8 October 2014
EMA/PDCO/544529/2014
Procedure Management and Business Support Division

Paediatric Committee (PDCO)

Minutes of the 10 - 12 September 2014 meeting

Chair: Dirk Mentzer - Vice-chair: Koenraad Norga

Note on access to documents

Some documents mentioned in the minutes cannot be released at present following a request for access to documents under 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).

Disclaimers

Some of the information contained in the PDCO discussions is considered commercially confidential or sensitive and therefore not disclosed in the present minutes. With regards to therapeutic indications 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. The procedures discussed by the PDCO are on-going and therefore certain aspects of them 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). Documents mentioned in these minutes cannot be released at present as they are currently in draft format or are classified as confidential. They will become public when adopted in their final form or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006). Of note, this set of minutes is a working document primarily designed for PDCO members and the work the Committee undertakes.

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I Introduction

I.1 Adoption of the minutes from previous meeting

The Minutes of the PDCO plenary session held 13-15 August 2014 were 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

The agenda was adopted with amendments.
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

All decisions taken at this meeting were made in presence of a quorum of members – i.e. 23 or more members were present in the room.

I.3 Declaration of Conflict of Interest

See Annex

I.4 External attendance

Please refer to the September 2014 PDCO monthly report published on 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 September 2014 PDCO monthly report published on the EMA Website:

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

II Opinions

II.1 Opinions on Products

II.2 Opinions on Compliance Check

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

II.4 Opinions on Re-examinations

Please refer to the September 2014 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 96 procedures in total[1], of which:

- 38 paediatric investigation plan applications;
- 9 product-specific waiver applications;
- 10 compliance check procedures (interim and final);
- 35 requests for modifications of an agreed paediatric investigation plan;
- 4 re-examination requests.

IV Nomination

IV.1 Nomination of Rapporteurs and Peer reviewers

• List of letters of intent received for submission of applications with start of procedure November 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.

IV.2 Nomination for other activities

Call for volunteers for joint PDCO/ SAWP membership Pre-requisites: • Member or alternate in the PDCO with ability to regularly and actively participate in the SAWP; • Expertise in paediatric clinical medicine/ paediatric pharmacology/ paediatric clinical trial investigation; • Provide feedback to PDCO during the joint PDCO/SAWP session during PDCO plenary.	The Committee nominated Karl-Heinz Hümer as PDCO representative in the Scientific Advice Working Party.
Election/designation of the new FWG Chair	The PDCO Chair asked for volunteers with the view that the FWG Chair should be elected in November, in correspondence with the FWG face-to-face meeting.
Nomination of Rapporteur for the • Pain Guideline; • Bipolar Disorder Guideline.	The Rapporteurs have been nominated.

[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).

V Update and finalisation of opinions and requests for modification

The opinions adopted during the Paediatric Committee meeting of September 2014 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.

VI Discussion on the applicability of class waiver

Active substance	Proposed indication	Condition	Outcome	Potential paediatric interest of this medicine suggested by PDCO
Anti PD-L1 monoclonal antibody (MEDI4736)	Treatment of squamous cell cancer of head and neck	Treatment of oropharyngeal, laryngeal or nasal epithelial carcinoma (excluding nasopharyngeal carcinoma or lymphoepithelioma)	Confirmed	Not applicable
ABT-199 (or GDC-0199)	1. As a single agent, for the treatment of patients with 17p deletion mutation positive Chronic Lymphocytic Leukaemia who have received at least one prior therapy 2. In combination with rituximab, for the treatment of patients with Chronic Lymphocytic Leukaemia who have received at least one prior therapy	Treatment of chronic lymphocytic leukaemia	Confirmed	Lymphoma, leukaemia
LEE011	In combination with letrozole, for the treatment of postmenopausal women with hormone receptor positive, HER-2 negative, advanced breast cancer who received no prior therapy for advanced disease	Treatment of breast carcinoma	Confirmed	Melanoma, other paediatric malignancies

Active substance	Proposed indication	Condition	Outcome	Potential paediatric interest of this medicine suggested by PDCO
2-(18F)Fluor-N-(2-hydroxyethyl)-N,N dimethylethan aminiumchlorid	To be used in oncological diagnostic procedures with PET-scans in patients with a valid suspicion of prostate cancer	Treatment of prostate carcinoma (excluding rhabdomyosarcoma)	Not confirmed as the medicinal product is to be used for diagnostic procedures whereas the class waiver condition covers the treatment of the disease	Not applicable
Losmapimod	To reduce the rate of major adverse cardiovascular events in patients during and following acute coronary syndrome (ACS) when added to standard of care	Treatment of coronary atherosclerosis	Confirmed	Focal Segmental Glomerulosclerosis (FSGS)
Everolimus	Treatment of adult patients with advanced non-functional neuroendocrine tumours of gastro-intestinal origin	Treatment of gastroentero-pancreatic neuroendocrine tumors (excluding neuroblastoma, neuro-ganglioblastoma, haeochromocytoma)	Confirmed	Not applicable
Tremelimumab	Treatment of unresectable pleural and peritoneal malignant mesothelioma that has progressed following 1 or 2 prior platinum-based systemic lines of therapy	Treatment of mesothelioma	Confirmed	Any other malignancy inducing T cells upregulating CTLA-4
Lucitanib	Treatment of metastatic breast cancer	Treatment of breast carcinoma	Confirmed	Any paediatric tumour responsive to anti-angiogenic therapy

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

No requests were received for the month of September.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan	Difficulties progressing the PIP?	Outcome
EMEA-001094-PIP01-10-M02	teriflunomide	Aubagio	No	No	The PDCO noted the report.
EMEA-000228-PIP01-08-M03	asenapine meleate	Sycrest	No	Yes	The PDCO noted the report, no modification of the PIP is necessary.
EMEA-000160-PIP01-07	Purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/..	Pandemrix, Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) (referring to Informed Consent for Prepandrix), Prepandrix	No	No	The PDCO noted the report.
EMEA-001072-PIP01-10	alemtuzumab	Lemtrada	No	Yes	The PDCO noted the report; a modification of the agreed PIP is planned.
EMEA-000827-PIP01-09	Aztreonam	Cayston	Yes	Yes	The PDCO noted the report; a modification of the agreed PIP is planned.
EMEA-000019-PIP02-07	Everolimus	Votubia	Yes	No	The PDCO noted the report.
EMEA-000019-PIP08-12	Everolimus	Afinitor, Certican and associated names	Yes	Yes	The PDCO noted the report and the recent modification procedure.
EMEA-000402-PIP02-11	lacosamide	Vimpat	No	Yes	The PDCO noted the recruitment issues reported for a study.
EMEA-000555-PIP01-09	decitabine	Dacogen	Yes	No	The PDCO noted the report.
EMEA-000020-PIP01-07	maraviroc	Celsentri	No	No	The PDCO noted the report.

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan	Difficulties progressing the PIP?	Outcome
EMEA-000018-PIP01-07	Tapentadol Hydrochloride	Palexia	No	No	The PDCO noted the report.
EMEA-000325-PIP01-08	Tapentadol hydrochloride	Palexia	No	No	The PDCO noted the report.
EMEA-000485-PIP01-08	Tapentadol hydrochloride	Palexia	No	No	The PDCO noted the report.
EMEA-000486-PIP01-08	Tapentadol hydrochloride	Palexia	No	No	The PDCO noted the report.
EMEA-000494-PIP01-08	Tapentadol hydrochloride	Palexia	No	No	The PDCO noted the report.
EMEA-000495-PIP01-08	Tapentadol hydrochloride	Palexia	No	No	The PDCO noted the report.
EMEA-000239-PIP01-08	Telavancin	Vibativ	No	Yes	The PDCO noted the manufacturing issues. A modification will be submitted in due course.
EMEA-000222-PIP01-08	Etravirine	Intelence	No	Yes	The PDCO noted the recruitment issues. A modification will be submitted in due course.

IX Other topics

Guidelines	
Revision of the asthma guideline Marek Migdal	Discussion on comments received during 6-month consultation period postponed to next month meeting.
Working groups	
Paediatric inventory	Breakout session took place in the margins of the PDCO plenary meeting.
Paediatric oncology	Breakout session took place in the margins of the PDCO plenary meeting.
Neonatology group	Breakout session took place in the margins of the PDCO plenary meeting.

Formulation	The PDCO was informed that a face-to-face meeting of the Formulation Working Group is scheduled during the last day of the November 2014 PDCO meeting.
Extrapolation	Cancelled.
Non-Clinical	Documents tabled for information.
Other topics	
CMDh request for PDCO advice on contraindication of medicines used for the treatment of cough and cold in children below 6 years of age Angeliki Siapkara	A list of products indicated for the treatment of cough and cold in adults and children has been selected by the CMDh. PDCO members have been asked to feedback, by the next plenary meeting, on the therapeutic need, use and identified or potential safety risks associated with these selected products in children below 6 years of age, based on their current clinical practice.
Art.31 referral of Ambroxol / Bromhexine	The Art.31 referral to PRAC investigating the potential risk of immediate and delayed hypersensitivity reactions with Ambroxol and bromhexine-containing products was presented to the PDCO members as well as a PRAC list of questions to be addressed by the PDCO. PDCO responses to PRAC list of questions will be discussed at the next plenary meeting.
Revision of class waiver (updated proposal) Koenraad Norga	The PDCO continued the discussion considering an updated proposal for the revision of the EMA Decision on the list of class waivers. An Opinion will be scheduled for November adoption.
Oncology inventory of paediatric therapeutic needs for public consultation	The inventory for the therapeutic area 'oncology' was adopted by the PDCO for public consultation.
Submission of applications by Eudralink only to PDCO members/alternates	PDCO members were asked to confirm if they accept to receive applications via Eudralink only, without the need for CD/ROM or DVD packages, to facilitate submissions. The website will be update to reflect this information, as soon as all PDCO members have provided a response.
Draft agenda of the EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting (16 September 2014)	Documents tabled for information.
D30 Products identified for the Non-Clinical Working Group Jacqueline Carleer	Documents tabled for information.
Gastrointestinal development Jan Taminiau	It was agreed that the GI-tract organ maturation table is revised and sent for comments to relevant European learned societies, including the relevant Enpr-EMA network.

PECCO/ESPGHAN: Placebo without active medication in trials of pediatric IBD Jan Taminiau	The letter from PECCO/ESPGHAN requesting placebo not to be used in paediatric IBD trials was presented. The PDCO endorsed the proposal to respond to the letter informing the societies that this issue will be discussed and addressed within the remits of the IBD guidelines drafting group.
EMA policy on DoI	The EMA presented the revised policy on the handling of declarations of interests of scientific committees' members and experts. The revised policy and a procedural guidance document will be published within the next weeks. The implementation date is still to be confirmed.
Debriefing on PDCO Improvement exercise Dirk Mentzer	The Chair presented the outcome of a meeting on the improvement of the PDCO agenda. It was proposed to re-arrange the agenda by grouping discussions according to the status of the procedure. Break-out sessions should no longer take place during lunch breaks, but at the end of the meeting day or the day before the meeting. Members were encouraged to send a wish-list of changes with regard to the agenda and/or how documents are provided to the Secretariat.
GRiP - Master of Science in Paediatric Medicines Development and Evaluation	The current status of the organisation of the GRiP multi-university M.Sc. course was presented by Francesca Rocchi.

Any other business

Annex to the Minutes of the PDCO of September 2014

List of Participants and 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).

No new or additional conflicts were declared.

PDCO Chair	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product/substance
Dirk Mentzer	Germany	Full Involvement	

PDCO Member	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product/substance
Karl-Heinz Huemer	Austria	Full Involvement	
Koenraad Norga	Belgium	Full Involvement	
Marina Dimov Di Giusti	Croatia	Full Involvement	
Georgios Savva	Cyprus	Full Involvement	
Pirjo Laitinen-Parkkonen	Finland	Full Involvement	
Sylvie Benchetrit	France	Full Involvement	
Birka Lehmann	Germany	Full Involvement	
Agnes Gyurasics	Hungary	Full Involvement	
Gylfi Oskarsson	Iceland	Full Involvement	
Paolo Rossi	Italy	XR	EMEA-001429-PIP01-13
Dina Apele-Freimane	Latvia	Full Involvement	
Carola de Beaufort	Luxembourg	Full Involvement	
John Joseph Borg	Malta	Full Involvement	
Hendrik van den Berg	Netherlands	Full Involvement	
Siri Wang	Norway	Full Involvement	

PDCO Member	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product/substance
Marek Migdal	Poland	DP	EMEA-000018-PIP01-07-M08 EMEA-000494-PIP01-08-M08 EMEA-000495-PIP01-08-M08 EMEA-001558-PIP02-14
Helena Fonseca	Portugal	Full Involvement	
Dana Gabriela Marin	Romania	Full Involvement	
Michaela Meciakova	Slovakia	Full Involvement	
Stefan Grosek	Slovenia	Full Involvement	
Fernando de Andrés Trelles	Spain	Full Involvement	
Viveca Lena Odlind	Sweden	Full Involvement	
Angeliki Siapkara	United Kingdom	Full Involvement	

PDCO Alternate	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product/substance
Christoph Male	Austria	DP/XR DP DP DP DP XP DP	EMEA-001107-PIP01-10-M02 EMEA-001174-PIP02-12-M01 EMEA-000312-PIP01-08-M07 EMEA-001203-PIP02-14 EMEA-001648-PIP01-14 EMEA-000480-PIP01-08-M07 EMEA-000914-PIP01-10-M02
Jacqueline Carleer	Belgium	Full Involvement	
Marina Fertek	Czech Republic	*Replacing PDCO member* DP	EMEA-001517-PIP01-13 EMEA-000694-PIP01-09-M04
Marta Granström	Denmark	Full Involvement	
Immanuel Barth	Germany	Full Involvement	
Brian Aylward	Ireland	*Replacing PDCO member* Full Involvement	
Francesca Rocchi	Italy	Full Involvement	
Herbert Lenicker	Malta	Full Involvement	
Ine Skottheim Rusten	Norway	Full Involvement	
Jolanta Witkowska-Ożogowska	Poland	Full Involvement	
Hugo Tavares	Portugal	Full Involvement	
Martina Riegl	United Kingdom	Full involvement	

PDCO Alternate	Country	Connected via TC for Product / substance
Maria Jesús Fernández Cortizo	Spain	Connected via TC for EMEA-001577-PIP01-13 EMEA-001661-PIP01-14 EMEA-000434-PIP01-08-M03 EMEA-000120-PIP01-07-M05

PDCO Representative of doctors' organisations	Role	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product / substance
Antje Neubert	Member	Representative of doctors' organisations	Full involvement	
Paolo Paolucci	Alternate	Representative of doctors' organisations	Full involvement	
Johannes Taminiau	Member	Representative of doctors' organisations	Full Involvement	
Maria Grazia Valsecchi	Alternate	Representative of doctors' organisations	*Replacing PDCO member* Full Involvement	

PDCO Representative of patients' organisations	Role	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which restriction applies Product / substance
Gunther Auerswald	Member	Representative of patients' organisations	XP	EMEA-000312-PIP01-08-M07 EMEA-001203-PIP02-14 EMEA-000914-PIP01-10-M02 EMEA-001107-PIP01-10-M02
Michal Odermarsky	Member	Representative of patients' organisations	XP	EMEA-001418-PIP01-13 EMEA-001577-PIP01-13 EMEA-001661-PIP01-14 EMEA-C1-001460-PIP01-13
Tsveta Schyns-Liharska	Member	Representative of patients' organisations	Full Involvement	

PDCO Expert	Country	Outcome restriction following evaluation of e-DoI for the meeting	Topics on the current Committee Agenda for which the expert is invited Product / substance
*Experts were only evaluated against the product they have been invited to talk about.			
Katherine McGinn	United Kingdom	Full involvement	
Dominik Karres	United Kingdom	Full involvement	

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