15 January 2014
EMA/PDCO/750981/2013
Human Medicines Research & Development Support Division

Paediatric Committee (PDCO)

Minutes of the 04-06 December 2013 meeting

Chair: Dirk Mentzer

I Introduction

I.1 Adoption of the minutes from previous meeting

Adopted
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

I.2 Adoption of the Agenda

Adopted with modifications

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

I.3 Declaration of Conflict of Interest

See Annex I

I.4 External attendance

Please refer to the December 2013 PDCO monthly report published in the EMA Website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

I.5 Leaving/New Members and Alternates

Please refer to the December 2013 PDCO monthly report published in the EMA Website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

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II Opinions

II.1 Opinions on Products

II.2 Opinions on Compliance Check

II.3 Opinions on Modification of an Agreed Paediatric Investigation Plan

Please refer to the December 2013 PDCO monthly report published in the EMA Website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

III Discussion of applications

The PDCO discussed 97 procedures in total[1], of which:

- 41 paediatric investigation plan applications;
- 10 product-specific waiver applications;
- 7 compliance check procedures (interim and final);
- 39 requests for modifications of an agreed paediatric investigation plan.

IV Nomination of Rapporteurs and Peer reviewers

• List of letters of intent received for submission of applications with start of procedure February 2014[1] for Nomination of Rapporteur and Peer reviewer • Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver	The PDCO approved the lists of Rapporteurs and Peer Reviewers.

V Update and finalisation of opinions and requests for modification

All opinions taken at this meeting (relating to adoption of opinions, recommendations, requests for modifications and applicability of class waivers) were made in the presence of the required quorum of members.

The opinions adopted during the Paediatric Committee meeting of December 2013 are published in the same month's meeting report published in the EMA website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab.

[1] The procedures discussed by the PDCO are on-going and therefore are considered confidential. Additional details on these procedures will be disclosed 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).

VI Discussion on the applicability of class waiver

Active substance	Proposed indication	Condition	Outcome	Potential paediatric interest of this medicine suggested by PDCO
Golvatinib (E7050, META)	Treatment of carcinoma of the liver	Treatment of liver and intrahepatic bile duct carcinoma (excluding hepatoblastoma)	Confirmed	Solid malignant tumors
Golvatinib (E7050, META)	Treatment of squamous cell carcinoma of the head and neck	Treatment of oropharyngeal, laryngeal or nasal epithelial carcinoma (excluding nasopharyngeal carcinoma or lympho-epithelioma)	Confirmed	Solid malignant tumors
Lesinurad	Treatment of adult patients with chronic gout in combination with a xanthine oxidase inhibitor where additional therapy is warranted and as monotherapy in patients with intolerance to a xanthine oxidase inhibitor	Treatment of primary gout (excluding Lesch-Nyhan syndrome and other secondary forms of gout)	Not confirmed. The medicinal product is aimed at controlling uric acid. A PIP and/or product-specific waiver should be submitted to cover the condition Treatment and/or prevention of hyperuricaemia.	Tumour Lysis Syndrome Lesch-Nyhan syndrome

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

PIP number	Active substance	Proposed indication	Condition	Outcome
Not applicable	Any	Treatment of axial spondyloarthritis without radiographic evidence of ankylosing spondylitis	Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis)	The PDCO agreed that the indication as worded is included in the condition “Treatment of chronic idiopathic arthritis (including rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis and juvenile idiopathic arthritis)”.
PIP EMEA-000597-PIP02-10-M01	Mirabregon	Combination use in the treatment of overactive bladder (OAB)	Treatment of idiopathic overactive bladder (OAB) Treatment of neurogenic detrusor overactivity (NDO)	The PDCO deemed the proposed indication to be covered by the conditions in the agreed PIP.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan	Difficulties progressing the PIP?	Outcome
EMEA-000689-PIP01-09	exenatide	BYETTA BYDUREON	No	Yes	Recruitment is slower than expected for the paediatric studies with byetta and bydureon. The paediatric study with bydureon has been temporarily halted. The applicant has performed a juvenile animal study. The applicant plans to continue recruitment in the paediatric study with bydureon in due course. However, before doing so some changes in the protocol are planned to be implemented.
EMEA-000237-PIP01-08	Azilsartan medoxomil	EDARBI IPREZIV	No	Yes	Discussed at the November PDCO meeting.
EMEA-000410-PIP01-08	Regadeno-son	RAPISCAN	No	No	The PDCO noted the report.
EMEA-000567-PIP01-09	Dasatinib	SPRYCEL	Yes	No	The PDCO noted the report.
EMEA-000282-PIP01-08	clevidipine butyrate	CleviprexTM (clevidipine butyrate injectable emulsion)	No	No	The PDCO noted the report.
EMEA-000147-PIP01-07	Dienogest	Visanne and related names	No	Yes	Difficulties are not impairing the completion of the PIP.
EMEA-000599-PIP01-09	Influenza virus surface antigens (haemag-glutinin and neuramini-dase)* of H5N1 st...	Focetria and associated names, Aflunov and associated names	No	Yes	Applicant has planned a modification procedure to change the study design in young children.

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan	Difficulties progressing the PIP?	Outcome
EMEA-000036-PIP01-07	Pneumococcal Polysaccharide Serotype 23F – Diphtheria CRM197 Conjugate / Pneumoc...	Prevenar 13	No	No	The PDCO noted the report.
EMEA-000317-PIP01-08	Rilpivirine	EDURANT	No	No	The PDCO noted the report.
EMEA-000774-PIP01-09	Rilpivirine (as hydrochloride) / emtricitabine / tenofovir disoproxil (as fumara...	EVIPLERA	No	Yes	Due to modifications in A PIP for one of the monosubstances, the initiation of the clinical studies is delayed. The submission of a request for modification of an agreed PIP is planned.

IX Other topics

Working groups	
Paediatric inventory	The therapeutic area of ophthalmology was discussed.
Paediatric oncology	The group discussed recent public meetings and the draft revised Addendum on paediatric oncology.
Extrapolation	The group discussed an on-going extrapolation application and agreed on the guidance to be published for PIP submission.
Formulation	No non-product related issues where reported to the Committee
Non-Clinical	No non-product related issues where reported to the Committee
Other topics	
CHMP update on paediatric topics	An update on CHMP procedures of products with a Paediatric Investigation plan was presented to the PDCO members.
Journal articles on topics related to Paediatric Regulation	The list of publications by PDCO members and external parties about paediatric activities related to the EU Paediatric Regulation is being updated. PDCO members are asked to flag publications they consider relevant.

Update on Enpr-EMA activities	The PDCO supported the Enpr-EMA's proposal of a corporate response to the EC public consultation on the EC guideline on the format and content of applications for a Paediatric Investigation Plan. It was suggested to update the published procedural advice, including a sentence to encourage companies to consider consulting networks when developing a PIP.
Communication from the European Commission	Florian Schmidt, legal officer at the European Commission, updated the PDCO on some ongoing topics: • The on-going public consultation on the guideline on the format and content of PIP applications; • The call on new civil society representatives in the PDCO; • A case at the European Court of Justice on the Paediatric Regulation; • The PDCO letter to the European Commission on communication strategies.
Call for interest for participation at a teleconference with the International Pediatric Multiple Sclerosis Study Group (IPMSSG) on 'Paediatric MS trials'	This informational teleconference initiated by IPMSSG will take place on 18 December 2013, 20:00 hrs (UK time). Participants planned include FDA and EMA/PDCO.
Draft proposal for establishment of the joint PDCO/COMP working group*	The proposal to create the PDCO/COMP working group and its mandate was adopted. Koenraad Norga, Karl-Heinz Huemer and Tsveta Schyns-Liharska were agreed as PDCO representatives to this working group.
ECDC-EMA Workshop on Vaccine schedules in PIPs-Preliminary programme *	The workshop is a kick-off meeting with experts in vaccines to explore the possibility of having one or two reference schedules for new routine vaccines in a standard PIP to be adopted by the PDCO. The meeting is co-organised with ECDC and the call for experts was launched by the European Commission (DG Sanco), via the Health Security Committee. Further work may be needed with a small working group via TC. Feedback regarding the outcome of the meeting will be provided during January PDCO plenary.
Draft Agenda Training session for patients and consumers involved in EMA activities (10 December 2013)*	The document was presented to the Committee for information.
Draft Agenda PCWP meeting with all eligible organisations (11 December 2013)*	The document was presented to the Committee for information.

Any other business

- Horizon 2020 project

  Feedback received from the EC was presented. Further information: http://ec.europa.eu/research/horizon2020/index_en.cfm?pg=h2020-documents

- Joint Informal Meeting CAT and PDCO on 25-26 November 2013, Trieste, Italy

  On 25-26 November 2013, the PDCO and CAT held an informal meeting in Trieste, organised by the Italian Agency and co-hosted by the Slovenian Agency, to review the work done. The PDCO discussed improvements, interactions with experts, learned societies and industry, and priorities in the implementation of the Paediatric Regulation.

Note on access to documents

Documents marked with an asterisk* in these minutes cannot be released at present as they are currently in draft format. They will become public when adopted in their final form.

Annex I to the Minutes of the PDCO of December 2013

Documentation on Declaration of interest of members, alternates 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 Committee members for the upcoming discussions.

In accordance with the Agency's revised Policy and Procedure on the handling of conflicts of interests, participants in this meeting were asked to declare any conflict of interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests).

Member, alternate, expert name	Outcome restriction following evaluation of electronic evaluation form	Topics on the current Committee Agenda for which this restriction applies
Adriana Ceci	Restriction level DP	EMEA-000380-PIP02-09-M01
Adriana Ceci	Restriction level DP	EMEA-001371-PIP01-12
Jaroslav Sterba	Restriction level XP	EMEA-001493-PIP01-13
Paolo Rossi	Restriction level XR	EMEA-000128-PIP03-13
Paolo Rossi	Restriction level DP	EMEA-000872-PIP02-13
Paolo Rossi	Restriction level XR	EMEA-001442-PIP01-13

Note: the procedures identified in the table above are on-going and therefore considered commercially confidential. Additional details on these procedures will be disclosed 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).

No new or additional conflicts were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee Secretariat at the start of meeting.

Restriction levels:

Evaluation of the conflict of interest	
Outcome	Impact
R-P	To be replaced for the discussions, final deliberations and voting as appropriate in relation to the relevant product or a competitor product.

XP	Where Individual product involvement is declared - PRODUCT INDICATION: - No involvement with respect to procedures involving the relevant product or a competitor product in the relevant indication i.e. no part in discussions, final deliberations and voting as appropriate as regards these medicinal products. - Cannot act as Rapporteur for these products - [Cannot act as Rapporteur for development of guidelines in concerned therapeutic area].
XC	Where cross product / general involvement is declared - COMPANY: - No involvement (as outlined above) with respect to products from the specified company. - Cannot act as Rapporteur for products from the relevant company(ies).
DP	Where Individual product involvement is declared - PRODUCT INDICATION: - Involvement in discussions only with respect to procedures involving the relevant product or a competitor product i.e. no part in final deliberations and voting as appropriate as regards these medicinal products. - Cannot act as Rapporteur for these products.
DC	Where cross product / general involvement is declared - COMPANY: - Involvement in discussions only with respect to products from the specified company. - Cannot act as Rapporteur on products from the relevant company(ies).
XR	Committee member cannot act as Rapporteur or Peer reviewer in relation to any medicinal product from the relevant company.
R-C	To be replaced for the discussions, final deliberations and voting as appropriate in relation to any medicinal product from the relevant company

Annex II to the Minutes of the PDCO of December 2013

List of Participants

Chair

Dirk MENTZER

Members appointed by Member States or CHMP

Karl Heinz HUEMER	Austria
Koenraad NORGA	Belgium
Violeta IOTOVA	Bulgaria
Marina DIMOV DI GUSTI	Croatia
Jaroslav STERBA	Czech Republic
Marianne ORHOLM	Denmark
Pirjo LAITINEN-PARKONNEN	Finland
Sylvie BENCHETRIT	France
Birka LEHMANN	Germany
Stefanos MANTAGOS	Greece
Agnes GYURASICS	Hungary
Gylfi OLKARSSON	Iceland
Kevin CONNOLLY	Ireland
Paolo ROSSI	Italy
Dina APELE-FREMIANE	Latvia
John Joseph BORG	Malta
Hendrik van den BERG	The Netherlands
Siri WANG	Norway
Marek MIGDAL	Poland
Helena FONSECA	Portugal
Stefan GROSEK	Slovenia
Fernando DE ANDRÉS TRELLES	Spain
Viveca Lena ODLIND	Sweden
Julia DUNNE	United Kingdom

Alternates appointed by Member States or CHMP

Christoph MALE	Austria
Jacqueline CARLEER	Belgium
Peter SZITANYI	Czech Republic
Marta GRANSTRÖM	Denmark
Jana LASS	Estonia
Ann Marie KAUKONEN	Finland
Immanuel BARTH	Germany
Brian AYLWARD	Ireland
Francesca ROCCHI	Italy
Jolanta WITKOWSKA-OZOGOWSKA	Poland
Hugo TAVARES	Portugal
Dana Gabriela MARIN	Romania
Maria Jesus FERNANDEZ CORTIZO	Spain
Ninna GULLBERG	Sweden
Angeliki SIAPKARA	United Kingdom

Members representing patients' organisations

Tsveta SCHYNS-LIHARSKA

Alternates representing patients' organisations

Gerlind BODE

Members representing health care professionals

Adriana CECI

Anthony James NUNN

Observers

Florian SCHMIDT	European Commission, Directorate General for Health
Katherine MCGINN	Medicines and Healthcare Products Regulatory Agency, United Kingdom
Parastoo KAROON	Medicines and Healthcare Products Regulatory Agency, United Kingdom
Martina RIEGL	Medicines and Healthcare Products Regulatory Agency, United Kingdom

European Medicines Agency

Zaide FRIAS	Head of Human Medicines Research & Development Support Division (ad interim)
Jordi Llinares GARCIA	Head of Product Development Scientific Support Department
Paolo TOMASI	Head of Paediatric Medicines
Sophie OLIVIER	Scientific Officer, Paediatric Medicines
Benjamin PELLE	Scientific Officer, Paediatric Medicines
Chrissi PALLIDIS	Scientific Officer, Paediatric Medicines
Dobromir PENKOV	Scientific Officer, Paediatric Medicines
Giovanni LESA	Scientific Officer, Paediatric Medicines
Gunter EGGER	Scientific Officer, Paediatric Medicines
Irmgard EICHLER	Scientific Officer, Paediatric Medicines
Janina KARRES	Scientific Officer, Paediatric Medicines
Peter KÁROLYI	Scientific Officer, Paediatric Medicines
Ralf HEROLD	Scientific Officer, Paediatric Medicines
Ralph BAX	Scientific Officer, Paediatric Medicines
Richard VESELY	Scientific Officer, Paediatric Medicines
Thorsten OLSKI	Scientific Officer, Paediatric Medicines
Cecile OLIVIER	Scientific Officer, Paediatric Medicines
Andrea ECKER	Scientific Officer, Paediatric Medicines
Alessandro JENKNER	National Expert on Secondment, Paediatric Medicines
Ramona ZEMACHE	Assistant, Paediatric Medicines
Aurelie HERVIEU	Assistant, Paediatric Medicines
Thomas GIRARD	Regulatory Affairs Officer, Regulatory Affairs Office