27 April 2016
EMA/PDCO/230626/2016
Procedure Management and Committees Support Division

Paediatric Committee (PDCO)

Minutes for the meeting on 30 March-1 April 2016

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

30 March 2016, 08:30- 19:00, room 3A

31 March 2016, 08:30- 19:00, room 3A

1 April 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. KEOC liquid extract ethanolic 30 per cent (w/w) of Allium cepa L. (fresh bulb) and Citrus lemon (L.) Burm. (fresh fruit), Paullinia cupana Kunth, Theobroma cacao L. - EMEA-001835-PIP01-15

Legacy Healthcare; Treatment of alopecia

Day 120 opinion

Dermatology

Summary of committee discussion:

The PDCO views expressed on day 90 were re-discussed and endorsed. The committee also endorsed the conclusions of the FWG.
In conclusion, based on the assessment of this application and further discussions at the Paediatric Committee The committee adopted a positive opinion for KEOC liquid extract ethanolic 30 per cent (w/w) of Allium cepa L. (fresh bulb) and Citrus lemon (L.) Burm. (fresh fruit), Paullinia cupana Kunth, Theobroma cacao L. for all subsets of the paediatric population (0 to 18 years of age) in the condition of "Treatment of alopecia."

2.1.2. A derivative of (2S,3S,4R)-3-ethyl-4- hydroxypyrrolidine-2-carboxylic acid / Velpatasvir / Sofosbuvir - EMEA-001822-PIP01-15

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

Day 120 opinion

Infectious Diseases

Summary of committee discussion:

The PDCO reviewed and discussed the additional information received after Day 90 as well as the assessors' comments and found all outstanding concerns resolved. The modified PIP has therefore been endorsed and the Committee adopted a positive opinion.

2.1.3. Anti-respiratory syncytial virus human IgG1κ monoclonal antibody - EMEA-001784-PIP01-15

MedImmune Limited; Prevention of respiratory syncytial viral infections

Day 120 opinion

Infectious Diseases

Summary of committee discussion:

The PDCO's views expressed at day 90 were re-discussed and endorsed. The committee also discussed the additional clarifications by the applicant and considered them agreeable.
In conclusion, based on the assessment of this application and further discussions, the PDCO agrees to adopt a positive opinion for the anti-respiratory syncytial virus human IgG1κ monoclonal antibody in the condition of "Prevention of lower respiratory tract infection caused by respiratory syncytial virus".

2.1.4. doravirine - EMEA-001676-PIP01-14

Merck Sharp & Dohme (Europe), Inc.; Treatment of human immunodeficiency virus-1 (HIV-1) infection / Antiretroviral therapy, in combination with other antiretroviral agents, for the treatment of HIV-1 infection in children aged from birth to 18 years

Day 120 opinion

Infectious Diseases

Summary of committee discussion:

Following the discussion at D90 and the clarifications received by the applicant, the PDCO made final remarks on the application for a PIP for doravirine covering the whole paediatric population for the treatment of HIV infected patients. The PDCO discussed some points raised by the formulation working group and the responses received from the company following day 90 discussion.
Therefore, with these further amendments, the PDCO adopted a positive opinion for the proposed PIP for doravirine.

2.1.5. tenofovir alafenamide / emtricitabine / cobicistat / darunavir - EMEA-001825-PIP01-15

Janssen-Cilag International NV; Treatment of human immunodeficiency virus type-1 (HIV-1) infection / Treatment of HIV-1 infection in adolescents aged from 12 years to <18 years, and weighing 40 kg or more

Day 120 opinion

Infectious Diseases

Summary of committee discussion:

The PDCO concluded its evaluation of the proposed PIP for the fixed dose combination tenofovir alafenamide / emtricitabine / cobicistat / darunavir including a waiver and a deferral. The applicant responses to the issues raised at the D90 PDCO discussion were debated. Since all the issues were resolved the PDCO adopted a positive opinion on the PIP for the above mentioned fixed dose combination for the Treatment of human immunodeficiency virus type-1 (HIV-1) infection with a waiver and a deferral.

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

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

Day 120 opinion

Infectious Diseases

Summary of committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee - following the clarification received by the applicant after Day 90 PDCO - discussion and comments received by the formulation working group (FWG) the PDCO agreed with the revised PIP.
In conclusion PDCO agreed with the applicant's proposed PIP for the fixed dose combination tenofovir disoproxil fumarate / lamivudine / doravirine in the condition of treatment of human immunodeficiency virus-1 (HIV-1) infection with a waiver and including a deferral.

2.1.7. Human recombinant IgG1 monoclonal antibody targeting fibroblast growth factor 23 - Orphan - EMEA-001659-PIP01-15

Ultragenyx Pharmaceutical Inc.; X-linked Hypophosphatemia

Day 120 opinion

Other

Summary of committee discussion:

The PDCO discussed this product and agreed with the conclusions reached at the Day 90 discussion.
The PDCO considered satisfactory the additional information provided by the applicant after Day 90.
The PDCO, therefore, adopted a positive Opinion.

2.1.8. Hydrogen Peroxide - EMEA-001884-PIP02-15

Aclaris Therapeutics, Inc.; Treatment of seborrhoeic keratosis / Treatment of seborrhoeic keratosis

Day 60 opinion

Dermatology

Summary of committee discussion:

The PDCO confirmed the outcome of the D30 discussion. The PDCO recommends granting a waiver for Hydrogen Peroxide for all subsets of the paediatric population (0 to 18 years of age) in the condition of Seborrhoeic keratosis.

2.1.9. Levodopa - EMEA-001874-PIP01-15

Acorda Therapeutics, Inc.; Parkinson's Disease

Day 60 opinion

Neurology

Summary of committee discussion:

The PDCO agreed with the conclusions of Day 30. The PDCO recommends granting a waiver for levodopa for all subsets of the paediatric population (0 to 18 years of age) in the condition of Parkinson's Disease.
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.

2.1.10. Diclofenac sodium / Capsaicin - EMEA-001861-PIP01-15

Boehringer Ingelheim International GmbH; Treatment of pain

Day 60 opinion

Pain

Summary of committee discussion:

The PDCO discussed the waiver application for EMEA-001861-PIP01-15 and confirmed the outcome at Day 30. The PDCO recommends granting a waiver for Capsaicin / Diclofenac sodium for all subsets of the paediatric population (0 to 18 years of age) for the "Treatment of musculoskeletal and connective tissue pain and discomfort".

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. Adalimumab - EMEA-C-000366-PIP04-12

AbbVie Ltd; Treatment of hidradenitis suppurativa

Day 60 opinion

Immunology-Rheumatology-Transplantation / Dermatology

Summary of committee discussion:

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/0121/2013) of 03 May 2013.

2.2.2. Ceftriaxone (in the form of sodium salt) / Sulbactam (in the form of sodium salt) - EMEA-C1-001568-PIP03-14

Venus Pharma GmbH; Treatment of bacterial infections

Day 30 opinion

Infectious Diseases

Summary of committee discussion:

The PDCO finalised on Day 30 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.

2.2.3. Nilotinib - EMEA-C3-000290-PIP01-08-M04

Novartis Europharm Ltd.; Treatment of chronic myeloid leukaemia

Day 30 opinion

Oncology

Summary of committee discussion:

The PDCO discussed on this third request to verify compliance with the PIP agreed for nilotinib

that is so far partially completed.
The PDCO discussed these study(ies) and considered that these are compliant with the latest Agency's Decision, taking into account the supplementary information received from the applicant.

The PDCO finalised this partially completed compliance procedure.

2.2.4. Pneumococcal polysaccharide serotype 6B conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 23F conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 1 conjugated to protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 18C conjugated to tetanus toxoid / Pneumococcal polysaccharide serotype 19F conjugated to diphtheria toxoid / Pneumococcal polysaccharide serotype 7F conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 9V conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 14 conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 4 conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein / Pneumococcal polysaccharide serotype 5 conjugated to Protein D (derived from non-typeable Haemophilus influenzae) carrier protein - EMEA-C5-000673-PIP01-09-M08

GlaxoSmithKline Biologicals S.A.; Prevention of diseases caused by streptococcus pneumoniae

Day 30 opinion

Vaccines

Summary of committee discussion:

A number of completed studies were checked for compliance: and the PDCO considered that these are compliant with the latest Agency's Decision (P/0270/2015) of 03 December 2015. The PDCO finalised this partially completed compliance procedure.

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

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

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

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

The PDCO maintained its position of the discussion at day 30. Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted. The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0268/2015 of 27 November 2015). The new PDCO Opinion on the modified

agreed PIP supersedes the previous PDCO Opinion.

2.3.2. Tadalafil - EMEA-000452-PIP02-10-M04

Eli Lilly and Company Ltd; Pulmonary arterial hypertension (already approved in adults) / Treatment of Persistent Pulmonary Hypertension of the Newborn, Treatment of Pulmonary Arterial Hypertension

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/0165/2015 of 07/08/2015).

2.3.3. vorapaxar - EMEA-000778-PIP02-12-M01

Merck Sharp & Dohme (Europe), Inc.; Prevention of Thromboembolism / Prevention of thromboemboloc events in paediatric patients

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/0222/2013 of 16 September 2013). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.4. exenatide - EMEA-000689-PIP01-09-M06

AstraZeneca AB; Non insulin dependant diabetes mellitus (treatment including thiazolidinediones), Non insulin dependant diabetes mellitus (excluding treatment with thiazolidinediones) / Treatment of 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, as outlined per day 30 PDCO discussion.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0197/2014 of 08/08/2014).

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

2.3.5. Lixisenatide - EMEA-000916-PIP01-10-M05

sanofi-aventis R&D; Type 2 diabetes mellitus / Treatment of type 2 diabetes mellitus

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

The PDCO re-discussed the proposed modification also taking into consideration the clarifications provided by the applicant after the D30 discussion which were considered satisfactory.

Applicant's comments into the draft Opinion were also taken into consideration.
In conclusion the PDCO considered that the proposed changes could be accepted and adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0037/2015 of 06/03/2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.6. sitagliptin phosphate - EMEA-000471-PIP01-08-M02

Merck Sharp and Dohme (Europe), Inc.; Type 2 diabetes mellitus / Treatment of type 2 diabetes mellitus

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

A positive opinion was adopted by the PDCO.

2.3.7. sitagliptin phosphate - EMEA-000472-PIP01-08-M02

Merck Sharp and Dohme (Europe), Inc.; Type 2 diabetes mellitus / Treatment of type 2 diabetes mellitus

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

A positive opinion was adopted by the PDCO.

2.3.8. Denosumab - EMEA-000145-PIP01-07-M08

Amgen Europe B.V.; Prevention of skeletal related events in patients with bone metastases, Treatment of hypercalcaemia of malignancy, Treatment of bone loss associated with sex hormone ablative therapy, Treatment of giant cell tumour of bone / Treatment of giant cell tumour of bone in children (12-17 years old), None (i.e. product-specific waiver across all

paediatric subsets already granted by the EMA for this condition), None (i.e. product-specific waiver across all paediatric subsets is being proposed for this indication)

Day 60 opinion

Immunology-Rheumatology-Transplantation /
Endocrinology-Gynaecology-Fertility-Metabolism / 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 (P/0006/2015 of 30/01/2015)
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.9. solithromycin - EMEA-001581-PIP01-13-M02

Triskel EU Services, Ltd; Treatment of community acquired pneumoniae, Treatment of infection by Francisella tularaensis (tularaemia), Treatment of infection by Bacillus anthracis (anthrax) / Treatment of community acquired pneumoniae, Treatment of inhalation tularaemia following exposure to Francisella tularaensis, Treatment of inhalation anthrax following exposure to Bacillus anthracis

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

The applicant has provided the requested justifications and information. 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/0254/2014 of 30 September 2014). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.10. ataluren - Orphan - EMEA-000115-PIP01-07-M07

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

Day 60 opinion

Neurology

Summary of committee discussion:

The committee's views expressed on day 30 were 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/0002/2016 of 14/01/2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.11. Dimethyl fumarate - EMEA-000832-PIP01-10-M03

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

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/0144/2015 of 10/07/2015)
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.12. Perampanel - EMEA-000467-PIP01-08-M07

Eisai Europe Limited; Treatment of treatment-resistant epilepsies / Adjunctive therapy in patients with other paediatric epilepsies, Adjunctive therapy in patients with refractory partial onset seizures including secondarily generalised seizures

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 and subsequent clarification documents provided by the applicant, the PDCO considered that most of 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/0301/2014 of 24/11/2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.13. Pitolisant - Orphan - EMEA-001176-PIP01-11-M02

BIOPROJET PHARMA; Narcolepsy / Treatment of narcolepsy with or without cataplexy

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/0200/2013 of 02 September 2013).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.14. Cabozantinib - Orphan - EMEA-001143-PIP01-11-M01

Exelixis Inc; Cancer

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO discussed the request for modification for cabozantinib, taking into account the supplementary information and comments on an opinion draft provided by the applicant as well as an exchange of the Rapporteur, Peer Reviewer and EMA with the external expert in advance of the plenary meeting.
Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that some of 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.

2.3.15. Selumetinib - EMEA-001585-PIP01-13-M01

AstraZeneca AB; Treatment of Neurofibromatosis-Type 1, Treatment of Thyroid cancer, Treatment of lung carcinoma, Treatment of Melanoma / , Selumetinib is indicated for the treatment of inoperable NF1 related plexiform neurofibroma in children and adolescents, Selumetinib in combination with dacarbazine is indicated for the first systemic therapy for the treatment of adolescents with metastatic uveal melanoma, Selumetinib in combination with adjuvant radioactive iodine therapy is indicated for the treatment of adolescents newly diagnosed with differentiated thyroid cancer who are at high risk of primary treatment failure.

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO discussed the request for modification of the agreed PIP for selumetinib and took into account the supplementary information provided by the applicant.
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.

2.4. 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. Bexagliflozin - EMEA-001841-PIP01-15

Type 2 Diabetes Mellitus

Day 90 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.2. Recombinant humanized anti-MMP9 monoclonal antibody IgG4 - EMEA-001813-PIP01-15

Crohn's Disease, Ulcerative Colitis

Day 90 discussion

Gastroenterology-Hepatology

3.1.3. cilastatin sodium / imipinem monohydrate - EMEA-001809-PIP01-15

Treatment of bacterial infections caused by Gram-negative bacteria

Day 90 discussion

Infectious Diseases

3.1.4. EMEA-001832-PIP01-15

Treatment of Chronic Hepatitis C / Treatment of Chronic Hepatitis C

Day 90 discussion

Infectious Diseases

3.1.5. pimavanserin - EMEA-001688-PIP02-15

Treatment of schizophrenia and other psychotic disorders

Day 90 discussion

Psychiatry

3.1.6. Influenza virus surface antigens (haemagglutinin and neuraminidase) of strain A (H1N1) / 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) - EMEA-001715-PIP01-14

Influenza / Prevention of influenza

Day 90 discussion

Vaccines

3.1.7. tralokinumab - EMEA-001900-PIP01-15

Atopic dermatitis

Day 60 discussion

Dermatology

3.1.8. Cathine hydrochloride (D-Norpseudoephedrine hydrochloride) - EMEA-001909-PIP01-15

Treatment of obesity / Adjunct therapy for patients with obesity and a body mass index (BMI) of at least 30 for adults and above the 97th percentile for children who failed to achieve adequate therapeutic response with comprehensive weight loss measures alone.

Day 60 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.9. Naldemedine Tosylate - EMEA-001893-PIP01-15

Opioid-induced constipation (OIC) / Opioid-induced constipation (OIC)

Day 60 discussion

Gastroenterology-Hepatology

3.1.10. Eculizumab - Orphan - EMEA-000876-PIP07-15

Alexion Europe SAS; Prevention of delayed graft function after solid organ transplantation / Prevention of delayed graft function after kidney transplantation in patients at increased risk of delayed graft function

Day 60 discussion

Immunology-Rheumatology-Transplantation

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

ICD-9 code 279.10 Immunodeficiency with predominant T-cell defect, unspecified / Non-malignant disorders amenable to cure by haematopoietic stem cell transplant (HSCT)

Day 60 discussion

Immunology-Rheumatology-Transplantation

3.1.12. Rimiducid - EMEA-001870-PIP01-15

Treatment of Graft Versus Host Disease (ICD 279.50) / Treatment of Graft Versus Host Disease (GvHD) in paediatric patients with non-malignant conditions who received BPX-501 T cell replacement

Day 60 discussion

Immunology-Rheumatology-Transplantation

3.1.13. Omadacycline - EMEA-000560-PIP02-15

Infections of the skin and subcutaneous tissue

Day 60 discussion

Infectious Diseases

3.1.14. Omadacycline - EMEA-000560-PIP03-15

Bacterial pneumonia

Day 60 discussion

Infectious Diseases

3.1.15. Humanised, affinity-optimised, afucosylated immunoglobulin G1 kappa monoclonal antibody - EMEA-001911-PIP01-15

Treatment of Neuromyelitis Optica (NMO) and Neuromyelitis Optica Spectrum Disorders (NMOSD)

Day 60 discussion

Neurology

3.1.16. Humanized monoclonal calcitonin gene-related peptide neutralizing antibody - EMEA-001860-PIP03-16

Prophylactic treatment of migraine headache

Day 60 discussion

Neurology

3.1.17. 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 60 discussion

Oncology

3.1.18. Sapacitabine - Orphan - EMEA-001901-PIP01-15

Cyclacel Limited; Treatment of acute myeloid leukaemia

Day 60 discussion

Oncology

3.1.19. Angiotensin II - EMEA-001912-PIP01-15

Treatment of Catecholamine-resistant hypotension associated with distributive shock

Day 60 discussion

Other

3.1.20. esketamine hydrochloride (2S)-2-(2-chlorophenyl)-2-(methylamino) cyclohexanone hydrochloride - EMEA-001428-PIP03-15

Major Depressive Disorder (MDD)

Day 60 discussion

Psychiatry

3.1.21. 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 60 discussion

Vaccines

3.1.22. Rosuvastatin (Calcium) / Olmesartan medoxomil - EMEA-001914-PIP01-15

Hypertension, Dyslipidaemia, Cardiovascular events / Treatment of dyslipidaemia/hypercholesterolaemia, Prevention of cardiovascular events, Treatment of hypertension

Day 30 discussion

Cardiovascular Diseases

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

Ionis Pharmaceuticals; Familial Chylomicronemia Syndrome

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.24. efpeglenatide - EMEA-001903-PIP01-15

Type 2 diabetes mellitus

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

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 preeclampsia to prolong gestation and decrease foetal and neonatal morbidity and mortality.

Day 30 discussion

Haematology-Hemostaseology

3.1.26. 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 30 discussion

Immunology-Rheumatology-Transplantation

3.1.27. 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 30 discussion

Infectious Diseases

3.1.28. solithromycin - EMEA-001581-PIP02-16 – early adoption of opinion

Treatment of gonococcal infection / Treatment of gonococcal infection

Day 30 discussion

Infectious Diseases

This opinion is the result of splitting PIP EMEA-001581-PIP01-13. The condition “treatment of gonococcal infection” is now covered by this opinion. 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 solithromycin for all subsets of the paediatric population (0 to 18 years of age) in the condition of Treatment of gonococcal infection.

3.1.29. 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 30 discussion

Neonatology - Paediatric Intensive Care

3.1.30. benzodiazepine - EMEA-001918-PIP01-15

ICD10 F84: Treatment of autism spectrum disorder

Day 30 discussion

Neurology

3.1.31. Imetelstat Sodium - Orphan - EMEA-001910-PIP01-15

Janssen-Cilag International N.V; Treatment of Myelofibrosis

Day 30 discussion

Oncology

3.1.32. Ciclosporin - EMEA-001916-PIP01-15

Keratoconjunctivitis sicca

Day 30 discussion

Ophthalmology

3.1.33. D-stereoisomer of c-Jun N-terminal Kinase Inhibitor 1 - Orphan - EMEA-001926-PIP01-16

Auris Medical Ltd.; ASNHL comprising idiopathic sudden sensorineural hearing loss (ISSNHL; also called sudden deafness), acute acoustic trauma (AAT), and surgery induced acoustic trauma

Day 30 discussion

Oto-rhino-laryngology

3.1.34. Tramadol hydrochloride / Ibuprofen arginine - EMEA-001887-PIP01-15

Acute pain

Day 30 discussion

Pain

3.1.35. Peanut flour - EMEA-001753-PIP02-15

Treatment of peanut allergy Z91.010

Day 30 discussion

Pneumology - Allergology

3.1.36. N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup A polysaccharide conjugated to tetanus toxoid - EMEA-001930-PIP01-16

Prevention of Meningococcal Disease

Day 30 discussion

Vaccines

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. Sirukumab - EMEA-C2-001043-PIP01-10-M02

Janssen-Cilag International N.V.; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylarthritis, psoriatic arthritis and juvenile idiopathic arthritis)

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.2.2. maraviroc - EMEA-C-000020-PIP01-07-M05

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

Day 30 discussion

Infectious Diseases

3.2.3. Dasatinib - EMEA-C3-000567-PIP01-09-M04

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

Day 30 discussion

Oncology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

3.3.1. dihydroartemisinin / piperaquine tetraphosphate - EMEA-000153-PIP01-07-M03

Sigma-Tau SpA; Uncomplicated malaria caused by Plasmodium falciparum (ICD-10 code B50) / Treatment of uncomplicated malaria caused by Plasmodium falciparum

Day 30 discussion

3.3.2. Allantoin - Orphan - EMEA-001590-PIP01-13-M02

Scioderm, Inc.; Treatment of epidermolysis bullosa

Day 30 discussion

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/0031/2015 of 12 February 2015). The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

3.3.3. Drospirenone - EMEA-001495-PIP01-13-M01

LABORATIORIOS LEÓN FARMA, S.A.; Contraception / Oral contraception

Day 30 discussion

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/0110/2014 of 5 May 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

3.3.4. Liraglutide - EMEA-000128-PIP02-09-M02

Novo Nordisk A/S; E66 Obesity / Treatment of obesity

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.5. retosiban - EMEA-001359-PIP01-12-M03

GlaxoSmithKline Trading Services Limited; Treatment of spontaneous preterm labour / Treatment of spontaneous preterm labour to improve neonatal outcomes by prolonging pregnancy in women with an uncomplicated singleton pregnancy between 24 and less than 34 weeks gestation

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.6. Tolvaptan - EMEA-001231-PIP02-13-M03

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. potassium sulphate / magnesium sulphate heptahydrate / sodium sulphate anhydrous - EMEA-000816-PIP02-10-M01

IPSEN Pharma; Diagnostic of organic and/or functional bowel diseases / In adults and children from 6 months of age for bowel cleansing prior to any procedure requiring a clean bowel (e.g. bowel visualisation including endoscopy and radiology or surgical procedure). Izinova is not a

treatment for constipation.

Day 30 discussion

Gastroenterology-Hepatology

3.3.8. efmorocotocog alfa - EMEA-001114-PIP01-10-M03

Biogen Idec Ltd; Hereditary Factor VIII Deficiency - D66 / Treatment and prophylaxis of bleeding in patients with severe Haemophilia A (congenital FVIII deficiency)

Day 30 discussion

Haematology-Hemostaseology

3.3.9. Secukinumab - EMEA-000380-PIP02-09-M03

Novartis Europharm Limited; Chronic Idiopathic Arthritis / Treatment of juvenile psoriatic arthritis, Treatment of enthesitis-related arthritis JIA

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.3.10. raltegravir - EMEA-000279-PIP01-08-M05

Merck Sharp & Dohme (Europe), Inc.; Human Immunodeficiency Virus (HIV-1) infection / In combination with other anti-retroviral medicinal products for the treatment of human immunodeficiency virus (HIV-1) infection

Day 30 discussion

Infectious Diseases

3.3.11. Alemtuzumab - EMEA-001072-PIP01-10-M02

Genzyme Europe B.V.; Multiple sclerosis / For paediatric patients with relapsing remitting multiple sclerosis (RRMS) with active disease on prior disease modifying treatment (DMT) defined by clinical or imaging features.

Day 30 discussion

Neurology

3.3.12. Clostridium Botulinum neurotoxin type A (150 kD), free from complexing proteins - EMEA-001039-PIP02-12-M02

Merz Pharmaceuticals GmbH; Treatment of sialorrhea / Treatment of chronic troublesome sialorrhea associated with neurological conditions (e.g. cerebral palsy, traumatic brain injury) and/or intellectual disability in children and adolescents aged 2 – 17 years.

Day 30 discussion

Neurology

3.3.13. Melatonin - Orphan - EMEA-000440-PIP02-11-M04

RAD Neurim Pharmaceuticals EEC Ltd; Insomnia - children, Insomnia - adults / Insomnia

Day 30 discussion

Neurology

3.3.14. Rufinamide - Orphan - EMEA-000709-PIP01-09-M05 – early adoption of opinion

Eisai Limited; Lennox-Gastaut Syndrome

Day 30 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 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/0038 of 19/02/2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

3.3.15. ibrutinib - Orphan - EMEA-001397-PIP03-14-M01

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

Day 30 discussion

Oncology

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

Amgen Europe B.V.; Drug-induced aplastic anaemia, Treatment of anaemia due to chronic disorders / Treatment of symptomatic anaemia in adult and paediatric cancer patients with non-myeloid malignancies receiving chemotherapy, Treatment of symptomatic anaemia associated with chronic renal failure (CRF) in adults and paediatric patients

Day 30 discussion

Oncology / Uro-nephrology

3.3.17. tafluprost - EMEA-001187-PIP01-11-M03

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

of age.

Day 30 discussion

Ophthalmology

3.3.18. Clostridium Botulinum neurotoxin type A (150 kD), free from complexing proteins - EMEA-001039-PIP01-10-M02

Merz Pharmaceuticals GmbH; Treatment of muscle spasticity, Treatment of dystonia, Treatment of muscle induced wrinkles / Treatment of spasticity of the upper and/or lower limb in children and adolescents (aged 2 - 17 years) with cerebral palsy

Day 30 discussion

Ophthalmology / Dermatology / Neurology

Atrasentan hydrochloride - EMEA-001666-PIP01-14-M01

AbbVie, Ltd; Nephropathies / Treatment of multidrug-resistant nephrotic syndrome (MDR-NS)

Day 30 discussion

Uro-nephrology

3.3.19. Ferric citrate coordination complex - EMEA-001213-PIP02-12-M02

Keryx Biopharma UK Ltd.; Treatment of hyperphosphataemia / The control of hyperphosphataemia in patients with chronic kidney disease (CKD)

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 26 May 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

Summary of committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

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

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

6. Discussion on the applicability of class waivers

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

6.1. Discussions on the applicability of class waiver for products

6.1.1. Dutasteride and Tamsulosin hydrochloride - EMEA-20-2015

Galenicum Health S.L.; Treatment of benign prostatic hyperplasia/ Treatment of moderate to severe symptoms of benign prostatic hyperplasia (BPH), Reduction in the risk of acute urinary retention(AUR) and surgery in patients with moderate to severe symptoms of BPH

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: currently none.

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. EMEA-07-2016

Gilead Sciences International Ltd.; Treatment of chronic lymphocytic leukaemia/ Treatment of chronic lymphocytic leukaemia

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: B-cell malignancies including activated B-cell–like diffuse large B-cell lymphoma.

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

6.1.3. EMEA-08-2016

Gilead Sciences International Ltd.; Treatment of follicular lymphoma/ Treatment of follicular lymphoma

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: B-cell malignancies including activated B-cell–like diffuse large B-cell lymphoma.

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.

6.1.4. Niraparib - EMEA-09-2016

TESARO, UK Ltd.; Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)-Treatment of Fallopian tube carcinoma ((excluding rhabdomyosarcoma and germ cell tumours)- Treatment of peritoneal carcinoma (excluding blastomas and sarcomas)/ Treatment of ovarian cancer including fallopian tube cancer and peritoneal cancers

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: currently none.

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.

6.1.5. EMEA-10-2016

Astellas Pharma Europe B.V.; Treatment of lung carcinoma (small cell and non-small cell carcinoma)/ Treatment of non-small cell lung 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: currently none.

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

The members of the PDCO took note of the products listed in the Annex B.

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. PDCO plenary meeting duration - survey results

PDCO Chair: Dirk Mentzer

Summary of committee discussion:

The Committee discussed the survey results concerning 2 options for extension of the duration of the plenary meetings. The Committee will further reflect on options in May 2016 after changes introduced in the timeschedule.

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 4 products, Alprolix, Descovy, Idelvion and Ruconest, for which the CHMP adopted positive opinions recommending paediatric indications during their meeting in February 2016.

9.2.2. Guideline on the development of new medicinal products for the treatment of Crohn's Disease

PDCO members: Peter Szitanyi and Johannes Taminiau

Summary of committee discussion:

The paediatric part of the guideline was presented to the PDCO and the committee was informed of the next steps.

9.2.3. Guideline on the development of new medicinal products for the treatment of Ulcerative Colitis

PDCO members: Peter Szitanyi and Johannes Taminiau

Summary of committee discussion:

The paediatric part of the guideline was presented to the PDCO and the committee was informed of the next steps.

9.2.4. Sodium-glucose co-transporter-2 (SGLT2) inhibitors: canagliflozin – INVOKANA (CAP); canagliflozin, metformin – VOKANAMET (CAP); dapagliflozin – FORXIGA (CAP); dapagliflozin, metformin – XIGDUO (CAP); empagliflozin - JARDIANCE (CAP); empagliflozin, metformin – SYNJARDY (CAP) - EMEA/H/A-20/1419

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

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

Summary of committee discussion:

The PDCO was informed about the outcome of the Article 20 referral procedure (as triggered by the European Commission) for currently authorized SGLT-2 transporter inhibitors in the use of type 2 diabetes mellitus following the detection of safety signals of diabetic ketoacidosis with atypical presentation. The PDCO was informed that the benefit/risk balance remains favourable for of SGLT2-transporter inhibitors. Changes to the Product Information and Risk Management Plan were deemed necessary by the CHMP/PRAC. Furthermore, a communication plan has been agreed (i.e. 2nd Direct healthcare professional communication (DHPC) with updated advice and conclusion of the review- DKA risk factors, cases where treatment should be temporarily or permanently discontinued).

9.2.5. Reflection paper on extrapolation of efficacy and safety in paediatric medicine development

Summary of committee discussion:

The PDCO adopted the reflection paper for release for the public consultation.

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 chairperson of the NcWG identified relevant products for NcWG discussion.

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Summary of committee discussion:

The chairperson of the FWG identified relevant products for FWG discussion

9.4. Cooperation within the EU regulatory network

9.4.1. Report on the status of the revision of the 'Ethical considerations for clinical trials on medicinal products conducted with the paediatric population'

Summary of committee discussion:

The Committee was informed about the latest draft of the revision.

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

9.8.1. PDCO Chair's report to Management Board - March 2016

PDCO Chair: Dirk Mentzer

Summary of committee discussion:

The Committee welcomed the positive feedback from the Management Board on PDCO Chair's report.

9.9. PDCO ORGAM

9.9.1. PDCO ORGAM Draft Minutes for 16 March 2016

Summary of committee discussion:

The PDCO ORGAM minutes for the meeting held on 16 March 2016 will be adopted at the PDCO 27-29 April 2016 meeting.

9.10. Other

9.10.1. Launch of PRIME (PRIority MEdicines) scheme

Summary of committee discussion:

The Committee was provided with an update on the PRIME project designed to facilitate the development and accelerated assessment of innovative medicines of major public health interest, in particular from the viewpoint of therapeutic innovation. Following the end of the public consultation in December 2015, the draft reflection paper has been revised and adopted by the CHMP during its February 2016 meeting. The PRIME scheme was launched in March 2016. An oversight group is being set up with the objective to discuss the eligibility requests received every month prior to their discussion at SAWP and CHMP. The aim of the group is to build and ensure consistency, particularly as this new activity is being implemented. It also supports any change of general guidance as experience on PRIME is gained. In addition, to SAWP and CHMP members, chairs or alternate representative from PDCO, COMP, CAT and PRAC are participating in the group.

9.11. Harmonisation - Referral procedure under Article 30 of Directive 2001/83/EC

9.11.1. Haldol and associated names (EMEA/H/A-30/1393) (haloperidol), Janssen-Cilag Group of companies and associated companies

CHMP List of Questions to the PDCO

Rapporteur: Martina Weise, Co-Rapporteur: Katarina Vučić

Summary of committee discussion:

The Committee was informed of the parallel discussion held at the CHMP.

9.11.2. Haldol decanoate and associated names (EMEA/H/A-30/1405) (haloperidol) Janssen-Cilag Group of companies and associated companies

CHMP List of Questions to the PDCO

Rapporteur: Martina Weise, Co-Rapporteur: Katarina Vučić

Summary of committee discussion:

The Committee was informed of the parallel discussion held at the CHMP.

10. Any other business

10.1. None

11. Breakout sessions

11.1.1. Paediatric oncology

Summary of discussion:
The participation and contributions to forthcoming congresses were discussed, as well a case where a pharmaceutical company proposed to notify a discontinuation of a PIP while contained studies are further conducted.

11.1.2. Neonatology

Summary of discussion:
The group discussed latest developments from the annual workshop of the International Neonatal Consortium in March as well as neonatal issues in Paediatric Investigation Plans.

11.1.3. Inventory

Summary of discussion:
The participants discussed the medicines and associated identified needs proposed to be included in the inventory of paediatric therapeutic needs (respiratory).

11.1.4. 10-Year Report Drafting Group

Summary of discussion:
The breakout session was postponed to the PDCO April meeting.

The Chair thanked the participants and closed the 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 PDCO 29 March – 1 April 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	
Christoph Male	Alternate	Austria	No participation in discussion, final deliberations and voting on:	EMEA-001114-PIP01-10-M03
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-001918-PIP01-15
Georgios Savva	Member	Cyprus	No interests declared	
Jaroslav Sterba	Member	Czech Republic	No interests declared	
Marianne Orholm	Member	Denmark	No interests declared	
Marta Granström	Alternate	Denmark	No interests declared	
Irja Lutsar	Member	Estonia	No interests declared	
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	
Immanuel Barth	Member	Germany	No interests declared	
Sabine Scherer	Alternate	Germany	No interests declared	
Grigorios Melas	Member	Greece	No interests declared	
Stefanos Mantagos	Alternate	Greece	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Ágnes Gyurasics	Member (CHMP member)	Hungary	No interests declared	
Brian Aylward	Member	Ireland	No interests declared	
Paolo Rossi	Member	Italy	No restrictions applicable to this meeting	
Francesca Rocchi	Alternate	Italy	No restrictions applicable to this meeting	
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	
Hendrik van den Berg	Member	Netherlands	No interests declared	
Siri Wang	Member	Norway	No interests declared	
Ine Skottheim Rusten	Alternate	Norway	No interests declared	
Marek Migdal	Member	Poland	No interests declared	
Helena Fonseca	Member	Portugal	No interests declared	
Hugo Tavares	Alternate	Portugal	No interests declared	
Dana Gabriela Marin	Member (CHMP alternate)	Romania	No interests declared	
Stefan Grosek	Member	Slovenia	No interests declared	
Fernando de Andrés Trelles	Member	Spain	No interests declared	
Ninna Gullberg	Member	Sweden	No interests declared	
Eva Agurell	Alternate	Sweden	No restrictions applicable to this meeting	
Angeliki Siapkara	Member	United Kingdom	No interests declared	
Martina Riegl	Alternate	United Kingdom	No interests declared	
Riccardo Riccardi	Member	Healthcare Professionals' Representative	No participation in discussion, final deliberations and voting on:	EMEA-001072-PIP01-10-M02
Johannes Taminiau	Member	Healthcare Professionals' Representative	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Günther Auerswald	Member	Patients' Organisation Representative	No participation in discussion, final deliberations and voting on:	EMEA-001114-PIP01-10-M03
Sara Homer	Expert - in person*		No interests declared	
Katherine McGinn	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/