14 September 2016
EMA/PDCO/557629/2016 Rev.2
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Minutes for the meeting on 17-19 August 2016

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

17 August 2016, 08:30- 19:00, room 3A

18 August 2016, 08:30- 19:00, room 3A

19 August 2016, 08:30- 13:00, room 3A

Disclaimers

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

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

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

Note on access to documents

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

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1. Introductions

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

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

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

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

1.2. Adoption of agenda

The agenda was adopted with amendments.

1.3. Adoption of the minutes

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

2. Opinions

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

2.1. Opinions on Products

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

Bristol-Myers Squibb International Corporation; Treatment of Duchenne Muscular Dystrophy / Treatment of Duchenne Muscular Dystrophy in patients aged ≥2 years to <18 years

Day 120 opinion

Neurology

Summary of committee discussion:

The Paediatric Committee endorsed a revision of the D90 PDCO Minutes

Based on the assessment of this application, the PDCO adopted a positive opinion for Bivalent anti-human myostatin adnectin recombinant human IgG1-Fc fusion protein in the condition of Treatment of Duchenne Muscular Dystrophy, grating a PIP with a waiver and a deferral.

2.1.2. copanlisib - EMEA-001757-PIP02-15

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

Day 120 opinion

Oncology

Summary of committee discussion:

The PDCO considered that a paediatric development may not be of therapeutic benefit in this situation. This scientific assessment may change with further discovery and data on mature B-cell lymphomas and molecular mechanisms in children and adults related to the pharmacology of copanlisib. A waiver related to the lack of significant benefit was therefore granted.

2.1.3. Guadecitabine - EMEA-001730-PIP02-15

Otsuka Europe Development and Commercialisation Ltd.; Treatment of acute myeloid leukemia / Adults with Previously Untreated Acute Myeloid Leukemia (AML) Who Are Not Considered Candidates or unfit for Intensive Remission Induction Chemotherapy, Treatment of pediatric subjects age 3 months or older to less than 18 years with relapsed refractory AML after failure of intensive remission induction chemotherapy

Day 120 opinion

Oncology

Summary of committee discussion:

The PDCO discussed on 19 August 2016 the application for agreement of a PIP for guadecitabine for treatment of acute myeloid leukaemia (AML), taking into account answers of an external expert (telephone conference 27 July 2016) and the applicant’s comments on a draft Opinion.
Similar to other PIPs, the PDCO agreed also a waiver.

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

Dyax Corp.; Hereditary angioedema / Treatment of hereditary angioedema

Day 120 opinion

Other

Summary of committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee agrees with the applicant's proposal. The PDCO recommends granting a waiver for Recombinant, CHO cell expressed, fully human IgG1, kappa light chain, monoclonal antibody for the subsets of the paediatric population less than 2 year of age in the condition of Hereditary angioedema.

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

ALK Abelló A/S; treatment of allergic rhinitis and/or conjunctivitis / treatment of ragweed pollen allergic rhinitis and/or conjunctivitis

Day 120 opinion

Pneumology - Allergology

Summary of committee discussion:

All issues are considered resolved satisfactorily at Day 120.
The PDCO granted a waiver for ragweed pollen extract in children less than 5 years of age.
A deferral was granted for the clinical paediatric study.
The PDCO adopted a positive opinion.

2.1.6. 18F fluoromisonidazole - EMEA-001977-PIP02-16

RadioMedic s.r.o.; Imaging of hypoxic tissue in Non-small Cell Lung Cancer (NSCLC) for diagnostic purposes, Imaging of hypoxic tissue in Renal Cell Carcinoma (RCC) for diagnostic purposes, Imaging of hypoxic tissue in Gliomas for diagnostic purposes, Imaging of hypoxic tissue in Head and Neck Squamous Cell Carcinoma (HNSCC) for diagnostic purposes

Day 60 opinion

Diagnostic / Oncology

Summary of committee discussion:

The PDCO discussed on 17 August 2016 the application for the granting of a waiver for 18FMISO, taking into account the applicant’s supplementary information and the applicant’s comments on a draft Opinion.
Based on the assessment of this application and further discussions at the Paediatric Committee including contributions of external experts, the PDCO refused the applicant's request for the granting a waiver for 18F fluoromisonidazole for all subsets of the paediatric population (birth to less than 18 years of age).

2.1.7. Recombinant respiratory syncytial virus vaccine - EMEA-001966-PIP01-16

MedImmune Limited; Prevention of RSV disease

Day 60 opinion

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 Recombinant respiratory syncytial virus vaccine for all subsets of the paediatric population (0 to 18 years of age) in the condition of Prevention of lower respiratory tract disease caused by respiratory syncytial virus.

2.1.8. lifitegrast - EMEA-001979-PIP01-16

Shire Pharmaceuticals Ireland Limited; Treatment of dry eye disease

Day 60 opinion

Ophthalmology

Summary of committee discussion:

A positive opinion was adopted on D60.
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 lifitegrast for all subsets of the paediatric population (0 to 18 years of age) in the condition of Treatment of dry eye disease.

2.1.9. paracetamol / ibuprofen - EMEA-002002-PIP01-16

FARMALIDER, S.A; Treatment of pain

Day 60 opinion

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 recommends granting a waiver for ibuprofen / paracetamol for all subsets of the paediatric population (0 to 18 years of age) in the condition of Treatment of pain.
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. Pitavastatin calcium - EMEA-C-000054-PIP01-07-M04

Kowa Pharmaceutical Europe Co. Ltd.; Treatment of disorders of lipoprotein metabolism and other lipidaemias

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The PDCO adopted on 19 August 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/0095/2016 of 15 April 2016)

2.2.2. Pitavastatin calcium - EMEA-C-000300-PIP01-08-M04

Kowa Pharmaceutical Europe Co. Ltd.; Treatment of disorders of lipoprotein metabolism and other lipidaemias

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The PDCO adopted on 19 August 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/0096/2016 of 15 April 2016).

2.2.3. icatibant - EMEA-C-000408-PIP01-08-M05

Shire Orphan Therapies GmbH; Treatment of hereditary angioedema (HAE)

Day 60 opinion

Other

Summary of committee discussion:

The PDCO re-discussed the compliance request on 17 August 2016 taking into account the additional information/documents provided by the applicant on 03 August 2016 and all the pending issues were considered solved.
The PDCO adopted an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0243/2015) of 30 October 2015.

2.2.4. deferasirox - EMEA-C5-001103-PIP01-10-M03

Novartis Europharm Limited; Treatment of chronic iron overload requiring chelation therapy

Day 30 opinion

Haematology-Hemostaseology

Summary of committee discussion:

The PDCO discussed the completed study and considered that all completed studies are compliant with the latest Agency's Decision (P/0175/2016) of 30 June 2016.
The PDCO finalised on 19 August 2016 this partially completed compliance procedure and confirmed the compliance of all those studies contained in the agreed paediatric investigation plan that were to be completed until this date.

2.2.5. pazopanib - EMEA-C4-000601-PIP01-09-M03

Novartis Europharm Limited; Non-rhabdomyosarcoma soft tissue sarcoma

Day 30 opinion

Oncology

Summary of committee discussion:

The PDCO discussed the completed study and considered that this is compliant with the latest Agency's Decision (P/0061/2016) of 18 March 2016.

2.2.6. Solithromycin – EMEA-C2-001581-PIP01-13-M03

Triskel EU Services, Ltd; Treatment of bacterial pneumonia/Treatment of tularaemia/ Treatment of anthrax

Day 1 opinion

Summary of committee discussion:

The PDCO was reminded about the written procedure which finalised on 9 August 2016 with a positive result.

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. apixaban - EMEA-000183-PIP01-08-M04

Bristol-Myers Squibb / Pfizer EEIG; Prevention of arterial thromboembolism, Prevention of venous thromboembolism / Prevention of venous thromboembolism (VTE) in paediatric subjects (1 to <18 years old) with a newly diagnosed acute lymphoblastic leukemia (ALL) or lymphoma (T or B cell), a functioning central venous access device (CVAD) and receiving PEG L-asparaginase during chemotherapy induction., Prevention of TE in paediatric patients (birth to below 18 years old) with cardiac disease.

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted. The PDCO therefore adopted a favourable Opinion on the modification of the

agreed PIP as set in the Agency's latest decision (P/0110/2015 of 05 June 2015). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.2. selepressin - EMEA-000506-PIP01-08-M02

Ferring Pharmaceuticals A/S; Septic shock / Vasopressor-dependent Septic Shock

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan and the additional clarification after D30, 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/0013/2016 of 29 January 2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.3. albiglutide - EMEA-001175-PIP01-11-M04

Glaxo Group Limited; Non-insulin dependent diabetes mellitus / type 2 diabetes mellitus

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0023/2016 of 29/01/2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.4. Alogliptin benzoate (as alogliptin) - EMEA-000496-PIP01-08-M05

Takeda Development Centre Europe Ltd; Type 2 diabetes melitus

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted (as per above).
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0114/2015 of 05/06/2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.5. Sapropterin Dihydrochloride - Orphan - EMEA-001476-PIP01-13-M01

BioMarin International Limited; Hyperphenylalaninemia / BH4 deficiency, Phenylketonuria

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed change – 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/0232/2013 of 23 September 2013).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.6. eftrenonacog alfa - Orphan - EMEA-000914-PIP01-10-M03

Biogen Idec Ltd; Hereditary Factor IX Deficiency - D67

Day 60 opinion

Haematology-Hemostaseology

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/0303/2014 of 24 November 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.7. Autologous CD34+ cells transduced with lentiviral vector containing the human Wiskott Aldrich Syndrom Protein gene - Orphan - EMEA-000786-PIP01-09-M02

Genethon; Treatment of Wiskott-Aldrich syndrome

Day 60 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted. The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0137/2014 of 11 June 2014). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.8. Delamanid - Orphan - EMEA-001113-PIP01-10-M05

Otsuka Europe Development and Commercialisation Ltd.; Treatment of multi drug resistant tuberculosis / Treatment of multi drug resistant tuberculosis

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

The PDCO adopted a positive opinion on the request for modification.

2.3.9. Elvitegravir - EMEA-000968-PIP02-11-M05

Gilead Sciences International Ltd; Human immunodeficiency virus [HIV] disease resulting in other conditions [ICD-10: B23] / indicated for use with a pharmacoenhancer and other antiretroviral agents for the treatment of HIV-1 infection in paediatric patients aged < 18 years.

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted. The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0265/2015 of 06 November 2015). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.10. Tedizolid phosphate - EMEA-001379-PIP01-12-M02

Merck Sharp & Dohme (Europe), Inc.; Treatment of complicated skin and soft tissue infections / Treatment of complicated skin and soft tissue infections

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

The committee's view expressed on day 30 was re-discussed and endorsed. The committee also endorsed the conclusions of the Formulation Working Group.
The PDCO therefore adopted a favourable Opinion on some but not all modifications of the agreed PIP as set in the Agency's latest decision (P/0258/2014 of 1 October 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.11. nusinersen - Orphan - EMEA-001448-PIP01-13-M02

Biogen Idec Ltd; Spinal muscular atrophy

Day 60 opinion

Neurology

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.

The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0082/2014 of 31 March 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.12. Recombinant Human TriPeptidyl Peptidase 1 (rhTPP1) - Orphan - EMEA-001362-PIP01-12-M03

BioMarin International Limited; Neuronal Ceroid Lipofuscinosis Type 2 (NCL2) / Treatment of Neuronal Ceroid Lipofuscinosis Type 2 (NCL2)

Day 60 opinion

Neurology

Summary of committee discussion:

The retrospective modifications of study 190-201 (age range at inclusion, Csteady state evaluation and measurement of total Hamburg score at screening) were endorsed.

The PDCO adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0209/2015 of 18 September 2015).

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

2.3.13. zuretinol acetate - Orphan - EMEA-001453-PIP01-13-M01

QLT Ophthalmics (UK), Ltd.; Retinitis Pigmentosa, Leber Congenital Amaurosis / Treatment of patients with Inherited Retinal Disease who have been phenotypically diagnosed as LCA or RP caused by mutations in retinal pigment epithelium protein 65 (RPE65) or lecithin: retinol acyltransferase (LRAT) genes

Day 60 opinion

Ophthalmology

Summary of committee discussion:

The applicant's responses to the D30 issues were acknowledged. 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/0023/2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.14. Human recombinant IgG1 monoclonal antibody targeting fibroblast growth factor 23 (FGF23) - Orphan - EMEA-001659-PIP01-15-M01

Ultragenyx Pharmaceutical Inc.; X-linked Hypophosphatemia

Day 60 opinion

Other

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0144/2016 of 23/5/2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.15. Human Thrombin (component 2) / Human Fibrinogen (component 1) - EMEA-001598-PIP01-13-M02

Instituto Grifols, S.A.; Treatment of haemorrhage resulting from a surgical procedure / Supportive treatment in surgery where standard surgical techniques are insufficient for improvement of haemostasis, and as a suture support in vascular surgery

Day 60 opinion

Other

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could not be accepted.
The PDCO therefore adopted a negative Opinion on the modification of the agreed PIP as set in the Agency's latest decision.
All the details and elements of the existing PIP remain therefore unchanged.

2.3.16. Peanut flour - EMEA-001734-PIP01-14-M01

Aimmune Therapeutics; Peanut Allergy / Peanut oral immunotherapy for the reduction in clinical reactivity to accidental exposure in peanut allergic children and adults

Day 60 opinion

Pneumology - Allergology

Summary of committee discussion:

The PDCO adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0222/2015 of 2 October 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.17. Reslizumab - EMEA-001202-PIP02-13-M01

Teva Pharmaceuticals Europe; Treatment of asthma / indicated as add- on treatment in adult patients with severe eosinophilic asthma

Day 60 opinion

Pneumology - Allergology

Summary of committee discussion:

The PDCO adopted a favourable Opinion on the modification of the agreed PIP as set in the

Agency's latest decision (P/0017/2015 of 30 January 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.18. vilanterol / fluticasone furoate - EMEA-000431-PIP01-08-M09

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

Day 60 opinion

Pneumology - Allergology

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/0164/2015 of 07 August 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.4. Opinions on Re-examinations

2.4.1. dulaglutide - EMEA-000783-PIP01-09-M04

Eli Lilly & Company; Type 2 diabetes mellitus

Day 30 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The Paediatric Committee, following the re-examination, adopted a positive Opinion on the PIP Modification request.

2.4.2. ivacaftor / lumacaftor - EMEA-001582-PIP01-13-M04

Vertex Pharmaceuticals (Europe) Limited; cystic fibrosis / Treatment of cystic fibrosis

Day 30 opinion

Other

Summary of committee discussion:

The committee adopted the partially revised final opinion on the request for modification.

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. Ascorbic Acid / Sodium Ascorbate / Potassium Chloride / Sodium Chloride / Sodium Sulfate / Macrogol 3350 - EMEA-001705-PIP02-15

Diagnosis of large intestine disorders / For bowel cleansing prior to any clinical procedures requiring a clean bowel e.g. bowel endoscopy or radiology

Day 90 discussion

Gastroenterology-Hepatology

3.1.2. Monoclonal IgG1 anti-influenza A antibody - EMEA-001831-PIP01-15

Treatment of influenza / Treatment of patients hospitalised with severe influenza A virus infection

Day 90 discussion

Infectious Diseases

3.1.3. Immunoglobulin G2 - EMEA-001877-PIP01-15

Episodic Migraine, Chronic Migraine / Prophylaxis of headache in children aged 12 to 18 years with chronic migraine, Prophylaxis of headache in children aged 6 to 18 years with episodic migraine

Day 90 discussion

Neurology

3.1.4. Humanised chimeric antibody with a humanised H chain and a chimeric (mouse V-domain, human C-domain) L chain against epidermal growth factor receptor conjugated to maleimidocaproyl monomethylauristatin F - Orphan - EMEA-001732-PIP02-15

AbbVie Ltd; Treatment of high-grade glioma. / Treatment of high-grade glioma.

Day 90 discussion

Oncology

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

Treatment of allergic rhinitis / rhino-conjunctivitis / Treatment of tree pollen allergic rhinitis and / or conjunctivitis

Day 90 discussion

Pneumology - Allergology

3.1.6. Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Victoria lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain B (Yamagata lineage) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H3N2) / Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) - EMEA-001894-PIP01-15

Prevention of influenza

Day 90 discussion

Vaccines

3.1.7. Human bone marrow-derived allogeneic mesenchymal precursor cells (MPCs) - EMEA-001827-PIP02-16

chronic heart failure

Day 60 discussion

Cardiovascular Diseases

3.1.8. Allogeneic, non-expanded, umbilical Cord blood-derived, hematopoietic mature myeloid and lymphoid cells (NF) / Allogeneic, ex vivo expanded, umbilical Cord blood-derived, hematopoietic CD34+ progenitor cells (CF) - Orphan - EMEA-001913-PIP01-15

Gamida Cell Limited; acute lymphoblastic leukaemia, myelodysplastic syndrome, acute myeloid leukaemia, chronic myeloid leukaemia / haematopoietic reconstitution of patients who are medically indicated for allogeneic haematopoietic stem cell transplantation

Day 60 discussion

Haematology-Hemostaseology

3.1.9. EMEA-001741-PIP02-16

Treatment of Ulcerative Colitis

Day 60 discussion

Immunology-Rheumatology-Transplantation

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

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

Day 60 discussion

Immunology-Rheumatology-Transplantation

3.1.11. blisibimod - EMEA-001972-PIP01-16

systemic lupus erythematosus

Day 60 discussion

Immunology-Rheumatology-Transplantation

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

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

Day 60 discussion

Immunology-Rheumatology-Transplantation / Oncology

3.1.13. EMEA-001975-PIP01-16

Treatment of influenza

Day 60 discussion

Infectious Diseases

3.1.14. Eubacterial Spores, Purified Suspension, Encapsulated - EMEA-001970-PIP01-16

ICD10 code A04.7: Enterocolitis due to Clostridium difficile / SER-109 is indicated as a treatment, at the completion of antibiotic therapy, of paediatric patients with active recurrent Clostridium difficile infection to prevent further recurrence

Day 60 discussion

Infectious Diseases

3.1.15. Fevipiprant - EMEA-001315-PIP02-16

Asthma / Treatment of moderate to severe asthma

Day 60 discussion

Pneumology - Allergology

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

Treatment of cystic fibrosis

Day 60 discussion

Pneumology - Allergology

3.1.17. 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 60 discussion

Vaccines

3.1.18. Amlodipine / Candesartan - EMEA-002014-PIP01-16

Hypertension

Day 30 discussion

Cardiovascular Diseases

3.1.19. Amlodipine / Perindopril - EMEA-001968-PIP01-16

Hypertension

Day 30 discussion

Cardiovascular Diseases

3.1.20. Hydrochlorothiazide / Valsartan / Amlodipine - EMEA-002006-PIP01-16

Essential hypertension / Treatment of essential hypertension as substitution therapy in adult patients whose blood pressure is adequately controlled on the combination of amlodipine, valsartan and hydrochlorothiazide (HCT), taken either as three single-component formulations or as a dual-component and a single-component formulation

Day 30 discussion

Cardiovascular Diseases

3.1.21. EMEA-001983-PIP01-16

Monitoring of renal function

Day 30 discussion

Diagnostic / Uro-nephrology

3.1.22. triheptanoin - Orphan - EMEA-001920-PIP02-16

Ultragenyx Pharmaceutical Inc.; Mitochondrial trifunctional protein (TFP) deficiency, Long-chain 3 hydroxyacyl-CoA dehydrogenase (LCHAD) deficiency, Carnitine palmitoyl transferase 2 (CPT-II) deficiency, Very long-chain acyl-CoA dehydrogenase (VLCAD) deficiency

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.23. Atorvastatin / Amlodipine - EMEA-002005-PIP01-16

Treatment of concomitant angina and dyslipidaemia, Prevention of cardiovascular events in hypertensive patients and diabetes mellitus type 2 patients with multiple risk factors for cardiovascular disease, Treatment of concomitant hypertension and dyslipidaemia / Substitution therapy in patients already taking concomitantly amlodipine and atorvastatin mono-products for the management of: Concomitant hypertension and dyslipidaemia, Substitution therapy in patients already taking concomitantly amlodipine and atorvastatin mono-products for the management of: Concomitant angina and dyslipidaemia, Substitution therapy in patients already taking concomitantly amlodipine and atorvastatin mono-products for the management of: Prevention of cardiovascular events in hypertensive patients and diabetes mellitus type 2 patients with multiple risk factors for cardiovascular disease

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases

3.1.24. Amiselimod - EMEA-001991-PIP01-16

Ulcerative colitis / Treatment of moderately to severely active ulcerative colitis

Day 30 discussion

Gastroenterology-Hepatology

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

Treatment of non-alcoholic steatohepatitis (NASH) in subjects with liver fibrosis

Day 30 discussion

Gastroenterology-Hepatology

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

Treatment of congenital fibrinogen deficiency

Day 30 discussion

Haematology-Hemostaseology

3.1.27. Pomalidomide - Orphan - EMEA-001457-PIP02-16

Celgene Europe Limited; Treatment of multiple myeloma / in combination with dexamethasone is indicated in the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy

Day 30 discussion

Haematology-Hemostaseology

3.1.28. Sirukumab - EMEA-001043-PIP02-16

Adults: Giant Cell Arteritis, Children: Paediatric vasculitides / N.A., Treatment of vasculitides

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.1.29. tazobactam / ceftolozane - EMEA-001142-PIP02-16

Treatment of abdominal and gastrointestinal infections, Treatment of urinary tract infections, Treatment of pneumonia / Treatment of nosocomial pneumonia, Treatment of complicated intra-abdominal infections (cIAI). Please refer to EMA decision (P/0126/2014) in relation to procedure EMEA-001142-PIP-01-11-M01., Treatment of complicated urinary tract infections (cUTI). Please refer to EMA decision (P/0126/2014) in relation to procedure EMEA-001142-PIP-01-11-M01

Day 30 discussion

Infectious Diseases

3.1.30. Gentamicin sulphate - EMEA-001982-PIP01-16

Infected diabetic foot ulcers

Day 30 opinion

Infectious Diseases / Dermatology

During its plenary on 19 August 2016 the PDCO discussed the full waiver application for gentamicin for the topical treatment of infected diabetic foot ulcers.
A positive opinion has been adopted.
The applicant is reminded that if the product will be further developed in other skin and soft

tissue infections (SSTI) suitable for topical treatment, another PIP/Waiver will have to be agreed with the PDCO.

3.1.31. acalabrutinib - Orphan - EMEA-001796-PIP03-16

ACERTA PHARMA, BV; Treatment of mature B cell neoplasms / Treatment of children from 1 to < 18 years of age with relapsed/refractory mature B-cell neoplasms (eg, diffuse large B-cell lymphoma [DLBCL], Burkitt lymphoma [BL] and primary mediastinal B-cell lymphoma [PMBCL])

Day 30 discussion

Oncology

3.1.32. PEGPH20 (PEGylated recombinant human hyaluronidase PH20, rHuPH20) - Orphan - EMEA-001883-PIP02-16

Halozyme Inc.; Pancreas cancer

Day 30 discussion

Oncology

3.1.33. Pexidartinib - Orphan - EMEA-001939-PIP02-16

Daiichi Sankyo Europe GmbH; Treatment of benign soft tissue neoplasm

Day 30 discussion

Oncology

3.1.34. Ciclosporin - EMEA-001998-PIP01-16

Dry eye disease/Keratoconjuntivitis Sicca

Day 30 discussion

Ophthalmology

3.1.35. Fluocinolone Acetonide - Orphan - EMEA-000801-PIP02-16

CAMPHARM Limited; Chronic non-infectious uveitis

Day 30 discussion

Ophthalmology

3.1.36. Rexlemestrocel-L (Allogeneic Mesenchymal Precursor Cells) - EMEA-001140-PIP02-15

Disc degeneration disease

Day 30 discussion

Other

3.1.37. triheptanoin - Orphan - EMEA-001920-PIP01-15

Ultragenyx Pharmaceutical Inc.; glucose transporter type-1 deficiency syndrome

Day 30 discussion

Other

3.1.38. Orphan - EMEA-001984-PIP01-16

Retrophin Europe Limited; Treatment of Focal Segmental Glomerulosclerosis (FSGS) / Treatment of Focal Segmental Glomerulosclerosis (FSGS)

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. ertugliflozin - EMEA-C1-001533-PIP01-13

MSD (Europe) Inc.; Treatment of type II diabetes mellitus

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.2. exanatide - EMEA-C1-000689-PIP01-09-M06

AstraZeneca AB; Treatment of type 2 diabetes mellitus

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.2.3. raxibacumab - EMEA-C1-001569-PIP01-13

GlaxoSmithKline Trading Services Limited; Treatment of bacillary infection

Day 30 discussion

Infectious Diseases

Summary of committee discussion:

The PDCO finalised on 19th August 2016 this partially completed compliance procedure and

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

3.2.4. Sofosbuvir / ledipasvir - EMEA-C1-001411-PIP01-12-M03

Gilead Sciences International Ltd.; Treatment of chronic hepatitis C

Day 30 discussion

Infectious Diseases

3.2.5. rufinamide - EMEA-C-000709-PIP01-09-M05

Eisai Limited; Treatment of Lennox-Gastaut Syndrome

Day 30 discussion

Neurology

3.2.6. Tralokinumab - EMEA-C1-000782-PIP01-09-M03

MedImmune Ltd; Treatment of asthma

Day 30 discussion

Pneumology - Allergology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. Alipogene Tiparvovec - Orphan - EMEA-000292-PIP01-08-M03

uniQure biopharma B.V.; Hyperchylomicronaemia

Day 30 discussion

Cardiovascular Diseases

3.3.2. riociguat - Orphan - EMEA-000718-PIP01-09-M06

Bayer Pharma AG; I27.2 Other secondary pulmonary hypertension, I27.0 Primary pulmonary hypertension / Treatment of drug and toxin-induced pulmonary arterial hypertension, Treatment of pulmonary hypertension with unclear multifactorial mechanisms, Treatment of pulmonary veno-occlusive disease (PVOD) and/or pulmonary capillary hemangiomatosis (PCH), Treatment of pulmonary hypertension due to lung disease and /or hypoxia, Treatment of chronic thromboembolic pulmonary hypertension (CTEPH), Treatment of pulmonary hypertension owing to left heart diseases, Treatment of pulmonary arterial hypertension (PAH)

Day 30 discussion

Cardiovascular Diseases

3.3.3. serelaxin - EMEA-001168-PIP01-11-M03

Novartis Europharm Limited; Treatment of Acute Heart Failure / Treatment of acute heart failure following surgical repair of a congenital heart defect

Day 30 discussion

Cardiovascular Diseases

3.3.4. dabigatran etexilate mesilate - EMEA-000081-PIP01-07-M09

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

Day 30 discussion

Cardiovascular Diseases / Haematology-Hemostaseology

3.3.5. Sodium zirconium cyclosilicate - EMEA-001539-PIP01-13-M01

ZS Pharma, Inc; Hyperkalaemia / Treatment of Hyperkalaemia

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. Tolvaptan - EMEA-001231-PIP02-13-M04

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

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.7. Autologous CD34+ haematopoietic stem cells transduced with lentiviral vector encoding the human βA-T87Q-globin gene - Orphan - EMEA-001665-PIP01-14-M01

bluebird bio France; β-thalassaemia

Day 30 discussion

Haematology-Hemostaseology

3.3.8. Human normal immunoglobulin for subcutaneous use - EMEA-000454-PIP01-08-M07

Kedrion S.p.A.; D80-D90 Certain disorders involving the immune mechanism. Primary Immunodeficiency Syndromes / Treatment of Primary Immunodeficiency Syndromes

Day 30 discussion

Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology

3.3.9. ataluren - Orphan - EMEA-000115-PIP01-07-M08

PTC Therapeutics International, Limited; Treatment of dystrophinopathy ICD-10: G71.0 Muscular dystrophy [of Duchenne and Becker] / Treatment of nonsense-mutation dystrophinopathy

Day 30 discussion

Neurology

3.3.10. eteplirsen - Orphan - EMEA-001722-PIP01-14-M01

Sarepta International C.V.; Duchenne muscular dystrophy

Day 30 discussion

Neurology

3.3.11. Olaratumab - Orphan - EMEA-001760-PIP01-15-M01

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 30 discussion

Oncology

3.3.12. Cenegermin - Orphan - EMEA-001729-PIP01-14-M01

Dompé farmaceutici S.p.A.; Neurotrophic Keratitis

Day 30 discussion

Ophthalmology

3.3.13. Xylitol / Procaine hydrochloride / Magnesium sulphate heptahydrate / Potassium chloride - EMEA-001171-PIP01-11-M01

MIT Gesundheit GmbH; Cardioplegia / Induction of immediate and prolonged diastolic

cardiac arrest in open heart surgery

Day 30 discussion

Other

3.3.14. Human thrombin / Human fibrinogen - EMEA-001340-PIP01-12-M02

ProFibrix BV (Mallinckrodt Pharmaceuticals); Treatment of haemorrhage resulting from a surgical procedure / Supportive treatment where standard surgical techniques are insufficient for improvement of haemostasis

Day 30 discussion

Other / Haematology-Hemostaseology

3.3.15. ataluren - Orphan - EMEA-000115-PIP02-09-M03

PTC Therapeutics International, Limited; Cystic Fibrosis ICD10: E84.9 Cystic fibrosis, unspecified / Treatment of cystic fibrosis

Day 30 discussion

Pneumology - Allergology

3.3.16. mepolizumab - Orphan - EMEA-000069-PIP04-13-M01

GSK Trading Services Limited; Vasculitides / Treatment of paediatric patients aged 6 to 17 years with eosinophilic granulomatosis with polyangiitis (EGPA) using corticosteroid therapy with or without concomitant immunosuppressant therapy.

Day 30 discussion

Pneumology - Allergology

3.3.17. Modified allergen extract of birch pollen - EMEA-000932-PIP01-10-M01

ROXALL Medizin GmbH; H10.1 Acute atopic conjunctivitis, J30.1 Allergic rhinitis due to pollen / Treatment of allergic rhinitis due to pollen of the birch group, Treatment of acute atopic conjunctivitis due to tree pollen of the birch group

Day 30 discussion

Pneumology - Allergology

3.3.18. mirabegron - EMEA-000597-PIP02-10-M05

Astellas Pharma Europe B.V.; Treatment of idiopathic overactive bladder / Symptomatic treatment of urge incontinence and/or increased urinary frequency and urgency as may occur in patients with overactive bladder syndrome

Day 30 discussion

Uro-nephrology

3.3.19. mirabegron - EMEA-000597-PIP03-15-M02

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

Day 30 discussion

Uro-nephrology

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 18 October 2016 for Nomination of Rapporteur and Peer reviewer

Summary of committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

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

Summary of committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

4.3. Nominations for other activities

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. Brexpiprazole – EMEA-24-2016 (EMEA-001185-PIP01-11)

Otsuka Europe; Treatment of Alzheimer's Disease/ Treatment of agitation associated with dementia of the Alzheimer's type

Summary of committee discussion:

The applicability of the class waiver as referred to in the Agency's Decision CW/1/2011 to the planned therapeutic indication was not confirmed.

The treatment of agitation associated with dementia of the Alzheimer's type was considered to be a distinct condition from the treatment of Alzheimer's disease.

6.1.2. Palucorcel - EMEA-25-2016

Janssen Biologics B.V.; All classes of medicinal products for the treatment of age-related macular degeneration and diabetic macular oedema/ Improvement of visual acuity in patients with vision loss from geographic atrophy secondary to age-related macular degeneration

Summary of committee discussion:

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

Other potential paediatric interest of this medicine suggested by PDCO: retinitis pigmentosa and Stargardt disease.

6.1.3. Buparlisib - EMEA-26-2016

Novartis Europharm Limited; Treatment of oropharyngeal, laryngeal or nasal epithelial carcinoma (excluding nasopharyngeal carcinoma or lymphoepithelioma)/ Treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma

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: paediatric solid malignant tumours.

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

7. Discussion on the inclusion of an indication within a condition in an agreed PIP/waiver

7.1. Discussion on the possibility to include an indication within a condition in an agreed PIP/waiver

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. Proposals for optimisation of PDCO plenary meetings

Summary of committee discussion:

The Committee agreed with a proposed process improvement for appointment of Rapporteurs and peer-reviewers.

9.1.2. Criteria for expertise and experience of PDCO members

Summary of committee discussion:

PDCO members supported the re-mapping exercise of the Committee's scientific expertise.

9.1.3. Preparations for elections of PDCO Chair

Summary of committee discussion:

PDCO members were reminded that Dirk Mentzer has served as Chair of the PDCO since September 2013 and his current term of office will shortly come to an end. The Chair thanked all members for the support received during his first mandate. In preparation for the Chair election to be conducted at the September 2016 PDCO meeting the members were reminded of the election procedure. PDCO eligible members were invited to indicate their interest in standing for this position before the September 2016 plenary meeting.

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 1 medicinal product, Sialanar, for which the CHMP adopted a positive opinion recommending paediatric indication during their meeting in July 2016. A new paediatric pharmaceutical form (oral solution 0.5 ml/mg) for Fycompa was approved for paediatric use.

9.2.2. CHMP-PDCO Interaction

PDCO Chair: Dirk Mentzer

Summary of committee discussion:

The committee discussed the draft the process for the coordination of CHMP-PDCO interactions during evaluation of paediatric aspects in initial MA and post-authorisation procedures.

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 NcWG identified the products which will require NcWG evaluation and discussion.

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Summary of committee discussion:

Relevant products for FWG discussion were identified.

9.4. Cooperation within the EU regulatory network

None

9.5. Cooperation with International Regulators

None

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

None

9.7. PDCO work plan

None

9.8. Planning and reporting

None

10. Any other business

10.1. None.

11. Breakout sessions

No breakout session took place in the margins of the PDCO August 2016 meeting.

12. List of participants

List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 17-19 August 2016 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Dirk Mentzer	Chair	Germany	No interests declared	
Karl-Heinz Huemer	Member	Austria	No interests declared	
Johanna Wernsperger	Alternate	Austria	No interests declared	
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-001831-PIP01-15
Jaroslav Sterba	Member	Czech Republic	No interests declared	
Peter Szitanyi	Alternate	Czech Republic	No interests declared	
Marianne Orholm	Member	Denmark	No interests declared	
Irja Lutsar	Member	Estonia	No interests declared	
Jana Lass	Alternate	Estonia	No interests declared	
Maija Pihlajamaki	Alternate	Finland	No interests declared	
Immanuel Barth	Member	Germany	No interests declared	
Sabine Scherer	Alternate	Germany	No interests declared	
Eleni Katsomiti	Member	Greece	No interests declared	
Ágnes Gyurasics	Member (CHMP member)	Hungary	No interests declared	
Brian Aylward	Member	Ireland	No interests declared	
Dina Apele-Freimane	Member	Latvia	No interests declared	
Carola de Beaufort	Member (CHMP alternate)	Luxembourg	No restrictions applicable to this meeting	
Herbert Lenicker	Alternate	Malta	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	
Dana Gabriela Marin	Member (CHMP alternate)	Romania	No interests declared	
Stefan Grosek	Member	Slovenia	No interests declared	
Fernando de Andrés Trelles	Member	Spain	No interests declared	
Maria Jesús Fernández Cortizo	Alternate	Spain	No interests declared	
Ninna Gullberg	Member	Sweden	No interests declared	
Angeliki Siapkara	Member	United Kingdom	No interests declared	
Martina Riegl	Alternate	United Kingdom	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Riccardo Riccardi	Member	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Jorrit Gerritsen	Alternate	Healthcare Professionals' Representative	No interests declared	
Antje Neubert	Member	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Doina Plesca	Alternate	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Günther Auerswald	Member	Patients' Organisation Representative	No participation in discussion, final deliberations and voting on:	EMEA-000914-PIP01-10-M03
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*		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/