12 December
EMA/PDCO/742434/2016
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Minutes for the meeting on 8-11 November 2016

Chair: Dirk Mentzer

8 November 2016, 13:00 - 17:00, room 3F

9 November 2016, 08:30 - 19:00, room 3A

10 November 2016, 08:30 - 19:00, room 3A

11 November 2016, 08:30 - 13:00, room 3A

Disclaimers

Some of the information contained in the 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).

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

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.

Adoption of agenda

The agenda was adopted with amendments.

Adoption of the minutes

The minutes were adopted with amendments and will be published on the EMA website.

2. Opinions

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

2.1. Opinions on Products

2.1.1. Antithrombin alfa - EMEA-001154-PIP02-15

GTC Biotherapeutics UK Limited; Treatment of congenital antithrombin deficiency, Treatment of acquired antithrombin deficiency (Preeclampsia), Treatment of acquired antithrombin deficiency (ECMO) / Prophylaxis of peri-partum thromboembolic events in

congenital antithrombin deficient patients, Antithrombin supplementation during ECMO procedure, Treatment of pregnant women less than 30 weeks GA with pre-eclampsia to prolong gestation and decrease foetal and neonatal morbidity and mortality

Summary of committee discussion:

The PDCO was informed on the written procedure for this application, which finalised on 19 October 2016.

2.1.2. Eculizumab - Orphan - EMEA-000876-PIP03-14

Alexion Europe SAS; Neuromyelitis Optica Spectrum Disorders / Treatment of Relapsing Neuromyelitis Optica Spectrum Disorders in the paediatric population

Day 120 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

The PDCO concluded that all issues have been addressed and resolved satisfactorily.
The Committee granted a waiver for eculizumab in children A deferral was granted
The PDCO adopted a positive opinion.

2.1.3. Octenidine (dihydrochloride) - Orphan - EMEA-001384-PIP01-12

Schülke & Mayr GmbH; Skin disinfection

Day 120 opinion

Neonatology - Paediatric Intensive Care

Summary of committee discussion:

The Committee reviewed and discussed the additional information received after Day 90, along with the assessors' comments, and considered all outstanding issues resolved. A positive opinion endorsing the modified PIP proposal has therefore been adopted.

2.1.4. synthetic surfactant protein B analogue / synthetic surfactant protein C analogue / 1-palmitoyl-2-oleoyl-sn-glycero-3-phosphoglycerol sodium salt / dipalmitoylphosphatidylcholine - Orphan - EMEA-001780-PIP01-15

Chiesi Farmaceutici SpA; treatment of respiratory distress syndrome (RDS) / treatment of respiratory distress syndrome (RDS) in preterm neonates of less than 37 weeks of gestational age

Day 120 opinion

Neonatology - Paediatric Intensive Care

Summary of committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee the PDCO adopted a favourable opinion for dipalmitoylphosphatidylcholine/1-palmitoyl-2-oleoyl-sn-glycero-3-phosphoglycerol sodium salt/synthetic surfactant protein C

analogue/synthetic surfactant protein B analogue for the treatment and early treatment of respiratory distress syndrome (RDS) in premature neonates.

2.1.5. Galcanezumab - EMEA-001860-PIP04-16

Eli Lilly and Company Limited; Prophylactic treatment of cluster headache

Day 120 opinion

Neurology

Summary of committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee the PDCO agreed at their November 2016 meeting with the applicant's request for a PIP including a waiver and a deferral

2.1.6. Dexamethasone / Complex of povidone and iodine - EMEA-001936-PIP01-16

Shire Pharmaceuticals Ireland Ltd; Treatment of Infectious conjunctivitis (adenoviral and bacterial)

Day 120 opinion

Ophthalmology

Summary of committee discussion:

The applicant provided further information between Day 90 and Day 120.
The PDCO agreed on a positive opinion for this PIP

2.1.7. Botulinum toxin, Type A - EMEA-002038-PIP01-16

Evolus Inc.; Treatment of glabellar lines

Day 60 opinion

Dermatology

Summary of committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee including contributions of external expert(s), the PDCO agrees with the applicant's request for a waiver. The PDCO recommends granting a waiver for Botulinum toxin, Type A for all subsets of the paediatric population (0 to 18 years of age) in the condition of Treatment of glabellar lines.

2.1.8. Netarsudil - EMEA-002037-PIP01-16

Aerie Pharmaceuticals Ireland, Ltd.; Open Angle Glaucoma / Ocular Hypertension

Day 60 opinion

Ophthalmology

Summary of committee discussion:

The PDCO discussed this waiver application on D60. The applicant's responses were acknowledged.
The PDCO recommends granting a waiver for Netarsudil for all subsets of the paediatric population (0 to 18 years of age) in the treatment of glaucoma.

2.1.9. palonosetron / fosnetupitant (netupitant prodrug) - EMEA-001198-PIP02-16

Helsinn Birex Pharmaceuticals Limited; Chemotherapy-Induced Nausea and Vomiting

Day 60 opinion

Other

Summary of committee discussion:

The PDCO's views expressed at day 30 were re-discussed and endorsed.
The PDCO adopted a negative opinion, refusing the applicant's request for a full product specific waiver.

2.1.10. Ibuprofen - EMEA-002017-PIP01-16

Strides Shasun Limited (Formulation Division); Treatment of pain, Treatment of febrile disorders / Treatment of pain of non-serious arthritic conditions, Treatment of backache, Treatment of dental pain, Treatment of neuralgia, Treatment of headache, Treatment of rheumatic or muscular pain, Treatment of migraine, Treatment of dysmenorrhoea, Treatment of fever

Day 60 opinion

Other / Pain

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 therefore recommends granting a waiver for all subsets of the paediatric population.
The PDCO emphasises that the granting of a waiver for the conditions 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.

2.1.11. DNA plasmid encoding HPV type 18 consensus E6 and E7 proteins (pGX3002) / DNA plasmid encoding HPV type 16 consensus E6 and E7 proteins (pGX3001) - EMEA-002022-PIP01-16

Inovio Pharmaceuticals Inc.; Treatment of high grade squamous intraepithelial lesions (HSIL) of the cervix caused by HPV types 16 and 18

Day 60 opinion

Vaccines / Infectious 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 DNA plasmid encoding HPV type 16 consensus E6 and E7 proteins (pGX3001) / DNA plasmid encoding HPV type 18 consensus E6 and E7 proteins (pGX3002) for all subsets of the paediatric population (0 to 18 years of age) in the condition of Treatment of squamous intraepithelial lesions of the cervix caused by HPV types 16 and 18
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.

2.1.12. Betrixaban - EMEA-001834-PIP02-16

Portola Pharma UK Limited; Prevention of venous thromboembolism / Adults and children

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

The PDCO discussed at their November 2016 meeting this second submission for a PIP for betrixaban in the condition prevention of venous thromboembolism with a deferral. Given that all issues were considered resolved the PDCO agreed a positive opinion at day 60 on this PIP.

2.1.13. Peramivir - EMEA-001856-PIP02-16

BioCryst UK Ltd. (c/o Morgan Lewis & Bockius); Treatment of influenza / Treatment of influenza

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

The PDCO re-discussed the proposed plan for peramivir taking into account the applicant's responses provided after the D30 discussion, the comments received by the applicant on the draft opinion and the inputs from the Modelling and Simulation Working Group. A CHMP Member also took part in the discussion.
The pending issues were considered solved.
In conclusion the PDCO recommended granting a paediatric investigation plan for peramivir for all subsets of the paediatric population (from birth to less than 18 years of age) and a deferral

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. Damoctocog alfa pegol - EMEA-C1-001229-PIP01-11-M02

Bayer Pharma AG; Treatment of hereditary Factor VIII deficiency

Day 30 opinion

Haematology-Hemostaseology

Summary of committee discussion:

The PDCO discussed the completed studies and considered that these are compliant with the latest Agency's Decision (P/0025/2016) of 29 January 2016.
The PDCO finalised on 11 November 2016 this partially completed compliance procedure and confirmed the compliance of all those studies contained in the agreed paediatric investigation plan that were to be completed by this date.

2.2.2. Gemtuzumab linked to Ozogamicin - EMEA-C1-001733-PIP02-15

Pfizer Limited; Treatment of acute myeloid leukaemia

Day 30 opinion

Oncology

Summary of committee discussion:

The PDCO discussed on 11 November 2016 the request to confirm compliance with the latest Agency's Decision (P/0078/2016) of 18 March 2016 taking into account the supplementary information provided by the applicant.
The PDCO confirmed the completion of studies is in compliance with the agreed PIP.
The PDCO finalised on 11 November 2016 this partially completed compliance procedure.

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. sacubitril / valsartan - EMEA-000316-PIP02-11-M03

Novartis Europharm Ltd.; Heart failure / Treatment of heart failure

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

The PDCO reviewed and discussed the application including the new information received after Day 30. Based on the rationale submitted by the applicant, 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.

2.3.2. Allantoin - Orphan - EMEA-001590-PIP01-13-M03

Scioderm, Inc.; Treatment of epidermolysis bullosa

Day 60 opinion

Dermatology

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted. The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0138/2016 of 20 May 2016). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.3. Liquid extract ethanolic 30 per cent (w/w) of Allium cepa L. (fresh bulb) and Citrus limon (L.) Burm. f. (fresh fruit), Paullinia cupana Kunth, Theobroma cacao L. - EMEA-001835-PIP01-15-M01

Legacy Healthcare; Treatment of alopecia

Day 60 opinion

Dermatology

Summary of committee discussion:

The PDCO's view expressed at day 30 was re-discussed and 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/0145/2016 of 23 May 2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.4. Rubidium Rb-82 Chloride - EMEA-000882-PIP03-11-M02

Jubilant DraxImage Inc.; Visualization of myocardial perfusion for diagnostic purposes

Day 60 opinion

Diagnostic

Summary of committee discussion:

The PDCO reviewed and discussed the additional information submitted after day 30
The PDCO refused to endorse this modification request.

2.3.5. Estetrol & Drospirenone - EMEA-001332-PIP01-12-M02

Estetra SPRL; Prevention of pregnancy

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The PDCO adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0146/2013 of 03/07/2013).

2.3.6. deferiprone - Orphan - EMEA-001126-PIP01-10-M02

Consorzio per Valutazioni Biologiche e Farmacologiche (CVBF) - Coordinator for DEEP Project (HEALTH-F4-2010-261483); treatment of chronic iron overload requiring chelation therapy / treatment of iron overload in paediatric patients affected by haemoglobinopathies requiring chronic transfusions and iron chelation

Day 60 opinion

Haematology-Hemostaseology

Summary of committee discussion:

Based on the review of the rationale and the additional documents submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that proposed changes could be accepted.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0331/2014 of 22 December 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.7. Ceftaroline fosamil (established INN) - EMEA-000769-PIP01-09-M06

AstraZeneca AB; Treatment of cSSTI (complicated skin and soft tissue infections), Treatment of CAP (community-aquired pneumonia) / Treatment of cSSTI (complicated skin and soft tissue infections), Treatment of CAP (community-aquired pneumonia)

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

The PDCO's view expressed at day 30 was re-discussed and endorsed. The committee also discussed the applicant's clarifications and considered them agreeable.
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/0301/2015 of 21/12/2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.8. Talimogene laherparepvec - EMEA-001251-PIP01-11-M02

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 application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted. The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision. The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.9. Finerenone - EMEA-001623-PIP01-14-M01

Bayer Pharma AG; Chronic Kidney Disease / Treatment of chronic kidney disease associated with proteinuria in addition to a therapy with ACEi or ARB

Day 60 opinion

Uro-nephrology

Summary of committee discussion:

The PDCO's view expressed at day 30 was re-discussed and 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/0025/2015 of 30 January 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.10. Metreleptin - Orphan - EMEA-001701-PIP01-14-M01

Aegerion Pharmaceuticals Ltd; Treatment of lipodystrophy

Day 30 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The PDCO discussed this procedure at day 30 on 8-11 November 2016.
Considering the above, the PDCO agreed that the changes requested 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/0194/2016 of 15 July 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. 2-hydroxypropyl-ß-cyclodextrin (HP-ß-CD) - Orphan - EMEA-001866-PIP01-15

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

Day 90 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

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

Day 90 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.3. Volanesorsen - Orphan - EMEA-001915-PIP01-15

Ionis Pharmaceuticals; Familial Chylomicronemia Syndrome

Day 90 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

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

Day 90 discussion

Haematology-Hemostaseology

3.1.5. vadadustat - EMEA-001944-PIP01-16

Anaemia secondary to chronic kidney disease / Treatment of anaemia secondary to chronic kidney disease

Day 90 discussion

Haematology-Hemostaseology

3.1.6. abatacept - EMEA-000118-PIP03-15

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

Day 90 discussion

Immunology-Rheumatology-Transplantation

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

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

Day 90 discussion

Infectious Diseases

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

Migraine headaches / Prophylaxis of migraine

Day 90 discussion

Neurology

3.1.9. EMEA-001428-PIP03-15

Major Depressive Disorder (MDD)

Day 90 discussion

Psychiatry

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

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

Day 90 discussion

Uro-nephrology / Haematology-Hemostaseology

3.1.11. Varicella-zoster virus (VZV), Oka/Merck, inactivated, vaccine - EMEA-001073-PIP02-14

Prevention of Varicella Zoster Virus disease / Prevention of HZ in immunocompromised patients from 1 to less than 18 years of age

Day 90 discussion

Vaccines

3.1.12. rAAV8-hUGT1A1 - Orphan - EMEA-002021-PIP01-16

GENETHON; Treatment of Crigler-Najjar syndrome / Treatment of Severe Crigler-Najjar syndrome requiring phototherapy

Day 60 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.13. Filgotinib - EMEA-001619-PIP03-16

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

Day 60 discussion

Gastroenterology-Hepatology

3.1.14. Methyl 3-((2R)-2-hydroxy-4-(((((S)-1-methoxy-1-oxopropan-2-yl) amino)(phenoxy)phosphoryl)oxy)-3,3-dimethylbutanamido)propanoate - Orphan - EMEA-002036-PIP01-16

Retrophin Europe Limited; Treatment of Pantothenate Kinase Associated Neurodegeneration (PKAN)

Day 60 discussion

Neurology

3.1.15. Sarizotan hydrochloride - Orphan - EMEA-001808-PIP02-16

Newron Pharmaceuticals SpA; Treatment of Rett syndrome

Day 60 discussion

Neurology

3.1.16. 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 60 discussion

Other

3.1.17. pimavanserin - EMEA-001688-PIP03-16

ACADIA Pharmaceuticals Inc.; Treatment of schizophrenia and other psychotic disorders

Day 60 opinion

Psychiatry

Summary of committee discussion:

The Committee reviewed and discussed the additional information received after Day 30, along with the assessors' comments, and considered all outstanding issues resolved. A positive opinion endorsing the modified PIP proposal has therefore been adopted.

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

Treatment of Acute Myocardial Infarction

Day 30 discussion

Cardiovascular Diseases

3.1.19. Candesartan cilexetil / Amlodipine besylate / Hydrochlorothiazide - EMEA-002024-PIP01-16

Treatment of essential hypertension (ICD9: 401, ICD10: I10)

Day 30 discussion

Cardiovascular Diseases

3.1.20. tadalafil / ambrisentan - EMEA-002030-PIP01-16

Pulmonary Arterial Hypertension

Day 30 discussion

Cardiovascular Diseases

3.1.21. Ligelizumab - EMEA-001811-PIP02-15

Treatment of chronic spontaneous urticaria / Treatment of chronic spontaneous urticaria

Day 30 discussion

Dermatology

3.1.22. EMEA-002039-PIP01-16

Treatment of uterine leiomyoma (fibroids), Treatment of endometriosis / Treatment of uterine fibroids, Treatment of endometriosis

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.23. Empagliflozin - EMEA-000828-PIP04-16

Treatment of type 1 diabetes mellitus

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.24. Synthetic double-stranded small interfering ribonucleic acid directed against delta-aminolevulinic acid synthase mRNA that is covalently linked to a ligand containing three N-acetylgalactosamine residues - EMEA-002048-PIP01-16

Acute Hepatic Porphyria (AHP)

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

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

Day 30 discussion

Gastroenterology-Hepatology

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

ProMetic BioTherapeutics Ltd; Plasminogen deficiency

Day 30 discussion

Haematology-Hemostaseology

3.1.27. anifrolumab - EMEA-001435-PIP02-16

Lupus nephritis, Systemic lupus erythematosis

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.1.28. EMEA-001989-PIP01-16

Staphylococcal skin infection / Treatment of acute bacterial skin and skin structure infections (ABSSSI) due to staphylococcus sensitive or resistant to meticillin

Day 30 discussion

Infectious Diseases

3.1.29. VIS410 (human immunoglobulin G1 monoclonal antibody directed against a unique, functionally conserved epitope on the influenza A haemagglutinin protein) - EMEA-001924-PIP01-15

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

Day 30 discussion

Infectious Diseases

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

ONXEO S.A.; Treatment of hepatocellular carcinoma / Treatment of hepatocellular carcinoma

Day 30 discussion

Oncology

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

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

Day 30 discussion

Oncology

3.1.32. 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 30 discussion

Ophthalmology

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

BioMarin International Limited; Treatment of achondroplasia / Treatment of achondroplasia

Day 30 discussion

Other

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

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

Day 30 discussion

Pneumology - Allergology

3.1.35. EMEA-002062-PIP01-16

Interstitial Cystitis/Bladder Pain Syndrome

Day 30 discussion

Uro-nephrology

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

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

Day 30 discussion

Haematology-Hemostaseology

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

LFB Biotechnologies; Treatment of congenital fibrinogen deficiency

Day 30 discussion

Haematology-Hemostaseology

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

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

Day 30 discussion

Infectious Diseases

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

Biogen Idec Ltd; Treatment of Multiple Sclerosis

Day 30 discussion

Neurology

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

United Therapeutics Europe Limited; Treatment of Neuroblastoma

Day 30 discussion

Oncology

3.2.6. Nilotinib - EMEA-C-000290-PIP01-08-M04

Novartis Europharm Ltd.; Treatment of chronic myeloid leukaemia

Day 30 opinion

Oncology

Summary of committee discussion:

The following completed study(ies)was/were checked for compliance:
The PDCO took note of preceding procedures and reports on partially completed compliance (EMEA-C1-000290-PIP01-08 and EMEA-C3-000290-PIP01-08-M04).
The PDCO adopted on 11 November 2016 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0297/2015) of 21 December 2015.

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

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

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

Day 30 discussion

Cardiovascular Diseases

3.3.2. ticagrelor - EMEA-000480-PIP01-08-M09

AstraZeneca AB; thromboembolic events (children), acute coronary syndrome / reduction in occurence of vaso- occlusive crisis in paediatric patients with sickle cell disease, waiver

Day 30 discussion

Cardiovascular Diseases / Haematology-Hemostaseology

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

Polichem SA; Treatment of onychomycosis / Treatment of onychomycosis

Day 30 discussion

Dermatology

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

Sanofi-aventis Recherche & Developpement; Prevention of cardiovascular events, Treatment of elevated cholesterol / Treatment of heterozygous and homozygous familial hypercholesterolemia, Proposed adult indication: to reduce the risk of cardiovascular events in adult patients with a history of an acute coronary syndrome.

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

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

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. Potassium chloride / Sodium chloride / Citric acid, anhydrous / Sodium citrate / Simeticone / Sodium sulphate, anhydrous / Macrogol 4000 - EMEA-001356-PIP02-12-M01

Alfa Wassermann S.p.A.; any clinical procedures requiring a clean bowel e.g. bowel endoscopy or radiology.

Day 30 discussion

Gastroenterology-Hepatology

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

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

Day 30 discussion

Haematology-Hemostaseology

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

Roche Registration Limited; Anaemia associated with chronic kidney disease

Day 30 discussion

Haematology-Hemostaseology

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

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

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.3.10. 4-amino-1-[5-chloro-2,5-dideoxy-2-fluoro-3-O-(2- methylpropanoyl)-4-[[(2-methylpropanoyl)oxy]methyl]-a- L-lyxofuranosyl]-2(1H)-pyrimidinone - EMEA-001758-PIP01-15-M01

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

Day 30 discussion

Infectious Diseases

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

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

Day 30 discussion

Infectious Diseases

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

Merck Sharp & Dohme (Europe), Inc.; treatment of chronic Hepatitis C infection / Treatment of chronic hepatitis C genotype 1, 4, and 6 infection with the combination regimen of MK-5172 and MK-8742 in children and adolescents from 3 years to less than 18 years of age with compensated liver disease who are previously untreated or who have failed previous Peg-Interferon/Interferon therapy with ribavirin with or without cirrhosis.

Day 30 discussion

Infectious Diseases

3.3.13. Rilpivirine (RPV) / Dolutegravir (DTG) - EMEA-001750-PIP01-15-M01

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

Day 30 discussion

Infectious Diseases

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

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

Day 30 discussion

Infectious Diseases

3.3.15. Amikacin sulfate - Orphan - EMEA-000525-PIP01-08-M05

Insmed Limited; Treatment of nontuberculous mycobacterial (NTM) lung infection / Treatment of nontuberculous mycobacterial (NTM) lung infection

Day 30 discussion

Infectious Diseases / Pneumology - Allergology

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

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

Day 30 discussion

Neonatology - Paediatric Intensive Care

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

Neurochlore; Autism Spectrum Disorder / Treatment of AutiSm Spectrum Disorder

Day 30 discussion

Neurology

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

CHUGAI PHARMA EUROPE LTD.; neuromyelitis optica

Day 30 discussion

Neurology

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

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

Day 30 discussion

Neurology

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

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

Day 30 discussion

Oncology

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

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

Day 30 discussion

Oncology

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

Novartis Europharm Ltd; C92.0 Acute myeloid leukaemia, C94.3 Mast cell leukaemia, C96.2 Malignant mastocytosis / Treatment of paediatric patients with FLT3 mutated AML, newly diagnosed

Day 30 discussion

Oncology

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

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

Day 30 discussion

Oncology

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

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

Day 30 discussion

Oncology

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

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

Day 30 discussion

Ophthalmology

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

Vifor Fresenius Medical Care Renal Pharma France; Hyperkalaemia

Day 30 discussion

Other

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

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

Day 30 discussion

Other / Dermatology

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

Vectura Limited; Treatment of asthma

Day 30 discussion

Pneumology - Allergology

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

sanofi-aventis recherche & développement; Asthma

Day 30 discussion

Pneumology - Allergology

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

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

Day 30 discussion

Pneumology - Allergology

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

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

Day 30 discussion

Vaccines

4. Nominations

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

4.1. List of letters of intent received for submission of applications with start of procedure February 2017 for Nomination of Rapporteur and Peer reviewer

Summary of committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

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

Summary of committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

4.3. Nominations for other activities

4.3.1. Nomination of PDCO member in the SmPC Advisory Group

PDCO Chair: Dirk Mentzer

Summary of committee discussion:

Siri Wang was appointed as PDCO representative in the SmPC Advisory Group.

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. Istradefylline - EMEA-31-2016

Kyowa Kirin Limited; Treatment of Parkinson's disease (non-juvenile)/ Treatment of moderate to severe Parkinson's disease

Summary of committee discussion:

The applicability of the class waiver as referred to in the Agency's Decision CW/1/2011 to the planned therapeutic indication was confirmed.

Other potential paediatric interest of this medicine suggested by PDCO: juvenile Parkinson´s disease

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. Anti-HER2 antibody-drug conjugate - EMEA-32-2016

Synthon Biopharmaceuticals BV; The class of Her- / epidermal growth factor-receptor antibody medicinal products for treatment of breast malignant neoplasms/ Monotherapy treatment of adult patients with HER2-positive, unresectable locally advanced or metastatic breast cancer who have previously been treated with at least two HER2-targeting treatment

regimens

Summary of committee discussion:

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

Other potential paediatric interest of this medicine suggested by PDCO: osteosarcoma known to be associated with significant ERBB2 expression, preclinical studies in other paediatric solid tumours are also suggested.

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. Elections of PDCO Vice-Chair

PDCO Chair: Dirk Mentzer

Summary of committee discussion:

The PDCO was reminded of the 'Procedure for the election of the PDCO Vice-Chair, according to which the election was conducted.

The PDCO noted the candidature of Koenraad Norga who had the opportunity to express in a short statement the motivation for which he was standing. Then, the PDCO proceeded with the election by secret ballot.

Koenraad Norga was elected as Vice-Chair.

9.2. Coordination with EMA Scientific Committees or CMDh-v

9.2.1. Committee for Medicinal Products for Human Use (CHMP)

Summary of committee discussion:

The PDCO members were informed about 2 medicinal products, Cystadrops and Zebinix for which the CHMP adopted a positive opinion recommending paediatric indication during their meeting in October 2016. A paediatric formulation, oral suspension 50 mg/ml, was approved for use in children.

9.2.2. Good practice guide (GPG) on recording, coding, reporting and assessment of medication errors: relevant recommendations for paediatric population

Summary of committee discussion:

The PDCO was presented with an outline of the current content of the best practice guide on medication errors concerning the paediatric population as well as some cases gathered after the first year of implementation of the guidance and a summary relevant paediatric data contained in EudraVigilance regarding paediatric cases as presented during a recent workshop organised at the EMA premises. The PDCO highlighted the relevance of such emerging knowledge for paediatric development and will welcome further updated in the future.

9.2.3. Referral under Article 31 of Directive 2001/83/EC for Vancomycin containing products

Summary of committee discussion:

The PDCO was presented with an outline of an ongoing referral procedure concerning products containing vancomycin. CHMP referred to the PDCO the question

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:

Based on PDCO discussions, the products requiring Formulation Working Group evaluation and discussion were identified.

9.3.3. Formulation Working Group session at PDCO

PDCO member: Brian Aylward

Delegation attending PDCO

Summary of committee discussion:

PDCO and FWG Members discussed ways to improve the interaction between the two groups and highlighted relevant formulation-specific topics on which the groups should concentrate their attention.

9.3.4. Finalisation of Post-Authorisation Efficacy Study (PAES) scientific guidance

Summary of committee discussion:

General feedback was received from PDCO on the draft for adoption. This largely related to the concept of compliance with requests for PAES to be conducted and it was clarified that the same requirements as for post-authorisation safety studies apply

There were no specific comments on the text and so the draft was adopted as proposed.

9.4. Cooperation within the EU regulatory network

9.4.1. European Network of Paediatric Research at EMA (EnprEMA)

Summary of committee discussion:

In the framework of the planned exchange of information and interaction between PDCO and Enpr-EMA, some National networks (from France, Finland and UK) were invited to PDCO to present their activities and their views on how to maximize synergies in promoting paediatric research.

The PDCO congratulated their excellent work and discussed options to improve a mutual exchange of information.

Training in regulatory science and procedures for members of networks was stressed as an important first step to be undertaken.

Direct expert input from individuals working in networks to PIPs will have to follow the rules for involvement of EU nominated experts and related EMA policy for undertaking of confidentiality agreement and evaluation of any conflict of interest.

The committee also agreed to increasingly encourage sponsors to seek early input from networks when preparing a PIP or modification application.

In addition, the PDCO explicitly expressed the wish to receive feedback from networks on the conduct of ongoing trials as part of the PIPs, which can be communicated to the committee at regular interaction meetings planned for 2017 to which members of the EnprEMA network will be invited to present their activity at PDCO.

9.4.2. Report from the expert meeting of the Pharmaceutical Committee held in Brussels on 19 September 2016

Summary of committee discussion:

The Committee was informed that on 19 September the European Commission held an expert meeting of the Pharmaceutical Committee in Brussels, entirely dedicated to the Paediatric Regulation. The scope of the meeting was to obtain feedback from the representatives of the member states on the results and the challenges encountered in the

implementation of the regulation at national level. The Chair and the vice-Chair of the PDCO attended, together with 2 staff members from EMA; in addition, some of the representatives nominated by the member states were also PDCO members. The expert group heard a presentation on the EMA/PDCO report and the lessons learned in terms of public health, and another one by the EC appointed contractors on the economic results analysis. The report on the meeting is published on the EC website: http://ec.europa.eu/health/files/paediatrics/2016_09_19_paediatric_meeting_report.pdf.

9.5. Cooperation with International Regulators

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

PDCO member: Sylvie Benchetrit

Summary of committee discussion:

The topic was postponed to the PDCO December 2016 meeting.

9.5.2. FDA and SmartTots (Strategies for Mitigating Anesthesia-Related neuroToxicity in Tots) initiative: Defining Safe Use of Anesthesia in Children and interpretation of non-clinical evidence

PDCO member: Jacqueline Carleer

Summary of committee discussion:

The EMA had been previously informed of the SmartTots initiative carried out by the FDA and by recent updates of the product information promoted by the FDA to reflect the non-clinical findings accrued so far in the area of products used for paediatric anaesthesia. A member of the PDCO who presented an overview of current con-clinical evidence available mentioned that indeed there is an increase of study findings for which assessment would need to be carried forward with the aim to understand any clinical implication. The PDCO will circulate to PRAC such minutes and the presentation for their information.

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

None

9.7. PDCO work plan

9.7.1. PDCO Work-plan 2017

Summary of committee discussion:

The Committee discussed the latest version of the PDCO work plan 2017. Few changes in identified resources for specific activities were suggested. The revised version will be distributed for endorsement at the PDCO December 2016 meeting.

9.8. Planning and reporting

9.8.1. Report from the Strategic Review and Learning Meeting (SRLM) held in Brussels on 19-21 October 2016

PDCO Chair: Dirk Mentzer

Summary of committee discussion:

The Strategic Review and Learning Meeting was held in Brussels on 19 September 2016, with a full day joint CHMP-PDCO meeting. Further collaboration aspects between the two committees were discussed, including the possible nomination of a CHMP expert for selected PDCO procedures, PDCO experts for centralised procedure at CHMP, joint sessions PDCO-CHMP during the plenary meeting at EMA, and interactions between the two Committees. The meeting was well attended and saw a climate of collaboration and mutual understanding throughout the discussions.

9.8.2. Draft Agenda of the Strategic Review and Learning Meeting (SRLM) to be held in Malta on 12-14 April 2017

PDCO member: John Joseph Borg

Summary of committee discussion:

The PDCO noted the proposed Agenda for the Strategic Review and Learning Meeting (SRLM) to be held in Malta, April 2017.

10. Any other business

None

11. Breakout sessions

11.1.1. Paediatric oncology

Summary of committee discussion:

The participants discussed reports on the recent SIOP and CAC2 meetings as well as an early / phase 1 trial in children with cancer.

11.1.2. Neonatology

Summary of committee discussion:

Issues concerning currently discussed PIP procedures were discussed as well as approaches to investigate 'neonatal sepsis'.

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 8-11 November 2016 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Dirk Mentzer	Chair	Germany	No interests declared	
Karl-Heinz Huemer	Member	Austria	No interests declared	
Koenraad Norga	Member (Vice-Chair)	Belgium	No restrictions applicable to this meeting	
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-000978-PIP03-16 EMEA-000172-PIP01-07-M02 EMEA-000310-PIP03-10-M02
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	
Jana Lass	Alternate	Estonia	No interests declared	
Ann Marie Kaukonen	Member	Finland	No interests declared	
Maija Pihlajamaki	Alternate	Finland	No interests declared	
Sylvie Benchetrit	Member	France	No interests declared	
Sabine Scherer	Member	Germany	No interests declared	
Immanuel Barth	Alternate	Germany	No interests declared	
Eleni Katsomiti	Member	Greece	No interests declared	
Ágnes Gyurasics	Member (CHMP member)	Hungary	No interests declared	
Brian Aylward	Member	Ireland	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Sara Galluzzo *via TC*	Member	Italy	No interests declared	
Dina Apele-Freimane	Member	Latvia	No interests declared	
Carola de Beaufort	Member (CHMP alternate)	Luxembourg	No restrictions applicable to this meeting	
John-Joseph Borg	Member	Malta	No interests declared	
Maaike van Dartel	Member	Netherlands	No interests declared	
Siri Wang	Member	Norway	No interests declared	
Marek Migdal	Member	Poland	No interests declared	
Helena Fonseca	Member	Portugal	No interests declared	
Hugo Tavares	Alternate	Portugal	No interests declared	
Dana Gabriela Marin	Member (CHMP alternate)	Romania	No interests declared	
Nela Vilceanu	Alternate (CHMP member)	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 final deliberations and voting on:	EMEA-001308-PIP01-12-M01
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	
Günther Auerswald	Member	Patients'	No restrictions	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
		Organisation Representative	applicable to this meeting	
Paola Baiardi	Alternate	Patients' Organisation Representative	No interests declared	
Tsvetana Schyns-Liharska	Member	Patients' Organisation Representative	No restrictions applicable to this meeting	
Sara Homer	Expert - in person*	United Kingdom	No interests declared	
Shiva Ramroop	Expert - in person*	United Kingdom	No restrictions applicable to this meeting	
Salma Malik	Expert - in person*	European Network of Paediatric Research (Enpr)	No interests declared	
Mark Turner	Expert -via telephone*	European Network of Paediatric Research (Enpr)	No restrictions applicable to this meeting	
Pirkko Lepola	Expert -via telephone*	European Network of Paediatric Research (Enpr)	No interests declared	
Anthony Nunn	Member	PDCO Formulation Working Group	No interests declared	
Isabelle Delneuville	Member	PDCO Formulation Working Group	No interests declared	
Sara Arenas-Lopez	Member	PDCO Formulation Working Group	No interests declared	
Anne Paavola	Member	PDCO Formulation Working Group	No interests declared	
Daniela Reins	Member	PDCO Formulation Working Group	No interests declared	
Vroom Fokaline	Member	PDCO Formulation Working Group	No interests declared	
Adela Núñez Velázquez	Member	PDCO Formulation Working	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
		Group		
Anna-Lena Axelson	Member	PDCO Formulation Working Group	No interests declared	
Karin Bracht	Member	PDCO Formulation Working Group	No interests declared	
Gary Inwards	Member	PDCO Formulation Working Group	No interests declared	
Filip Josephson	CHMP Alternate	Sweden	No interests declared	
Meeting run with support from relevant EMA staff				

* Experts were only evaluated against the agenda topics or activities they participated in.

13. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

Paediatric investigation plan (PIP) (section 2.1 Opinion on PIPs and section 3.1 Discussions on PIPs)
A paediatric investigation plan (PIP) is a development plan aimed at ensuring that the necessary data are obtained through studies in children, when it is safe to do so, to support the authorisation of a medicine for children. Pharmaceutical companies submit proposals for PIPs to the European Medicines Agency's Paediatric Committee (PDCO). This Committee is responsible for agreeing or refusing the plan.

Compliance checks (section 2.2 Opinions on Compliance check, section 3.2 Discussions on Compliance check)
A compliance check may be necessary before any application for marketing authorisation (even for an adult indication) can be considered valid, if there was no deferral for at least one of the studies agreed in the PIP, or after the due date of initiation or completion of a study/measure. The same applies to some regulatory applications for authorised products, as described above.

Modification of an Agreed Paediatric Investigation Plan (section 2.3 Opinions on Modification of an agreed PIP, section 3.3 Discussions on Modification of an agreed PIP)
The development plan for a medicine can be modified at a later stage as knowledge increases. Modifications can also be made if the applicant encounters such difficulties with the implementation of a PIP, which render it unworkable or no longer appropriate.
In some cases, studies can be deferred until after the studies in adults have been conducted. This ensures that research in children is done only when it is safe and ethical to do so. Even when studies are deferred, the PIP will include details of the paediatric studies and their timelines.

Class waiver (section 6 Discussion on the applicability of class waiver)
As some diseases do not affect children (for example Parkinson's disease), the development of medicines for these diseases should not be performed in children. In these cases, a PIP is not required and it will be waived**.** For more information on the classes of diseases subject to waivers, see class waivers.

Annual reports on deferrals (section 8)
If the medicinal product is approved in the EU, annual reports on the deferred measures in the PIP must be submitted to the Agency.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/