30 March 2016
EMA/PDCO/150499/2016
Procedure Management and Committees Support Division

Paediatric Committee (PDCO)

Minutes for the meeting on 24-26 February 2016

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

24 February 2016, 08:30- 19:00, room 3E

25 February 2016, 08:30- 19:00, room 3E

26 February 2016, 08:30- 13:00, room 3E

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).

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

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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. certolizumab pegol - EMEA-001071-PIP03-14

UCB Pharma S.A.; Treatment of psoriasis / treatment of severe chronic plaque psoriasis

Day 120 opinion

Dermatology

Summary of committee discussion:

This application was discussed on D120. The PDCO considered that the applicant's response was acceptable and a positive opinion was granted.

2.1.2. Recombinant Human alpha-galactosidase A - EMEA-001828-PIP01-15

Protalix Ltd; Treatment of Fabry disease

Day 120 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO agreed with the applicant's request for a PIP with a waiver and a deferral. The PDCO adopted a positive opinion.

2.1.3. Human normal immunoglobulin for subcutaneous administration - EMEA-001853-PIP01-15

Grifols Therapeutics Inc.; Treatment of primary immunodeficiency

Day 120 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

The PDCO concluded that all issues have been addressed and resolved satisfactorily.
The Committee granted a waiver for human normal immunoglobulin.
The PDCO adopted a positive opinion.

2.1.4. Humanised monoclonal antibody against myostatin - Orphan - EMEA-001763-PIP01-15

Pfizer Limited; Duchenne Muscular Dystrophy

Day 120 opinion

Neurology

Summary of committee discussion:

Based on the assessment of this application and further discussions at the Paediatric Committee following an oral explanation with the applicant, the PDCO agreed with a PIP with a waiver and a deferral.
The PDCO adopted a positive opinion.

2.1.5. Octenidine (dihydrochloride) - EMEA-001514-PIP01-13

Cassella-med GmbH & Co. KG; Treatment of upper respiratory tract infections / Treatment of sore-throat due to infectious pharyngitis

Day 120 opinion

Oto-rhino-laryngology

Summary of committee discussion:

The PDCO discussed this product.
The Committee confirmed the conclusions reached at Day 90. The PDCO confirmed that a waiver for children younger than 6 years of age is agreeable on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2.1.6. Finasteride - EMEA-001878-PIP01-15

Polichem S.A.; Treatment of androgenetic alopecia

Day 60 opinion

Dermatology

Summary of committee discussion:

The PDCO's view expressed at Day 30 was re-discussed and endorsed.
Based on the assessment of this application the PDCO agrees with the applicant's request for a waiver. The PDCO recommends granting a waiver for Finasteride in the condition of treatment of androgenetic alopecia.
The PDCO adopted a positive opinion on the granting of a product-specific waiver.

2.1.7. Perindopril arginine / Atorvastatin - EMEA-001876-PIP01-15

Les Laboratoires Servier; Treatment of cardiovascular diseases, Treatment of ischaemic coronary artery disorders, Treatment of hypertension, Treatment of elevated cholesterol

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases

Summary of committee discussion:

Based on the assessment of this application the PDCO agrees with the applicant's request for a waiver.
The PDCO therefore recommends granting a waiver for perindopril/atorvastatin in the condition for the treatment of cardiovascular diseases.
The PDCO emphasises that the granting of a waiver for the condition mentioned above should not prevent the applicant from considering a development in the paediatric population in indications where there is a paediatric need. In principle according to the Paediatric Regulation, incentives for the development for use in the paediatric population are available even if a waiver has been granted in another condition.

2.1.8. Gallium68 chloride (Ga68Cl3) - EMEA-001842-PIP02-15

IRE-Elit SA; This medicinal product is not intended for direct use in patients. Visualisation of function and/or specific organs or lesions in the body, depending on the carrier molecule

used

Day 60 opinion

Other

Summary of committee discussion:

The PDCO continued and finalised the discussion of the request for the granting of a product-specific waiver for the radionuclide 68Gallium (68Ga), in part together with the external expert.
The Committee therefore granted a waiver on this product.

2.1.9. Levocetirizine dihydrochloride / Montelukast sodium - EMEA-001908-PIP01-15

Invest Bielany Sp. z o.o.; Treatment of asthma

Day 60 opinion

Pneumology - Allergology

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 Committee adopted a positive opinion recommends granting a waiver for montelukast (sodium) / levocetirizine (dihydrochloride) in the condition of treatment of asthma.

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. Canakinumab - EMEA-C-000060-PIP04-14-M01

Novartis Europharm Ltd.; Treatment of hyperimmunoglobulin D syndrome

Day 60 opinion

Immunology-Rheumatology-Transplantation

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/0238/2015 of 30 October 2015.

2.2.2. Canakinumab - EMEA-C-000060-PIP05-14-M01

Novartis Europharm Ltd.; Treatment of tumour necrosis factor receptor associated periodic syndrome

Day 60 opinion

Immunology-Rheumatology-Transplantation

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/0239/2015 of 30 October 2015.

2.2.3. Bevacizumab - EMEA-C-000056-PIP01-07-M02

F.Hoffmann-La Roche Ltd; Treatment of non-rhabdomyosarcoma soft tissue sarcoma

Day 60 opinion

Oncology

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/0004/2014) of 22 January 2014.

2.2.4. rurioctocog alfa pegol - EMEA-C1-001296-PIP01-12-M03

Baxalta Innovations GmbH; Treatment and prophylaxis of bleeding in patients with haemophilia A (congenital factor VIII deficiency)

Day 30 opinion

Haematology-Hemostaseology

Summary of committee discussion:

The PDCO finalised 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, and the one that was to be initiated.

2.2.5. Tofacitinib citrate - EMEA-C3-000576-PIP01-09-M05

Pfizer Limited; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis and juvenile idiopathic arthritis)

Day 30 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

The PDCO finalised 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.

2.2.6. Recombinant Human TriPeptidyl Peptidase 1 (rhTPP1) - EMEA-C1-001362-PIP01-12-M02

BioMarin International Limited; Treatment of Neuronal Ceroid Lipofuscinosis Type 2 (CLN2)

Day 30 opinion

Neurology

Summary of committee discussion:

The PDCO discussed the completed study and considered that this is compliant with the latest Agency's Decision (P/0209/2015) of 18 September 2015.
The PDCO finalised this partially completed compliance procedure.

2.2.7. Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily A) / Neisseria meningitidis serogroup B recombinant lipoprotein (rLP2086; subfamily B) - EMEA-C1-001037-PIP02-11-M03

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

Day 30 opinion

Vaccines

Summary of committee discussion:

The PDCO finalised this partially completed compliance procedure and confirmed the compliance of all those studies contained in the agreed paediatric investigation plan that were to be completed until this date.

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Alirocumab - EMEA-001169-PIP01-11-M01

Sanofi-aventis Recherche & développement; Treatment of elevated cholesterol / Treatment of heterozygous and homozygous familial hypercholesterolemia

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

Following the clarifications received from the applicant between D30 and D60, 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/0297/2013 of 29/11/2013).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.2. Pitavastatin - EMEA-000054-PIP01-07-M04

Kowa Pharmaceutical Europe Company Ltd; Endocrine, nutritional and metabolic diseases - Metabolic disorders - Disorders of lipoprotein metabolism and other lipidaemias E78 / Treatment of high-risk hyperlipidaemia (excluding homozygous familial hypercholesterolaemia) in children and adolescents who are not controlled on diet

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 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/0230/2012 of 5 October 2012).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.3. Pitavastatin - EMEA-000300-PIP01-08-M04

Kowa Pharmaceutical Europe Company Ltd; Endocrine, nutritional and metabolic diseases - Metabolic disorders - Disorders of lipoprotein metabolism and other lipidaemias E78 / Treatment of high-risk hyperlipidaemia (excluding homozygous familial hypercholesterolaemia) in children and adolescents who are not controlled on diet

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 proposed changes could be accepted.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0231/2012 of 5 October 2012).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.4. Heterologous Human Adult Liver-derived Progenitor Cells (HHAPLC) - Orphan - EMEA-001155-PIP01-11-M03

Promethera Biosciences; Urea Cycle Disorders, Crigler-Najjar Syndrome / Treatment of inborn errors of liver metabolism

Day 60 opinion

Gastroenterology-Hepatology

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 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 (P/0314/2014 of 24 November 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.5. Coagulation Factor VIIa (Recombinant) - EMEA-001203-PIP02-14-M01

LFB SA; Treatment of congenital coagulation disorders, Treatment of acquired haemophilia / Treatment of bleeding and prevention of bleeding in those undergoing surgery or invasive procedures in patients with haemophilia A or B with inhibitors to Factors VIII or IX, Treatment of bleeding and prevention of bleeding in those undergoing surgery or invasive procedures in patients with acquired haemophilia

Day 60 opinion

Haematology-Hemostaseology

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that most of the proposed changes, as per above, 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/0042/2015 of 06/03/2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.6. ixekizumab - EMEA-001050-PIP01-10-M01

Eli Lilly & Company Limited; Treatment of psoriasis vulgaris, Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis) / Treatment of moderate to severe chronic plaque psoriasis in paediatric patients from the age of 6 years who are not adequately controlled by topical therapies., Treatment of JIA (including polyarticular arthritis, extended oligoarticular arthritis, sJIA without active systemic features, and ERA including JoAS and JPsA) in paediatric patients from the age of 2 years and for the treatment of sJIA with active systemic features in paediatric patients from the age of 1 year.

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/0090/2012 of 29 May 2012).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.7. Adalimumab - EMEA-000366-PIP05-12-M01

AbbVie Limited; Non-infectious uveitis

Day 60 opinion

Immunology-Rheumatology-Transplantation / Ophthalmology / Dermatology / Gastroenterology-Hepatology

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/0070/2014 of 18 March 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.8. boceprevir - EMEA-000583-PIP01-09-M07

Merck Sharp & Dohme Ltd; Treatment of chronic viral hepatitis C / Treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alpha and ribavirin, in children and adolescents from 3 years to less than 18 years of age with compensated liver disease who are previously untreated or who have failed previous therapy.

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

2.3.9. Fidaxomicin - EMEA-000636-PIP01-09-M04

Astellas Pharma Europe B.V.; Treatment of enterocolitis caused by clostridium difficile / Treatment of Clostridium difficile infections (CDI) also known as C. difficile-associated diarrhoea (CDAD)

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/0264/2014 of 3 October 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.10. Olesoxime - Orphan - EMEA-001414-PIP01-12-M01

Roche Registration Limited; 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 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/0044/2015 of 6 March 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.11. Talimogene laherparepvec - EMEA-001251-PIP01-11-M01

Amgen Europe B.V.; Treatment of melanoma in adults / Treatment of solid malignant non-CNS tumours

Day 60 opinion

Oncology

Summary of committee discussion:

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

2.3.12. Tapentadol - EMEA-000018-PIP01-07-M10

Grünenthal GmbH; Acute pain / Treatment of acute pain

Day 60 opinion

Pain

Summary of committee discussion:

Based on the review of the rationale submitted by the application for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0056/2015 of 1 April 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.
This Paediatric Investigation Plan and all its subsequent modifications thereof is to supersede decision P/103/2009 issued 5 June 2009 and decision P/104/2009 issued 5 June 2009.

2.3.13. Tapentadol - EMEA-000494-PIP01-08-M09

Grünenthal GmbH; Acute pain / Treatment of acute pain

Day 60 opinion

Pain

Summary of committee discussion:

The PDCO discussed the applicant's clarifications and considered them agreeable. The committee's views expressed at 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/0238/2014 of 19 September 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.
With this modification the PIP is closed and is superseded by PIP [P/48/2008 issued 11 August 2008] and all its subsequent modifications.

2.3.14. Tapentadol - EMEA-000495-PIP01-08-M09

Grünenthal GmbH; Acute pain / Treatment of acute pain

Day 60 opinion

Pain

Summary of committee discussion:

The PDCO discussed the applicant's clarifications and considered them agreeable. The committee's views expressed at 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/0238/2014 of 19 September 2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.
With this modification the PIP is closed and is superseded by PIP [P/48/2008 issued 11 August 2008] and all its subsequent modifications.

2.3.15. mometasone furoate / indacaterol acetate (dose expressed as free base) - EMEA-001217-PIP01-11-M02

NOVARTIS EUROPHARM LTD.; Treatment of asthma

Day 60 opinion

Pneumology - Allergology

Summary of committee discussion:

The PDCO's view expressed at Day 30 was re-discussed and endorsed. The committee also discussed all clarifications submitted by the applicant.
The PDCO adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0193/2015 of 4 September 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.16. tralokinumab - EMEA-000782-PIP01-09-M03

MedImmune Ltd; Asthma / Treatment of adults and adolescents whose asthma is inadequately controlled with medium or high-dose inhaled corticosteroids (ICS) and at least one additional controller medication

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/0198/2014 of 08/08/2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.17. potassium hydrogen carbonate / potassium citrate monohydrated - EMEA-001357-PIP01-12-M01

Advicenne Pharma; Treatment of renal tubular acidosis

Day 60 opinion

Uro-nephrology

Summary of committee discussion:

The PDCO discussed at D60 the modification request for EMEA-001357-PIP01-12-M01.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0257/2014 of 01/10/2014).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.18. Everolimus - Orphan - EMEA-000019-PIP08-12-M02

Novartis Europharm Limited; Tuberous Sclerosis Complex (TSC) / Treatment of refractory epilepsy associated with tuberous sclerosis complex (TSC)

Day 60 opinion

Uro-nephrology / 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/0236/20015 of 30 October 2015).
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. 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

Treatment of alopecia

Day 90 discussion

Dermatology

3.1.2. A derivative of (2S,3S,4R)-3-ethyl-4-hydroxypyrrolidine-2-carboxylic acid / A derivative of (S)-methyl (2-(2-(1H-imidazol-2-yl)pyrrolidin-1-yl)-2-oxoethyl)carbamate / Sofosbuvir - EMEA-001822-PIP01-15

Treatment of chronic hepatitis C / Treatment of chronic Hepatitis C in adolescents and children 3 years of age and older

Day 90 discussion

Infectious Diseases

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

Prevention of respiratory syncytial viral infections

Day 90 discussion

Infectious Diseases

3.1.4. doravirine - EMEA-001676-PIP01-14

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 90 discussion

Infectious Diseases

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

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 90 discussion

Infectious Diseases

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

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 90 discussion

Infectious Diseases

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

Ultragenyx Pharmaceutical Inc.; X-linked Hypophosphatemia

Day 90 discussion

Other

3.1.8. - EMEA-001868-PIP01-15

Treatment of Persistent Pulmonary Hypertension of the Newborn [PPHN], Treatment of Pulmonary Arterial Hypertension (PAH), Treatment of Pulmonary Veno-Occlusive Disease and Pulmonary Capillary Hemangiomatosis [PVOD/PCH] / Treatment of PAH in pediatric patients aged 1 to <18 years of age

Day 60 discussion

Cardiovascular Diseases

3.1.9. 2-hydroxypropyl-ß-cyclodextrin (HP-ß-CD) - Orphan - EMEA-001866-PIP01-15

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

Day 60 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.1.10. Synthetic double-stranded siRNA oligonucleotide directed against antithrombin mRNA and covalently linked to a ligand containing three N-acetylgalactosamine residues - Orphan - EMEA-001855-PIP01-15

Alnylam UK Limited; Treatment of Haemophilia B, Treatment of Haemophilia A / ALN-AT3SC is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in children aged ≥1 year with severe haemophilia A, including patients who express neutralizing antibodies to exogenous factor VIII substitution, ALN-AT3SC is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in children aged ≥1 year with severe haemophilia B, including patients who express neutralizing antibodies to exogenous factor IX substitution

Day 60 discussion

Haematology-Hemostaseology

3.1.11. Eculizumab - Orphan - EMEA-000876-PIP06-15

Alexion Europe SAS; Prevention of graft rejection following solid organ transplantation / Prevention of acute antibody-mediated rejection in sensitized recipients after kidney transplantation

Day 60 discussion

Immunology-Rheumatology-Transplantation

3.1.12. Recombinant human monoclonal antibody to GM-CSF - EMEA-001882-PIP01-15

Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, psoriatic arthritis, ankylosing spondylarthritis and juvenile idiopathic arthritis) / Treatment of active systemic juvenile idiopathic arthritis (sJIA) in patients 1 year of age and older, Treatment of active polyarticular juvenile idiopathic arthritis (pJIA) in patients 2 years of age and older

Day 60 discussion

Immunology-Rheumatology-Transplantation

3.1.13. Immunoglobulin G2, anti-(human α-calcitonin gene-related peptide/β-calcitonin gene-related peptide) (human-Mus musculus monoclonal heavy chain), disulphide with human-Mus musculus monoclonal light chain, dimer - EMEA-001877-PIP01-15

Migraine / Prophylaxis of headache in children aged 6 to 18 years with episodic and chronic migraine

Day 60 discussion

Neurology

3.1.14. andexanet alfa - EMEA-001902-PIP01-15

Prevention of factor Xa inhibitor associated haemorrhage, Treatment of factor Xa inhibitor associatedhaemorrhage / (as above), For the reversal of anticoagulation due to direct and

indirect factor Xa inhibitors in patients experiencing an acute major bleeding event or requiring urgent surgery.

Day 60 discussion

Other

3.1.15. 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 60 discussion

Other

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

J30.1 Allergic rhinitis due to pollen / Treatment of tree pollen allergic rhinitis and/or conjunctivitis

Day 60 discussion

Pneumology - Allergology

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

Treatment of allergic rhinitis and/or conjunctivitis / treatment of ragweed pollen allergic rhinitis and/or conjunctivitis

Day 60 discussion

Pneumology - Allergology

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

Treatment of seborrhoeic keratosis / Treatment of seborrhoeic keratosis

Day 30 discussion

Dermatology

3.1.19. tralokinumab - EMEA-001900-PIP01-15

Atopic dermatitis

Day 30 discussion

Dermatology

3.1.20. 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 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

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

Day 30 discussion

Gastroenterology-Hepatology

3.1.22. 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 30 discussion

Immunology-Rheumatology-Transplantation

3.1.23. 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 30 discussion

Immunology-Rheumatology-Transplantation

3.1.24. 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 30 discussion

Immunology-Rheumatology-Transplantation

3.1.25. Omadacycline - EMEA-000560-PIP02-15

Infections of the skin and subcutaneous tissue

Day 30 discussion

Infectious Diseases

3.1.26. Omadacycline - EMEA-000560-PIP03-15

Bacterial pneumonia

Day 30 discussion

Infectious Diseases

3.1.27. 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 30 discussion

Neurology

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

Prophylactic treatment of migraine headache

Day 30 discussion

Neurology

3.1.29. Levodopa - EMEA-001874-PIP01-15

Parkinson's Disease

Day 30 discussion

Neurology

3.1.30. 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 30 discussion

Oncology

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

Cyclacel Limited; Treatment of acute myeloid leukaemia

Day 30 discussion

Oncology

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

Treatment of Catecholamine-resistant hypotension associated with distributive shock

Day 30 discussion

Other

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

Treatment of pain

Day 30 discussion

Pain

3.1.34. Anti IL-4 and IL-13 humanized bispecific monoclonal antibody - EMEA-001804-PIP02-15

Interstitial Lung Diseases

Day 30 discussion

Pneumology - Allergology

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

Major Depressive Disorder (MDD)

Day 30 discussion

Psychiatry

3.1.36. 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 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. C1inhibitor (human) - EMEA-C-000568-PIP01-09-M06

NPS Pharma Holdings Limited (now part of Shire); Treatment of C1 inhibitor deficiency

Day 30 discussion

Immunology-Rheumatology-Transplantation

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

AbbVie Ltd; Treatment of hidradenitis suppurativa

Day 30 discussion

Immunology-Rheumatology-Transplantation / Dermatology

3.2.3. rufinamide - EMEA-C2-000709-PIP01-09-M04

Eisai Limited; Treatment of Lennox-Gastaut Syndrome

Day 30 discussion

Neurology

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

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

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

Day 30 discussion

Cardiovascular Diseases

3.3.2. 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 30 discussion

Cardiovascular Diseases

3.3.3. vorapaxar sulfate - EMEA-000778-PIP02-12-M01

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

Day 30 discussion

Cardiovascular Diseases

3.3.4. 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 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

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

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

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

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

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

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

3.3.8. 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 30 discussion

Immunology-Rheumatology-Transplantation / Endocrinology-Gynaecology-Fertility-Metabolism / Oncology

3.3.9. 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 30 discussion

Infectious Diseases

3.3.10. 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 30 discussion

Neurology

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

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

Day 30 discussion

Neurology

3.3.12. 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 30 discussion

Neurology

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

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

Day 30 discussion

Neurology

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

Exelixis Inc; Cancer

Day 30 discussion

Oncology

3.3.15. 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 30 discussion

Oncology

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 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. Duvelisib - EMEA-54-2015

Abbvie Ltd; Treatment of chronic lymphocytic leukaemia/ treatment of adult patients with chronic lymphocytic leukaemia who have received at least one prior treatment

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: treatment of hematological malignancies, asthma and juvenile idiopathic arthritis.

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. Duvelisib - EMEA-55-2015

Abbvie Ltd; Treatment of follicular lymphoma/ treatment of adult patients with follicular lymphoma who have received at least two prior treatments

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: treatment of hematological malignancies, asthma and juvenile idiopathic arthritis.

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. Mesmulogene ancovacivec - EMEA-56-2015

TRANSGENE S.A.; Treatment of lung carcinoma (small cell and non-small cell carcinoma)/ Treatment of advanced non-squamous non-small cell lung cancer

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.

6.1.4. Crenezumab - EMEA-57-2015

Roche Registration Limited; Treatment of Alzheimer's Disease/ Treatment of prodromal Alzheimer's Disease to mild 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 confirmed.

Other potential paediatric interest of this medicine suggested by PDCO: currently none.

6.1.5. In vitro transcribed (IVT) ribonucleic acid (RNA)-electroporated and cultured autologous mature dendritic cells (DCs) - EMEA-01-2016

Argos Therapeutics, Inc.; Treatment of kidney and renal pelvis carcinoma (excluding nephroblastoma, nephroblastomatosis, clear cell sarcoma, mesoblastic nephroma, renal medullary carcinoma and rhabdoid tumour of the kidney),CW/1/2011-All medicines for treatment of kidney and renal pelvis carcinoma, CW/0001/2015 / Treatment of advanced renal 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.

The applicability of the class waiver as referred to in the Agency's Decision CW/0001/2015 to the planned therapeutic indication was not confirmed.

Other potential paediatric interest of this medicine suggested by PDCO: renal cell carcinoma.

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.

6.1.6. Pegpleranib - EMEA-02-2016

Novartis Europharm Limited; All classes of medicinal products for treatment of age-related macular degeneration and diabetic macular oedema/ Treatment of neovascular age related macular degeneration (nAMD) in combination with anti-VEGF agents

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: currently none.

6.1.7. Masitinib - EMEA-03-2016

AB Science; Treatment of amyotrophic lateral sclerosis/ Treatment of amyotrophic lateral sclerosis

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: multiple sclerosis, progressive supranuclear palsy, asthma, Crohn´s disease.

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

6.1.8. Paracetamol - EMEA-04-2016

GlaxoSmithKline Consumer Healthcare (UK) Trading Limited; Treatment of primary and secondary osteoarthrosis/ Relief of pain associated with osteoarthritis

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.

Other potential paediatric interest of this medicine suggested by PDCO: chronic joint pain requiring long term analgesia secondary to for example juvenile idiopathic arthritis, systemic lupus erythematosus, Behçet's disease.

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

6.1.9. Plitidepsin - EMEA-05-2016

Pharma Mar, S.A.; Treatment of multiple myeloma/ Plitidepsin in combination with dexamethasone, is indicated in adults for the treatment of relapsed/refractory multiple

myeloma who have received at least three prior regimens including bortezomib, and either lenalidomide or thalidomide

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.

Other potential paediatric interest of this medicine suggested by PDCO: haematological malignancies and solid 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.

6.1.10. Recombinant human anti-human VEGF-A and anti-human Ang-2 mAb (RO6867461) - EMEA-06-2016

Roche Products Limited; All classes of medicinal products for treatment of age-related macular degeneration and diabetic macular oedema/ Treatment of diabetic macular oedema

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: retinopathy of prematurity.

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

8.1.1. (GS-7977) - EMEA-001276-PIP01-12-M01

Gilead Sciences International Ltd.

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.2. Fidaxomicin - EMEA-00636-PIP01-09-M03

Astellas Pharma Europe B.V.

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report. A modification of the agreed PIP has been adopted.

8.1.3. Aciclovir - EMEA-001066-PIP02-11-M01

BioAlliance Pharma

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.4. AGOMELATINE - EMEA-001181-PIP-11- M02

Les Laboratoires Servier

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.5. Apremilast - EMEA-000715-PIP03-11-M03

Celgene Europe Limited

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.6. Apremilast - EMEA-000715/PIP02-11-M02

Celgene Europe Limited

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.7. apremilast - Orphan - EMEA-000715/PIP05-13

Celgene Europe Limited

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.8. corifollitropin alfa - EMEA-000306-PIP01-08-M02

N.V. Organon

Difficulties progressing the PIP? Yes

Summary of committee discussion:

Due to technical difficulties the paediatric clinical trials are not progressing as fast as planned. A modification may be required to amend the timelines in the PIP opinion.

8.1.9. Dimethyl fumarate - EMEA-000832-PIP01-10

Biogen Idec Ltd.

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.10. Eliglustat (tartrate) - Orphan - EMEA-000461-PIP02-11

Genzyme Europe B.V.

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.11. N.meningitidis Outer Membrane Vesicles (OMV) from NZ 98/254 strain / N.meningitidis936-741 purified antigen / N.meningitidis 961c purified antigen / N.meningitidis 287-953 purified antigen - EMEA-00139-PIP01-07

Novartis Vaccines and Diagnostics S.r.l.

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.12. Nanoparticle albumin-bound paclitaxel - Orphan - EMEA-001308-PIP01-12

Celgene Europe Limited

Difficulties progressing the PIP? No

Summary of committee discussion:

The Paediatric Committee noted the report.

8.1.13. Natalizumab - 001095-PIP02-12

Biogen Idec Limited

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.14. pegylated human interferon beta-1a - EMEA-001129-PIP01-11-M01

Biogen Idec Ltd.

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.15. Potassium sulphate / Magnesium sulphate, heptahydrate / Sodium sulphate, anhydrous - EMEA-000816-PIP02-10

Ipsen Pharma

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report. A modification will be submitted to PDCO for first discussion in March 2016.

8.1.16. Recombinant human monoclonal antibody to human interleukin-17A of the IgG1/kappa-class (secukinumab) - EMEA-000380-PIP01-08-M03

Novartis Europharm Ltd

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.17. Recombinant human monoclonal antibody to human interleukin-17A of the IgG1/kappa-class (secukinumab) - Orphan - EMEA-000380-PIP02-09-M02

Novartis Europharm Limited

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.18. Romiplostim - Orphan - EMEA-000653-PIP01-09-M04

Amgen Europe B.V

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.19. rufinamide - Orphan - EMEA-000709-PIP01-09-M03

Eisai Ltd.

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.20. Sodium (4R,9aS)-5-Hydroxy-4-methyl-6,10-dioxo-3,4,6,9,9a,10-hexahydro-2H-1-oxa-4a,8a-diaza-anthracene-7-carboxylic acid 2,4-difluoro-benzylamide - EMEA-000409-PIP01-08-M03

GlaxoSmithKline Trading Services Ltd.

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.21. Tenofovir disoproxil (as fumarate) - EMEA-000533-PIP01-08-M06

Gilead Sciences International Limited

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.22. ustekinumab - EMEA-000311-PIP01-08

Janssen-Cilag International NV

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.23. ustekinumab - EMEA-000311-PIP04-13

Janssen-Cilag International NV

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.24. vorapaxar - EMEA-000778-PIP02-12

Merck Sharp & Dohme (Europe), Inc

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.25. zanamivir - EMEA-001318-PIP01-12-M01

GlaxoSmithKline Trading Services Limited

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. Follow-up actions - PDCO members training 26 January 2016

Summary of committee discussion:

The Committee endorsed the follow-up actions from the PDCO members' training held on 26 January 2016. The PDCO Chair and Vice-Chair will start working on draft guidance for Rapporteurs and Peer-Reviewers on drafting PIP comments.

A survey will be launched on the extension of the duration of PDCO plenary meetings.

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

Summary of committee discussion:

The PDCO members were informed about 2 products, Coagadex and Revolade, for which the CHMP adopted positive opinions recommending paediatric indications during their meeting in January 2016.

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:

The chair of the FWG identified the products which will require FWG evaluation and discussion.

9.4. Cooperation within the EU regulatory network

9.4.1. The Innovative Medicines Initiative (IMI) Workshop on Paediatric Clinical trials to be held on 5 April 2016 in Brussels, Belgium

PDCO Chair: Dirk Mentzer

Summary of committee discussion:

The Committee was informed about the upcoming workshop on paediatric clinical trials organised by IMI to be held on 5 April 2016. It was felt that a stronger representation of PDCO members with expertise in paediatric research and conducting clinical trials as well as broad geographical representation would be important. Several PDCO members expressed their interest and availability to attend the workshop.

9.4.2. Announcement of Review and Learning Meeting to be organised in Belgium on 19-21 October 2016

PDCO Member: Koenraad Norga

Summary of committee discussion:

The Committee was invited to attend, on 19-21 October 2016, the Strategic Review and Learning Meeting in Brussels, Belgium. Members were invited to propose topics for discussion during this meeting.

9.5. Cooperation with International Regulators

9.5.1. Draft Programme of EMA Extrapolation Workshop

Summary of committee discussion:

The draft programme of the EMA extrapolation workshop, to be held at the Agency on 17-18 May 2016, was presented.

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. Report on the 'Data Gathering Initiative'

Summary of committee discussion:

The Committee was informed about per procedure/per delegation data to be recorded and collected over 3 months. Further detailed information will be provided via a dedicated webinar (attendance by invitation).

9.9. PDCO ORGAM

9.9.1. PDCO ORGAM Draft Minutes for 17 February 2016

Summary of committee discussion:

The minutes of the PDCO ORGAM meeting held on 17 February 2016 were adopted.

10. Any other business

None

11. Breakout sessions

11.1.1. Paediatric oncology

Summary of committee discussion:

The participants discussed recent developments concerning paediatric clinical trials, recent publications and upcoming projects funded by the European Union.

11.1.2. Neonatology

Summary of committee discussion:

The participants discussed recent developments including the activities of the International Neonatal Consortium.

11.1.3. Inventory

Summary of committee 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 committee discussion:

The participants discussed allocation of tasks and next steps.

The Chair thanked all 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 24-26 February 2016 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Dirk Mentzer	Chair	Germany	No interests declared	
Karl-Heinz Huemer	Member	Austria	No interests declared	
Koenraad Norga	Member (Vice-Chair)	Belgium	When chairing the meeting, to be replaced for discussions, final deliberations and voting	EMEA-001882-PIP01-15 EMEA-04-2016 EMEA-000409-PIP01-08-M03 EMEA-001318-PIP01-12-M01
Jacqueline Carleer	Alternate	Belgium	No interests declared	
Dimitar Roussinov	Member	Bulgaria	No restrictions applicable to the meeting	
Adriana Andrić	Member	Croatia	No interests declared	
Suzana Mimica Matanovic	Alternate	Croatia	No participation in discussions, final deliberations and voting	EMEA-C-000056-PIP01-07-M02 EMEA-001414-PIP01-12-M01 EMEA-57-2015 EMEA-06-2016 EMEA-001739-PIP01-14 EMEA-000018-PIP01-07-M10 EMEA-000494-PIP01-08-M09 EMEA-000495-PIP01-08-M09 EMEA-001861-PIP01-15
Georgios Savva	Member	Cyprus	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	
Maija Pihlajamaki	Alternate	Finland	No interests declared	
Sylvie Benchetrit	Member	France	No interests declared	
Immanuel Barth	Member	Germany	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Sabine Scherer	Alternate	Germany	No interests declared	
Grigorios Melas	Member	Greece	No interests declared	
Ágnes Gyurasics	Member (CHMP member)	Hungary	No interests declared	
Brian Aylward	Member	Ireland	No interests declared	
Francesca Rocchi	Alternate	Italy	No restrictions applicable to the meeting	
Dina Apele-Freimane	Member	Latvia	No interests declared	
Carola de Beaufort	Member (CHMP alternate)	Luxembourg	No restrictions applicable to the meeting	
Herbert Lenicker	Alternate	Malta	No interests declared	
Maaike van Dartel	Alternate	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	
Jolanta Witkowska-Ozogowska	Alternate	Poland	No interests declared	
Hugo Tavares	Alternate	Portugal	No interests declared	
Dana Gabriela Marin	Member (CHMP alternate)	Romania	No interests declared	
Stefan Grosek	Member	Slovenia	No interests declared	
Fernando de Andrés Trelles	Member	Spain	No interests declared	
Maria Jesús Fernández Cortizo	Alternate	Spain	No interests declared	
Ninna Gullberg	Member	Sweden	No interests declared	
Angeliki Siapkara	Member	United Kingdom	No interests declared	
Martina Riegl	Alternate	United Kingdom	No interests declared	
Riccardo Riccardi	Member	Healthcare Professionals' Representative	No participation in discussions, final deliberations and voting	EMEA-000461-PIP02-11
Paolo Paolucci	Alternate	Healthcare Professionals' Representative	No interests declared	
Johannes Taminiau	Member	Healthcare Professionals' Representative	No interests declared	
Doina Plesca	Alternate	Healthcare	No participation in	EMEA-001908-

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
		Professionals' Representative	discussions, final deliberations and voting	PIP01-15 EMEA-001217-PIP01-11-M02 EMEA-000782-PIP01-09-M03 EMEA-000467-PIP01-08-M07
Günther Auerswald	Member	Patients' Organisation Representative	No participation in discussions, final deliberations and voting	EMEA-001203-PIP02-14-M01 EMEA-001855-PIP01-15 EMEA-C1-001296-PIP01-12-M03
Paola Baiardi	Alternate	Patients' Organisation Representative	No interests declared	
Tsvetana Schyns-Liharska	Member	Patients' Organisation Representative	No restrictions applicable to the meeting	
Michael Lassmann	Expert - via telephone*	Germany	Direct interests declared	
Juliana Min	Expert - in person*	United Kingdom	Direct interests declared	
A representative from the European Commission attended the meeting				
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/