyx Pharmaceutical Inc.; X-linked Hypophosphatemia

Day 60 opinion

Other

Summary of committee discussion:

The PDCO re-discussed this procedure at the April 2017 plenary.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0265/2016 of 5 October 2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.14. ivacaftor - Orphan - EMEA-000335-PIP01-08-M11

Vertex Pharmaceuticals (Europe) Limited; Treatment of Cystic Fibrosis

Day 60 opinion

Other

Summary of committee discussion:

The PDCO's views expressed at day 30 were re-discussed taking into account the applicant's additional information
The PDCO adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0112/2015 of 05/06/2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.15. Tapentadol - EMEA-000325-PIP01-08-M07

Grünenthal GmbH; Treatment of chronic pain

Day 60 opinion

Pain

Summary of committee discussion:

The PDCO's views expressed at day 30 were re-discussed taking into account the applicant's additional information.

The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0319/2016 of 02/12/2016)
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.16. Mometasone furoate / Indacaterol acetate - EMEA-001217-PIP01-11-M03

NOVARTIS EUROPHARM LTD.; Treatment of asthma

Day 60 opinion

Pneumology - Allergology

Summary of committee discussion:

The PDCO's view expressed at day 30 was re-discussed, taking into account the applicant's supplementary information, and endorsed.

The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0104/2016 of 15 April 2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.17. Cinacalcet (as hydrochloride) - EMEA-000078-PIP01-07-M08

Amgen Europe B.V.; Hyperparathyroidism and other disorders of parathyroid gland (E21), Other disorders resulting from impaired renal tubular function. Secondary hyperparathyroidism of renal origin (N25.8), Treatment of secondary hyperparathyroidism (HPT) in patients with end-stage renal disease (ESRD) on maintenance dialysis therapy

Day 30 opinion

Uro-nephrology

Summary of committee discussion:

The PDCO discussed the modification request on D30.
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/0008/2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.4. Opinions on Re-examinations

No items.

2.5. Finalisation and adoption of opinions

3. Discussion of applications

Disclosure of some information related to this section cannot be released at the present time as it is

deemed to contain commercially confidential information.

3.1. Discussions on Products D90-D60-D30

3.1.1. Empagliflozin - EMEA-000828-PIP04-16

Treatment of type 1 diabetes mellitus

Day 90 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.2. Cenicriviroc mesylate - EMEA-001999-PIP01-16

Treatment of liver fibrosis in patients with nonalcoholic steatohepatitis

Day 90 discussion

Gastroenterology-Hepatology

3.1.3. Seletalisib - EMEA-001938-PIP01-16

Primary Immunodeficiency syndrome

Day 90 discussion

Immunology-Rheumatology-Transplantation

3.1.4. Omadacycline - EMEA-000560-PIP02-15

Treatment of acute bacterial skin and skin structure infections (ABSSSI)

Day 90 discussion

Infectious Diseases

3.1.5. Omadacycline - EMEA-000560-PIP03-15

Treatment of bacterial pneumonia

Day 90 discussion

Infectious Diseases

3.1.6. Larotrectinib - Orphan - EMEA-001971-PIP02-16

Loxo Oncology, Inc.; Treatment of solid tumours / The treatment of adults, adolescents, children and infants with advanced solid tumours harbouring an NTRK fusion, as established prior to initiation of larotrectinib therapy.

Day 90 discussion

Oncology

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

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

Day 90 discussion

Ophthalmology

3.1.8. Mexiletine hydrochloride - Orphan - EMEA-002012-PIP01-16

Lupin (Europe) Ltd.; Treatment of myotonic disorders / Symptomatic treatment of myotonic disorders

Day 90 discussion

Other

3.1.9. Live attenuated, chimeric dengue virus, serotype 4 / Live, attenuated, chimeric dengue virus, serotype 3 / Live, attenuated dengue virus, serotype 2 / Live, attenuated, chimeric dengue virus, serotype 1 - EMEA-001888-PIP01-15

Prevention of dengue fever

Day 90 discussion

Vaccines

3.1.10. Omega-3-carboxylic acids - EMEA-001865-PIP02-16

Hypertriglyceridaemia or mixed dyslipidaemia to reduce the risk of atherosclerotic cardiovascular disease (ACVD), Mixed dyslipidaemia with persistent hypertriglyceridaemia.

Day 60 discussion

Cardiovascular Diseases

3.1.11. lucerastat - Orphan - EMEA-002095-PIP01-16

Actelion Registration Ltd.; Treatment of Fabry disease

Day 60 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.12. Iron hydroxyethyl amylopectin heptonate - EMEA-002094-PIP01-16

Iron deficiency anemia, Iron deficiency.

Day 60 discussion

Haematology-Hemostaseology

3.1.13. Human anti-interferon gamma monoclonal antibody - Orphan - EMEA-002031-PIP01-16

Novimmune B.V; Treatment of histiocytosis haematophagic conditions

Day 60 discussion

Immunology-Rheumatology-Transplantation

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

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

Day 60 discussion

Oncology

3.1.15. vamorolone - Orphan - EMEA-001794-PIP02-16

ReveraGen BioPharma Ltd; Treatment of Duchenne muscular dystrophy

Day 60 discussion

Other

3.1.16. (S)-6-hydroxy-2,5,7,8-tetramethyl-N-((R)-piperidin-3-yl)chroman-2-carboxamide hydrochloride - Orphan - EMEA-002113-PIP01-16

Khondrion BV; Treatment of mitochondrial respiratory chain/oxidative phosphorylation defects

Day 60 discussion

Other

3.1.17. Bupivacaine - EMEA-000877-PIP02-16

postsurgical analgesia

Day 60 discussion

Pain

3.1.18. allopregnanolone - EMEA-002051-PIP02-16

Treatment of postpartum depression

Day 60 discussion

Psychiatry

3.1.19. calcifediol - EMEA-002093-PIP01-16

secondary Hyperparathyroidism (SHPT)

Day 60 discussion

Uro-nephrology

3.1.20. Amlodipine / Rosuvastatin - EMEA-002130-PIP01-17

Treatment of angina and dyslipidaemia, Treatment of concomitant hypertension and dyslipidemia, Treatment of essential hypertension in patients who are estimated to have a high risk for a first cardiovascular event

Day 30 discussion

Cardiovascular Diseases

3.1.21. Amlodipine / Rosuvastatin - EMEA-002136-PIP01-17

Treatment of angina and dyslipidaemia, Treatment of concomitant hypertension and dyslipidemia, Treatment of essential hypertension in patients who are estimated to have a high risk for a first cardiovascular event

Day 30 discussion

Cardiovascular Diseases

3.1.22. dezamizumab - Orphan - EMEA-002110-PIP02-17

GlaxoSmithKline Trading Services Limited; Treatment of transthyretin amyloidosis (ATTR)

Day 30 discussion

Cardiovascular Diseases

3.1.23. Ezetimibe / Rosuvastatin (calcium) - EMEA-002131-PIP01-17

Treatment of hypercholesterolaemia

Day 30 discussion

Cardiovascular Diseases

3.1.24. Ezetimibe / Rosuvastatin (calcium) - EMEA-002135-PIP01-17

Treatment of hypercholesterolaemia

Day 30 discussion

Cardiovascular Diseases

3.1.25. Hydrochlorothiazide / Amlodipine besilate / Olmesartan medoxomil - EMEA-002104-PIP01-16

Essential Hypertension (MedDRA PT: 10015488)

Day 30 discussion

Cardiovascular Diseases

3.1.26. miridesap - Orphan - EMEA-002111-PIP02-17

GlaxoSmithKline Trading Services Limited; Treatment of transthyretin amyloidosis (ATTR)

Day 30 discussion

Cardiovascular Diseases

3.1.27. EMEA-001749-PIP02-16

Treatment of Atopic Dermatitis

Day 30 discussion

Dermatology

3.1.28. Benzydamine hydrochloride / Econazole nitrate - EMEA-002143-PIP01-17

Treatment of vulvovaginal candidosis (VVC)

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.29. dezamizumab - Orphan - EMEA-002110-PIP01-17

GlaxoSmithKline Trading Services Limited; Systemic AL amyloidosis

Day 30 discussion

Haematology-Hemostaseology

3.1.30. miridesap - Orphan - EMEA-002111-PIP01-17

GlaxoSmithKline Trading Services Limited; Systemic AL amyloidosis

Day 30 discussion

Haematology-Hemostaseology

3.1.31. (6aR,10aR)-1-Hydroxy-6,6-dimethyl-3-(2-methyl-2-octanyl)-6a,7,10,10a-tetrahydro-6H-benzo[c]chromene-9-carboxylic acid - Orphan - EMEA-002069-PIP01-16

Corbus Pharmaceuticals Inc.; Treatment of Systemic Sclerosis

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.1.32. efavirenz / lamivudine / abacavir - EMEA-002114-PIP01-16

Treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Infectious Diseases

3.1.33. pseudoephedrine HCl / ibuprofen - EMEA-002102-PIP01-16

J06.9

Day 30 discussion

Infectious Diseases / Oto-rhino-laryngology

3.1.34. recombinant humanised IgG4 monoclonal antibody against MSRV-Envelope protein - EMEA-002127-PIP01-17

Treatment of Multiple Sclerosis (RRMS), Treatment of Multiple Sclerosis (PMS) / Treatment of patients from 10 to less than 18 years old with relapsing-remitting multiple sclerosis

Day 30 discussion

Neurology

3.1.35. trazodone hydrochloride - EMEA-002142-PIP01-17

Treatment of insomnia

Day 30 discussion

Neurology

3.1.36. Radium Ra 223 dichloride - EMEA-001986-PIP01-16

C00 - C70, C73 - C80, C97: Treatment of all conditions contained in the category of malignant neoplasms (except central nervous system tumours, haematopoietic and lymphoid tissue neoplasms), C90: Treatment of Multiple Myeloma

Day 30 discussion

Oncology

3.1.37. Sulindac / Eflornithine - Orphan - EMEA-001518-PIP02-16

Cancer Prevention Pharma Ltd.; Treatment of Familial Adenomatous Polyposis

Day 30 discussion

Oncology

3.1.38. Lactobacillus reuteri - Orphan - EMEA-001895-PIP01-15

Infant Bacterial Therapeutics AB; Prevention of necrotising enterocolitis

Day 30 discussion

Other / Neonatology - Paediatric Intensive Care / Gastroenterology-Hepatology

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. glucagon - EMEA-C1-001657-PIP01-14

Eli Lilly and Company Limited; Treatment of hypoglycemia

Day 30 letter

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The PDCO discussed the completed studies and considered that these are compliant with the latest Agency's Decision (P/0184/2015) of 21 August 2015.
The PDCO finalised on 21 April 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 by this date.

3.2.2. emicizumab - EMEA-C1-001839-PIP01-15

Roche Registration Limited; Treatment of Hereditary FVIII Deficiency

Day 30 discussion

Haematology-Hemostaseology

3.2.3. Galcanezumab - EMEA-C1-001860-PIP03-16

Eli Lilly Nederland B.V.; Prevention of migraine headaches

Day 30 discussion

Neurology

3.2.4. Melatonin - EMEA-C-000440-PIP02-11-M05

RAD Neurim Pharmaceuticals EEC Ltd; Treatment of insomnia

Day 30 opinion

Neurology

Summary of committee discussion:

The completed studies were checked for compliance
The PDCO adopted on 21 April 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/0089/2017 of 6 April 2017).

3.2.5. mepolizumab - EMEA-C1-000069-PIP04-13-M01

GSK Trading Services Limited; Treatment of vasculitides

Day 30 discussion

Pneumology - Allergology

3.2.6. mirabegron - EMEA-C2-000597-PIP02-10-M05

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

Day 30 discussion

Uro-nephrology

3.2.7. mirabegron - EMEA-C2-000597-PIP03-15-M03

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

Day 30 discussion

Uro-nephrology

3.2.8. Purified antigen fractions of inactivated split virion Influenza virus type A, H1N1 / Influenza virus type A, H3N2 / Influenza virus type B, Victoria lineage / Influenza virus type B, Yamagata lineage - EMEA-C-000817-PIP02-11-M01

GlaxoSmithKline Biologicals S.A.; Prevention of influenza infection

Day 30 opinion

Vaccines

Summary of committee discussion:

The completed studies were checked for compliance.
The PDCO took note of preceding procedures and reports on partially completed compliance EMEA-C1-000817-PIP02-11.
The PDCO adopted on 14 June 2013 an opinion confirming the compliance of all studies in

the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0171/2013) of 30 July 2013.

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Dobutamine - EMEA-001262-PIP01-12-M03

Proveca Limited; Circulatory impairment / haemodynamic insufficiency

Day 30 discussion

Cardiovascular Diseases

3.3.2. ticagrelor - EMEA-000480-PIP01-08-M10

AstraZeneca AB; thromboembolic events (children), acute coronary syndrome, history of myocardial infarction / reduction in occurrence of vaso-occlusive crises in paediatric patients with sickle cell disease

Day 30 discussion

Cardiovascular Diseases / Haematology-Hemostaseology

3.3.3. Lonoctocog alfa - EMEA-001215-PIP01-11-M05

CSL Behring GmbH; Haemophilia A

Day 30 discussion

Haematology-Hemostaseology

3.3.4. Apremilast - Orphan - EMEA-000715-PIP05-13-M01

Celgene Europe Limited; Treatment of Behcets Disease / Treatment of patients with active oral ulcers (with or without genital ulcers) associated with Behcets Disease, who are candidates for systemic therapy

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.3.5. Certolizumab pegol - EMEA-001071-PIP02-12-M02

UCB Pharma S.A.; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis) / Treatment of juvenile idiopathic arthritis

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.3.6. Aciclovir - EMEA-001066-PIP02-11-M02

ONXEO; Treatment of herpes simplex labialis / Treatment of recurrent herpes simplex virus infections of the lips in immunocompetent children aged 10 to less than 18 years

Day 30 discussion

Infectious Diseases

3.3.7. cobicistat / atazanavir sulphate - EMEA-001465-PIP01-13-M01

Bristol-Myers Squibb Pharma EEIG; Treatment of HIV-1 infection / indicated in combination with other ARV medicinal products for the treatment of HIV-1 infected adults and adolescents from 12 years of age without known mutations associated with resistance to atazanavir

Day 30 discussion

Infectious Diseases

3.3.8. Colistimethate sodium - Orphan - EMEA-000176-PIP01-07-M05

TEVA B.V.; Cystic fibrosis with pulmonary manifestations ICD-10 (version 2007) E84.0 / Treatment of Pseudomonas aeruginosa pulmonary infection in patients with cystic fibrosis aged 6 years and over

Day 30 discussion

Infectious Diseases

3.3.9. Velpatasvir / Sofosbuvir - EMEA-001646-PIP01-14-M01

Gilead Sciences International Ltd.; Treatment of Chronic Hepatitis C / Treatment of chronic Hepatitis C in adolescents and children 3 years of age and older

Day 30 discussion

Infectious Diseases

3.3.10. Dimethyl fumarate - EMEA-000832-PIP01-10-M04

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

Day 30 discussion

Neurology

3.3.11. ozanimod - EMEA-001710-PIP02-14-M01

Celgene Europe Limited; Treatment of multiple sclerosis / Treatment of relapsing remitting forms of multiple sclerosis

Day 30 discussion

Neurology

3.3.12. Teriflunomide - EMEA-001094-PIP01-10-M04

Genzyme Europe B.V. / Sanofi-Aventis groupe; Multiple Sclerosis / Treatment of children and adolescents from 10 to less than 18 years of age with relapsing forms of Multiple Sclerosis

Day 30 discussion

Neurology

3.3.13. pazopanib - EMEA-000601-PIP01-09-M04

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

Day 30 discussion

Oncology / Uro-nephrology

3.3.14. CYSTEAMINE HYDROCHLORIDE - Orphan - EMEA-000322-PIP01-08-M05

ORPHAN EUROPE SARL; CYSTINOSIS / Treatment of corneal cystine crystal deposits in cystinosis

Day 30 discussion

Ophthalmology

3.3.15. Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with lentiviral vector that encodes for the human ARSA cDNA sequence - Orphan - EMEA-001765-PIP02-15-M01

GlaxoSmithKline Trading Services Limited; Metachromatic leukodystrophy (MLD) / For the treatment of metachromatic leukodystrophy (MLD)

Day 30 discussion

Other

3.3.16. methoxyflurane - EMEA-000334-PIP01-08-M06

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

Day 30 discussion

Pain

3.3.17. Ivacaftor - EMEA-001640-PIP01-14-M02

Vertex Pharamceuticals (Europe) lTd; Treatment of Cystic Fibrosis

Day 30 discussion

Pneumology - Allergology

3.3.18. vilanterol - EMEA-000431-PIP01-08-M10

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

Day 30 discussion

Pneumology - Allergology

4. Nominations

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

4.1. List of letters of intent received for submission of applications with start of procedure 20 June 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:

None

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. Melphalan flufenamide (melflufen) - EMEA-03-2017

Oncopeptides AB; The class of primarily alkylating medicinal products for treatment of myeloproliferative neoplasms and mature B, T and NK cell neoplasms/ Treatment of multiple myeloma

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.

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. Synthetic double-stranded siRNA oligonucleotide directed against transthyretin mRNA - EMEA-001520-PIP01-13

Alnylam UK Limited.; Familial Amyloidotic Polyneuropathy (FAP)/Treatment of polyneuropathy in patients with hATTR amyloidosis

Summary of committee discussion:

The planned new indication is considered to fall within the scope of the waived condition.

7.1.2. rilpivirine (as hydrochloride) - EMEA-000317-PIP01-08-M09

Janssen Infectious Diseases BVBA/Janssen-Cilag International NV; Treatment of human immunodeficiency virus (HIV-1) infection/Treatment of HIV-1 infection, in combination with dolutegravir, in virologically-suppressed (HIV-1 RNA<50 c/mL) adult subjects without known or suspected resistance to rilpivirine or dolutegravir

Summary of committee discussion:

The planned new indication is considered to fall within the scope of the PIP.

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

9.2. 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 March 2017.

The members were also informed about 3 medicinal products, Dinutuximab beta Apeiron, Refixia and Trumenba for which the CHMP adopted a positive opinion recommending a paediatric indication during their meeting in March 2017.

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. Extrapolation principles for PIP evaluation

PDCO Chair: Dirk Mentzer

Summary of committee discussion:

The Extrapolation principles required to develop an adequate strategy to support a paediatric authorisation have been presented to PDCO in view of the publication of the Extrapolation reflection Paper. A review of the cases collected recently will be presented to PDCO during 3Q2017 for training and learning purposes.

9.3.4. Respiratory Drafting Group request for advice from CHMP and PDCO on how to address issues related to therapeutic equivalence for orally inhaled products for children

PDCO member: Eva Agurell

Summary of committee discussion:

The PDCO re-discussed the responses from the CHMP and PDCO task force to the Respiratory Drafting Group letter and adopted them.

9.3.5. Guideline on the clinical development of medicinal products for the treatment of Autism Spectrum Disorder (ASD)

PDCO member: Martina Riegl

Summary of committee discussion:

The draft guideline was presented to and discussed by the PDCO and several comments have been made for consideration for the final version.

9.3.6. Minutes of the PCWP meeting with all eligible organisations - 30 Nov 2016 (EMA/801985/2016)

Summary of committee discussion:

Document tabled for information

9.3.7. Agenda of the Workshop on personalised medicines: role of patients, consumers and healthcare professionals - 14 March 2017 (EMA/762357/2016): Document tabled for information

Summary of committee discussion:

Document tabled for information

9.3.8. Agenda of the PCWP/HCPWP joint meeting – 15 March 2017 (EMA/69326/2017): Document tabled for information

Summary of committee discussion:

Document tabled for information

9.4. Cooperation within the EU regulatory network

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

Summary of committee discussion:

The agenda of the annual Enpr-EMA workshop was presented to the committee and PDCO members were invited to attend the workshop which will be held on Tuesday 16 May 2017.

9.5. Cooperation with International Regulators

9.5.1. Gaucher disease - A strategic collaborative approach from EMA and FDA

PDCO member: Sylvie Benchetrit

Summary of committee discussion:

The Gaucher disease strategy has been endorsed by PDCO for publication. The document will be adopted and published in May 2017.

9.5.2. Presentation of the draft 'Agenda : EMA/FDA/Health Canada workshop on paediatric pulmonary arterial hypertension (PAH)' to be held on 12 June 2017 at EMA

Summary of committee discussion:

The PDCO endorsed the workshop agenda's due to take place June 12th and 13th.

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

9.6.1. EMA framework of collaboration with academia

Summary of committee discussion:

The committee noted a presentation on the EMA framework of collaboration with academia.

9.7. PDCO work plan

None

9.8. Planning and reporting

9.8.1. Report from the Strategic Review and Learning Meeting (SRLM) held in Malta on 10-11 April 2017

PDCO member: Herbert Lenicker

Summary of committee discussion:

PDCO Chair thanked the organisers of the Strategic Review and Learning Meeting in Malta. Further report will be given at the May plenary meeting.

10. Any other business

10.1.1. Involvement of young people at EMA

Summary of committee discussion:

The committee was informed about the "Principles on the involvement of young patients/consumers within EMA activities" which was recently endorsed by EMA management. This document aims to establish guidance for the Agency to involve young patients in its work.

11. Breakout sessions

11.1.1. Paediatric oncology

Summary of committee discussion:

The participants discussed the plan for the forthcoming stakeholder paediatric oncology strategy workshop and other future oncology events of potential interest to the group.

11.1.2. Neonatology

Summary of committee discussion:

The break-out session focused on a discussion of PIP strategy and timelines.

11.1.3. Inventory

Summary of committee discussion:

The participants focused on how to reach and gather input from learned societies and academia for the inventory list as well as the next steps forward.

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 18-21 April 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	
Johanna Wernsperger	Alternate	Austria	No interests declared	
Koenraad Norga	Member (Vice-Chair)	Belgium	When chairing the meeting: To be replaced for discussions, final deliberations and voting on:	EMEA-C-000817-PIP02-11-M01; EMEA-C1-000069-PIP04-13-M01; EMEA-002110-PIP01-17; EMEA-002111-PIP01-17; EMEA-002110-PIP02-17; EMEA-002111-PIP02-17; EMEA-001749-PIP02-16; EMEA-001765-PIP02-15-M01; EMEA-000431-PIP01-08-M10
Jacqueline Carleer	Alternate	Belgium	No interests declared	
Dimitar Roussinov	Member	Bulgaria	No restrictions applicable to this meeting	
Adriana Andrić	Member	Croatia	No interests declared	
Eirini Perikleous	Alternate	Cyprus	No interests declared	
Jaroslav Sterba	Member	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 declared	
Ágnes Gyurasics	Member (CHMP member)	Hungary	No interests declared	
Brian Aylward	Member	Ireland	No interests declared	
Alessandro Jenkner	Alternate	Italy	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Dina Apele-Freimane	Member	Latvia	No interests declared	
Carola de Beaufort	Member (CHMP alternate)	Luxembourg	No interests declared	
John-Joseph Borg	Member	Malta	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	
Eva Agurell	Alternate	Sweden	No restrictions applicable to this meeting	
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:	EMEA-001094-PIP01-10-M04
Johannes Taminiau	Member	Healthcare Professionals' Representative	No interests declared	
Michal Odermarsky	Member	Patients' Organisation Representative	No interests declared	
Milena Stevanovic	Alternate	Patients' Organisation Representative	No restrictions applicable to this meeting	
Tsvetana Schyns-Liharska	Member	Patients' Organisation Representative	No restrictions applicable to this meeting	
Eleni Gaki	Expert - in person*	United Kingdom	No interests declared	
Juliana Min	Expert - in person*	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
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/