18 April 2017
EMA/PDCO/193146/2017
Inspections, Human Medicines Pharmacovigilance and Committees Division

Paediatric Committee (PDCO)

Minutes for the meeting on 21-24 March 2017

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

21 March 2017, 14:00- 19:00, room 3A

22 March 2017, 08:30- 19:00, room 3A

23 March 2017, 08:30- 19:00, room 3A

24 March 2017, 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 of the February PDCO plenary meeting were adopted with amendments and will be published on the EMA website.

2. Opinions

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

2.1. Opinions on Products

2.1.1. Recombinant modified human growth hormone - Orphan - EMEA-001152-PIP02-16

Richardson Associates Regulatory Affairs Ltd; Growth hormone deficiency / Treatment of children with growth failure due to inadequate secretion of endogenous growth hormone

Day 60 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

Summary of committee discussion:

On 24 March 2017, in line with the detailed PDCO discussion at day 30 in February 2017, the PDCO adopted a refusal of the PIP and agreement of a full waiver in all paediatric subsets on the grounds of lack of significant therapeutic benefit and likely lack of safety.

2.1.2. 3,6-diamino-2,5-bis{N-[(1R)-1-carboxy-2-hydroxyethyl]carbamoyl}pyrazine - EMEA-001983-PIP01-16

MediBeacon Inc.; Monitoring of renal function

Day 120 opinion

Diagnostic / Uro-nephrology

Summary of committee discussion:

All issues identified at Day 90 were satisfactorily addressed by the applicant. A positive opinion was adopted.

2.1.3. avacopan - Orphan - EMEA-002023-PIP01-16

ChemoCentryx, Ltd.; Treatment of ANCA-associated vasculitis

Day 120 opinion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

The PDCO concluded that all issues have been addressed and resolved satisfactorily.
The PDCO adopted a positive opinion.

2.1.4. Indapamide / Ramipril - EMEA-002081-PIP01-16

Pharmaceutical Works Polpharma SA; Treatment of hypertension ICD10 I10-I15 / Treatment of hypertension as substitution therapy in adults whose blood pressure is adequately controlled by the use of ramipril and indapamide with the individual products given concurrently at the same dose level as in the combination, but as separate medicinal products, Treatment of hypertension in adults whose blood pressure is not adequately controlled by the use of ramipril monotherapy and for whom the use of the second medicinal product is an optimal therapeutic procedure

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

The PDCO confirmed the Day 30 discussion at their February 2017 meeting. Based on the assessment of this application and further discussions at the Paediatric Committee, the PDCO agrees with the applicant's request granting a waiver for indapamide /ramipril for all subsets of the paediatric population (0 to 18 years of age) in the condition of treatment of

hypertension.

2.1.5. erdafitinib - EMEA-002042-PIP01-16

Janssen-Cilag International N.V; Treatment of Ureter and Bladder Carcinoma

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO re-discussed the application for a waiver for all subsets of the paediatric population for erdafitinib also taking into account the clarification provided by the applicant after the D30 discussion.
The PDCO agreed with the applicant's request for a waiver and recommends granting a waiver for erdafitinib for all subsets of the paediatric population (0 to 18 years of age) in the condition 'treatment of urothelial carcinoma'

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.

2.1.6. nintedanib - Orphan - EMEA-001006-PIP03-16

Boehringer Ingelheim International GmbH; Treatment of lung carcinoma (small cell and non-small cell carcinoma), Treatment of mesothelioma

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO recommends granting a product specific waiver for all subsets of the paediatric population (0 to 18 years of age) based on the grounds of lack of significant therapeutic benefit.

2.1.7. Small interfering RNA targeting human TRPV1 - EMEA-002061-PIP01-16

Sylentis SAU; Treatment of dry eye disease

Day 60 opinion

Ophthalmology

Summary of committee discussion:

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 Small interfering RNA targeting human TRPV1 for all subsets of the paediatric population (0 to 18 years of age) in the condition of Treatment of dry eye disease. A positive opinion was adopted .

2.1.8. mepolizumab - Orphan - EMEA-000069-PIP05-16

GSK Trading Services Limited; Treatment of nasal polyposis / indicated for the add-on maintenance treatment of adult patients with severe bilateral nasal polyposis who have had prior nasal polyp surgery

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 PDCO recommends granting a waiver for mepolizumab for all subsets of the paediatric population (0 to 18 years of age) in the condition of Treatment of nasal polyposis.

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

Amgen Ltd.; Treatment of anaemia due to chronic disorders

Day 60 opinion

Oncology / Uro-nephrology

Summary of committee discussion:

The completed studies were checked for compliance
The PDCO adopted on 24 March 2017 an opinion refusing the compliance of one or more studies in the agreed paediatric investigation plan as set out in the Agency's Decision (P/0147/2016) of 14/06/2016.

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.3.1. Dopamine hydrochloride - EMEA-001105-PIP01-10-M03

BrePco Biopharma Limited; Treatment of vascular hypotensive disorders / Treatment of hypotension in neonates including the extremely low gestational age newborn, Treatment of hypotension in infants and children

Day 60 opinion

Cardiovascular Diseases

Summary of committee discussion:

A response to the issues raised at Day 30 was provided on 6 March 2017, and a further response to the draft opinion was received on 17 March 2017.

Thus, based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a positive Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0213/2015 of 2 October 2015).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.2. 3-[[5-chloro-1-[3-(methylsulfonyl)propyl]-1H-indol-2-yl]methyl]-1-(2,2,2-trifluoroethyl)-1,3-dihydro-2H-imidazo[4,5-c]pyridine-2-one - EMEA-001838-PIP01-15-M01

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

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

The PDCO's view expressed at day 30 was re-discussed and endorsed. The committee also discussed the applicant's additional information and clarifications and considered them agreeable.
Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that the proposed changes could be accepted.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0223/2016 of 12 August 2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.3. doravirine - EMEA-001676-PIP01-14-M01

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 60 opinion

Infectious Diseases

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan and the additional information received after the D30 discussion the PDCO supported the majority of the changes requested at their March 2017 meeting.

2.3.4. tenofovir disoproxil fumarate / lamivudine / doravirine - EMEA-001695-PIP01-14-M01

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 children aged 2 to 18 years

Day 60 opinion

Infectious Diseases

Summary of committee discussion:

Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan and the additional information received after the D30 discussion the PDCO supported the majority of the changes requested at their March 2017 meeting.
In conclusion the PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0140/2016 of 20/5/2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.5. ponatinib - Orphan - EMEA-001186-PIP01-11-M01

Incyte Biosciences UK Ltd.; Chronic myeloid leukaemia, Philadelphia chromosome positive acute lymphoblastic leukaemia / Paediatric population with Chronic phase, accelerated phase, or blast phase chronic myeloid leukaemia (CML) who are resistant or intolerant to at least one prior BCR-ABL TKI therapy; or who have the T315I mutation, Paediatric population with Philadelphia chromosome positive acute lymphoblastic leukaemia (Ph+ ALL) who are resistant or intolerant to at least one prior BCR-ABL TKI therapy; or who have the T315I mutation

Day 60 opinion

Oncology

Summary of committee discussion:

The PDCO re-discussed the procedure also taking into account the clarifications received by the applicant.
The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0131/2012 of 04/ 07/2012).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.6. Tapentadol - EMEA-000018-PIP01-07-M13

Grünenthal GmbH; Treatment of acute pain

Day 60 opinion

Pain

Summary of committee discussion:

The PDCO views expressed at day 30 were re-discussed and endorsed. The committee also discussed the applicant's clarifications.
Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan, the PDCO considered that some but not all 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/0315/2016 of 2 December 2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

2.3.7. Melatonin - Orphan - EMEA-000440-PIP02-11-M05

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

Day 30 opinion

Neurology

Summary of committee discussion:

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

The PDCO therefore adopted a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0148/2016 of 14/06/2016).

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

2.4. Opinions on Re-examinations

2.4.1. dupilumab - EMEA-001501-PIP01-13-M04

Regeneron Pharmaceuticals, Inc; Atopic Dermatitis

Day 30 opinion

Dermatology

Summary of committee discussion:

The applicant has requested re-examination.

Consequently a new Rapporteur and Peer Reviewer were appointed and the applicant attended an oral explanation meeting at the PDCO Plenary on 22 March 2017.

PDCO conclusion:

Based on the review of the rationale submitted by the applicant for modifying the agreed paediatric investigation plan and the grounds for re-examination, the PDCO therefore considered that the proposed changes could be accepted.

The PDCO therefore adopted a favourable final Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0219/2016 of 12 August 2016).

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

2.4.2. Fingolimod hydrochloride - EMEA-000087-PIP01-07-M05

Novartis Europharm Limited; Multiple Sclerosis

Day 30 opinion

Neurology

Summary of committee discussion:

During the oral explanation the applicant presented their grounds for re-examination
PDCO conclusion:
The PDCO agreed to revise its opinion and therefore adopted, after re-examination, a favourable Opinion on the modification of the agreed PIP as set in the Agency's latest decision (P/0230/2016 of 9 September 2016).
The new PDCO Opinion on the modified agreed PIP supersedes the previous PDCO Opinion.

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

Bellicum Pharma Ltd.; Treatment in haematopoietic stem cell transplantation / Treatment of immunodeficiency after mismatched, related, allogeneic transplantation in paediatric patients with malignant and non-malignant disorders amenable to haematopoietic stem cell transplantation

Day 90 discussion

Immunology-Rheumatology-Transplantation

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

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

Day 90 discussion

Immunology-Rheumatology-Transplantation

3.1.3. EMEA-001975-PIP01-16

Treatment of influenza

Day 90 discussion

Infectious Diseases

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

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

Day 90 discussion

Neurology

3.1.5. Polihexanide (PHMB) - Orphan - EMEA-002053-PIP01-16

Società Industria Farmaceutica Italiana (S.I.F.I.) SpA; ICD10: B.60.1 Keratitis and keratoconjunctivitis (interstitial) in acanthamoebiasis

Day 90 discussion

Ophthalmology

3.1.6. Chloroprocaine Hydrochloride - EMEA-000639-PIP03-16

Peripheral nerve block (local anesthesia by perineural injection)

Day 60 discussion

Anaesthesiology

3.1.7. Selonsertib - EMEA-001868-PIP03-16

K75.8 Other specified inflammatory liver diseases (non-alcoholic steatohepatitis [NASH]) / Treatment of Non-Alcoholic Steatohepatitis (NASH) with moderate to severe fibrosis (F2-F4) in paediatric subjects, 8 to < 18 years of age

Day 60 discussion

Gastroenterology-Hepatology

3.1.8. Human normal immunoglobulin - EMEA-002084-PIP01-16

Primary Immunodeficiency Diseases

Day 60 discussion

Immunology-Rheumatology-Transplantation

3.1.9. Human Normal Immunoglobulin for Intravenous Administration (IVIg) - EMEA-002092-PIP01-16

Treatment of primary immunodeficiency (PID), Treatment of idiopathic thrombocytopenic purpura (ITP) / Primary immunodeficiency syndromes with impaired antibody production, Primary immune thrombocytopenia (ITP), in patients at high risk of bleeding or prior to surgery to correct the platelet count

Day 60 discussion

Immunology-Rheumatology-Transplantation

3.1.10. maribavir - Orphan - EMEA-000353-PIP02-16

Shire Pharmaceuticals Ireland Limited; Treatment of CMV infection / Treatment of CMV infection in transplant patients who are ≥2 to <18 years of age

Day 60 discussion

Infectious Diseases

3.1.11. allopregnanolone - EMEA-002051-PIP01-16

Super Refractory Status Epilepticus

Day 60 discussion

Neurology

3.1.12. GIVINOSTAT - Orphan - EMEA-000551-PIP03-16

Italfarmaco S.p.A.; Treatment of Duchenne Muscular Dystrophy (DMD)

Day 60 discussion

Neurology

3.1.13. Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta chimeric antigen receptor - Orphan - EMEA-001862-PIP01-15

Kite Pharma EU B.V.; Treatment of B-precursor Acute Lymphoblastic Leukaemia (ALL)

Day 60 discussion

Oncology

3.1.14. Autologous T cells transduced with retroviral vector encoding an anti-CD19 CD28/CD3-zeta chimeric antigen receptor - Orphan - EMEA-002010-PIP01-16

Kite Pharma EU B.V.; Treatment of primary mediastinal B cell lymphoma (PMBCL), Treatment of follicular lymphoma (FL), Treatment of diffuse large B cell lymphoma (DLBCL)

Day 60 discussion

Oncology

3.1.15. Brimapitide - Orphan - EMEA-001926-PIP02-16

Auris Medical Ltd.; Idiopathic Sudden Sensorineural Hearing Loss (ISSNHL)

Day 60 discussion

Oto-rhino-laryngology

3.1.16. gpASIT+TM - EMEA-001815-PIP02-16

Treatment of grass pollen induced seasonal allergic rhinoconjunctivitis (SAR)

Day 60 discussion

Pneumology - Allergology

3.1.17. ivacaftor / tezacaftor / N-(benzenesulfonyl)-6-[3-fluoro-5-(2-methylpropoxy)phenyl]-2-[(4S)-2,2,4-trimethylpyrrolidin-1-yl]pyridine-3-carboxamide - EMEA-002086-PIP01-16

Treatment of Cystic Fibrosis

Day 60 discussion

Pneumology - Allergology

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

Treatment of hypercholesterolaemia

Day 30 discussion

Cardiovascular Diseases

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

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

Day 30 discussion

Cardiovascular Diseases

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

Actelion Registration Ltd.; Treatment of Fabry disease

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

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

Iron deficiency anemia, Iron deficiency

Day 30 discussion

Haematology-Hemostaseology

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

Novimmune B.V; Treatment of histiocytosis haematophagic conditions

Day 30 discussion

Immunology-Rheumatology-Transplantation

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

Edge Therapeutics, Inc.; Treatment of aneurysmal subarchnoidal haemorrhage

Day 30 discussion

Neurology

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

Need for parenteral nutrition

Day 30 discussion

Nutrition

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

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

Day 30 discussion

Oncology

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

ReveraGen BioPharma Ltd; Treatment of duchenne muscular dystrophy

Day 30 discussion

Other

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

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

Day 30 discussion

Other

3.1.28. Bupivacaine - EMEA-000877-PIP02-16

postsurgical analgesia

Day 30 discussion

Pain

3.1.29. allopregnanolone - EMEA-002051-PIP02-16

Treatment of postpartum depression

Day 30 discussion

Psychiatry

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

Treatment of opioid dependence

Day 30 discussion

Psychiatry

3.1.31. calcifediol - EMEA-002093-PIP01-16

secondary Hyperparathyroidism (SHPT)

Day 30 discussion

Uro-nephrology

3.2. Discussions on Compliance Check

The following compliance checks have been put up for discussion and the members of the PDCO have been invited to comment on issues of possible non-compliance

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

St. Renatus, LLC; Local anesthesia

Day 30 discussion

Anaesthesiology

3.2.2. Autologous CD34+ enriched cell fraction that contains CD34+ cells transduced with lentiviral vector that encodes for the human Wiskott Aldrich Syndrome (WAS) cDNA sequence - EMEA-C-001792-PIP01-15

GlaxoSmithKline Trading Services Ltd; Treatment of Wiskott Aldrich Syndrome

Day 30 discussion

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

The PDCO discussed the compliance request on 24 March 2017.
The completed study was checked for compliance.
The PDCO adopted on 24 March 2017 an opinion confirming the compliance of all studies in the agreed paediatric investigation plan as set out in the latest Agency's Decision (P/0083/2016) of 18 March 2016.

3.2.3. Certolizumab Pegol - EMEA-C1-001071-PIP03-14

UCB PHARMA S.A.; Treatment of Psoriasis

Day 30 letter

Immunology-Rheumatology-Transplantation

Summary of committee discussion:

The completed study(ies)was/were checked for compliance.
The PDCO discussed the completed study(ies) and considered that these are compliant with the latest Agency's Decision (P/0101/2016) of 15 April 2016.
The PDCO finalised on D30 this partially completed compliance procedure.

3.2.4. voretigene neparvovec (INN) - EMEA-C-001684-PIP01-14

Spark Therapeutics Inc.; Treatment of genetic congenital retinal disorders

Day 30 discussion

Ophthalmology

3.2.5. EMEA-C1-001664-PIP02-15

Novartis Europharm Limited; Prevention of migraine headaches

Day 30 letter

Neurology

Summary of committee discussion:

The PDCO discussed the completed study and considered that this was compliant with the latest Agency's Decision (P/0370/2016) of 04 January 2017.
The PDCO finalised on 22 March 2017 this partially completed compliance procedure and confirmed the compliance of all those studies contained in the agreed paediatric investigation plan that were to be completed until this date.

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

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

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

Day 30 discussion

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

Ethicare GmbH; Treatment of Heart Failure

Day 30 discussion

Cardiovascular Diseases

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

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

Day 30 discussion

Cardiovascular Diseases

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

Celgene Europe Limited; Psoriasis in children

Day 30 discussion

Dermatology

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

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

Day 30 discussion

Gastroenterology-Hepatology

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

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

Day 30 discussion

Gastroenterology-Hepatology

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

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

Day 30 discussion

Haematology-Hemostaseology

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

Janssen-Cilag International NV; Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, spondyloarthritis, psoriatic arthritis and juvenile idiopathic arthritis) (ICD: M08), Adults: Rheumatoid Arthritis (ICD: M05) / N.A., Treatment of juvenile idiopathic arthritis

Day 30 discussion

Immunology-Rheumatology-Transplantation

3.3.9. bezlotoxumab - EMEA-001645-PIP01-14-M01

Merck Sharp & Dohme (Europe), Inc.; Treatment of Clostridium difficile infection / indicated for the prevention of recurrence of Clostridium difficile infection (CDI) in paediatric patients at high risk for recurrence of CDI

Day 30 discussion

Infectious Diseases

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

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

Day 30 discussion

Infectious Diseases

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

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

Day 30 discussion

Neurology

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

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

Day 30 discussion

Oncology

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

Ultragenyx Pharmaceutical Inc.; X-linked Hypophosphatemia

Day 30 discussion

Other

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

Vertex Pharmaceuticals (Europe) Limited; Cystic Fibrosis (E84 of ICD10)

Day 30 discussion

Other

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

Grünenthal GmbH; Treatment of chronic pain

Day 30 discussion

Pain

3.3.16. Mometasone furoate / Indacaterol acetate (dose expressed as free base) - EMEA-001217-PIP01-11-M03

NOVARTIS EUROPHARM LTD.; Treatment of asthma

Day 30 discussion

Pneumology - Allergology

4. Nominations

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

4.1. List of letters of intent received for submission of applications with start of procedure 24 May 2017 for Nomination of Rapporteur and Peer reviewer

Summary of committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

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

Summary of committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

4.3. Nominations for other activities

Summary of committee discussion:

None.

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

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

6. Discussion on the applicability of class waivers

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

6.1. Discussions on the applicability of class waiver for products

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

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

Summary of committee discussion:

The discussion was postponed to next PDCO meeting.

6.1.2. Veliparib (EMEA-000499-PIP02-10) - EMEA-04-2017

AbbVie Ltd.; Treatment of lung carcinoma (small cell and non-small cell carcinoma)/ Veliparib in combination with carboplatin and paclitaxel for the treatment of adult patients with advanced or metastatic squamous non-small cell lung cancer (NSCLC)

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 indications was confirmed.

Other potential paediatric interests of this medicine suggested by PDCO: leukaemias, Non- Hodgkin's lymphomas and solid malignant tumours.

PIP already agreed for 'treatment of high-grade glioma'.

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. co-formulation of durvalumab and tremelimumab - EMEA-05-2017

AstraZeneca AB; Treatment of oropharyngeal, laryngeal or nasal epithelial carcinoma (excluding nasopharyngeal carcinoma or lympho-epithelioma)/ second line treatment for recurrent or metastatic squamous cell carcinoma of the head and neck, progressed during or after treatment with 1 platinum-based regimen; first line treatment of recurrent locoregional disease or metastatic squamous cell carcinoma of the head and neck

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 indications was confirmed.

Other potential paediatric interests of this medicine suggested by PDCO: solid malignant tumours.

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

6.1.4. co-formulation of durvalumab and tremelimumab - EMEA-06-2017

AstraZeneca AB; Treatment of ureter and bladder carcinoma/ first line treatment of patients with unresectable stage IV urothelial bladder 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 interests of this medicine suggested by PDCO: solid malignant tumours.

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

6.1.5. co-formulation of durvalumab and tremelimumab - EMEA-07-2017

AstraZeneca AB; Treatment of lung carcinoma (small cell and non-small cell carcinoma)/ first line treatment of patients with locally advanced or metastatic NSCLC with tumours with no sensitizing EGFR mutation or ALK translocation; treatment of patients with locally advanced or metastatic NSCLC which has progressed on or after platinum-based chemotherapy

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 indications was confirmed.

Other potential paediatric interests of this medicine suggested by PDCO: solid malignant tumours.

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

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

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

None

8. Annual reports on deferrals

Note: The annual reports on deferrals to be noted by the members of the PDCO are flagged in the Annex B.

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

None

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

Summary of committee discussion:

The PDCO members were presented the list of procedures with paediatric indications to be evaluated by the CHMP, starting in February 2017.

The members were also informed about 1 medicinal product, Truvada for which the CHMP adopted a positive opinion recommending a paediatric indication during their meeting in February 2017.

9.2.2. Joint CHMP-PDCO session

Summary of committee discussion:

The second joint CHMP-PDCO session took place.

9.3. Coordination with EMA Working Parties/Working Groups/Drafting Groups

9.3.1. Non-clinical Working Group: D30 Products identified

PDCO member: Jacqueline Carleer

Summary of committee discussion:

The chair of the Non-clinical Working Group identified the products which will require Non-clinical Working Group evaluation and discussion.

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Summary of committee discussion:

The chair of the Formulation Working Group identified the products which will require Formulation Working Group evaluation and discussion.

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

PDCO member: Eva Agurell

Summary of committee discussion:

The PDCO discussed the Respiratory Drafting Group request for advice.

9.4. Cooperation within the EU regulatory network

9.4.1. European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA): Interaction between CROs and networks

Summary of committee discussion:

In a joint presentation and discussion representatives from 2 national multispecialty networks together with the current president of EUCROF (European CRO Federation) informed the committee about the roles and tasks of CROs and those of networks. As there is some overlap, the need for clear definitions and communication between sponsors and CROs/networks, of who does what would help avoiding duplication of work. It is planned to put this topic on the agenda of next year's annual Enpr-EMA workshop.

9.4.2. Paediatric Curriculum

Summary of committee discussion:

It was announced that all EU NTC Paediatric Curriculum lectures have now been recorded. The information on how to access the lectures within the Curriculum will be provided to all National Competent Authorities and EMA Committee Members (not part of an NCA) within the next few weeks.

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. Business Pipeline Report for the human scientific committees - Forecast for 2017 - Update Q1/2017

Summary of committee discussion:

Document tabled for information.

9.8.2. Strategic Review and Learning Meeting (SRLM) to be held in Malta on 10-11 April 2017

PDCO member: John Borg

Summary of committee discussion:

The Committee was presented with the final agenda for the Strategic Review and Learning Meeting (SRLM) to be held in Malta on 10-11 April 2017.

9.8.3. Strategic Review and Learning Meeting (SRLM) to be held in Estonia on 4-6 October 2017

PDCO member: Irja Lutsar / Jana Lass

Summary of committee discussion:

The Committee was encouraged to propose topics for the agenda of the next Strategic Review and Learning Meeting (SRLM) to be held in Estonia on 4-6 October 2017.

10. Any other business

10.1.1. 'Early Notification System' (ENS) and PDCO

Summary of committee discussion:

PDCO noted presentation on 'Early Notification System' - system to notify the European Union regulatory network and International partners of emerging safety issues for which regulatory action and communication are envisaged.

It was agreed that a pilot of 3-months will be initiated at the PDCO level in order to integrate all the PDCO members in the mailings.

11. Breakout sessions

11.1.1. Paediatric oncology

Summary of committee discussion:

The participants were informed about a recent Paediatric oncology conference. In addition, they discussed the addendum to the guideline on paediatric oncology and the organisation of the forthcoming stakeholder paediatric oncology strategy workshop.

11.1.2. Neonatology

Summary of committee discussion:

The participants discussed the revision of the neonatal guideline, focusing on definitions.

11.1.3. Inventory

Summary of committee discussion:

The participants worked on a pilot project testing a new methodology to draft an inventory of paediatric needs.

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 21 – 24 March 2017 meeting.

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Dirk Mentzer	Chair	Germany	No interests declared	
Karl-Heinz Huemer	Member	Austria	No interests declared	
Koenraad Norga	Member (Vice-Chair)	Belgium	When chairing the meeting: To be replaced for discussions, final deliberations and voting on:	EMEA-000069-PIP05-16 EMEA-C-001792-PIP01-15
Jacqueline Carleer	Alternate	Belgium	No interests declared	
Dimitar Roussinov	Member	Bulgaria	No restrictions applicable to this meeting	
Adriana Andrić	Member	Croatia	No interests declared	
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 via TC	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	
Sylvie Benchetrit	Member	France	No interests declared	
Dominique Ploin	Alternate	France	No interests declared	
Sabine Scherer	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
Immanuel Barth	Alternate	Germany	No interests declared	
Eleni Katsomiti	Member	Greece	No interests declared	
Anastasia Mountaki	Alternate	Greece	No interests declared	
Ágnes Gyurasics	Member (CHMP member)	Hungary	No interests declared	
Brian Aylward	Member	Ireland	No interests declared	
Alessandro Jenkner	Alternate	Italy	No interests declared	
Dina Apele-Freimane	Member	Latvia	No interests declared	
Carola de Beaufort	Member (CHMP alternate)	Luxembourg	No interests declared	
Maaike van Dartel	Member	Netherlands	No interests declared	
Siri Wang	Member	Norway	No interests declared	
Marek Migdal	Member	Poland	No interests declared	
Helena Fonseca	Member	Portugal	No interests declared	
Hugo Tavares	Alternate	Portugal	No interests declared	
Dana Gabriela Marin	Member (CHMP alternate)	Romania	No interests declared	
Stefan Grosek	Member	Slovenia	No interests declared	
Fernando de Andrés Trelles	Member	Spain	No interests declared	
Maria Jesús Fernández Cortizo	Alternate	Spain	No interests declared	
Ninna Gullberg	Member	Sweden	No interests declared	
Eva Agurell	Alternate via TC	Sweden	No restrictions applicable to this meeting	
Angeliki Siapkara	Member	United Kingdom	No interests declared	
Martina Riegl	Alternate	United Kingdom	No interests declared	

Name	Role	Member State or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Riccardo Riccardi	Member	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Jorrit Gerritsen	Alternate	Healthcare Professionals' Representative	No interests declared	
Johannes Taminiau	Member	Healthcare Professionals' Representative	No interests declared	
Doina Plesca	Alternate	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Günter Karl-Heinz Auerswald	Member	Patients' Organisation Representative	No restrictions applicable to this meeting	
Tsvetana Schyns-Liharska	Member	Patients' Organisation Representative	No restrictions applicable to this meeting	
Martine Dehlinger Kremser	Industry Stakeholder - in person*	Clinical Research Organisation	Not applicable	
Mark Turner	Stakeholder - via telephone*	Enpr-EMA	Not applicable	
Pirkko Lepola	Stakeholder - via telephone*	Enpr-EMA	Not applicable	
Shiva Ramroop	Expert - in person*	United Kingdom	No restrictions applicable to this meeting	
Catriona Elizabeth Baker	Expert - in person*	United Kingdom	No interests declared	
Eleni Gaki	Expert - in person*	United Kingdom	No interests declared	
Meeting run with support from relevant EMA staff				

* Experts were only evaluated against the product(s) they have been invited to talk about.

13. Explanatory notes

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

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

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

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

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

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

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