



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 January 2015
EMA/PDCO/764791/2014
Procedure Management and Business Support Division

Paediatric Committee (PDCO)

Minutes of the 10-12 December 2014 meeting

Chair: Dirk Mentzer - Vice-chair: Koenraad Norga

Disclaimers

Some of the information contained in the PDCO minutes 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.

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).



I Introduction

1.1 Adoption of the minutes from previous meeting

The Minutes of the PDCO plenary session held on 12-14 November 2014 were adopted.

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

1.2 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

1.3 Declaration of Conflict of Interest

See Annex I

1.4 External attendance

Please refer to the Annex of this document.

1.5 Leaving/New Members and Alternates

Please refer to the December 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

11.1 Opinions on Products

11.2 Opinions on Compliance Check

11.3 Opinions on Modification of an Agreed Paediatric Investigation Plan

Please refer to the December 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 86 procedures in total¹, of which:

- 30 paediatric investigation plan applications;
- 13 product-specific waiver applications;
- 11 compliance check procedures (interim and final);
- 31 requests for modifications of an agreed paediatric investigation plan;
- 1 re-examination request.

IV Nomination

IV.1 Nomination of Rapporteurs and Peer reviewers

<ul style="list-style-type: none">• List of letters of intent received for submission of applications with start of procedure February¹ 2015 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.
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IV.2 Nomination for other activities

<ul style="list-style-type: none">• Nomination of Rapporteur and Peer Reviewer for different types of activities.	No requests were received.
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V Update and finalisation of opinions and requests for modification

The opinions adopted during the Paediatric Committee meeting of December 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
Palbociclib	Treatment of advanced breast cancer in	Treatment of breast cancer	Positive	Brain tumours, neuroblastoma and T-cell

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).

Active substance	Proposed indication	Condition	Outcome	Potential paediatric interest of this medicine suggested by PDCO
	combination with endocrine therapy			malignancies. Potentially any paediatric tumours for which a paediatric preclinical testing program is highly recommended.

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

No requests were received for the month of December.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan	Difficulties progressing the PIP?	Outcome
EMA-000480-PIP01-08	Ticagrelor	Brilique, Possia	No	No	The PDCO noted the report.
EMA-000636-PIP01-09	3-[[[6-Deoxy-4-O-(3,5-dichloro-2-ethyl-4,6-dihydroxybenzoyl)-2-O-methyl-β-D-man	Dificid	No	No	The PDCO noted the report.
EMA-000056-PIP01-07	Bevacizumab	Avastin	No	No	The PDCO noted the report.
EMA-000056-PIP03-10	Bevacizumab	Avastin	No	Yes	The PDCO noted the report.
EMA-000279-PIP01-08	raltegravir	Isentress	No	No	The PDCO noted the report.
EMA-000455-PIP02-10	Lu AA21004	Brintellix	No	No	The PDCO noted the report.

EMA-001272-PIP02-13	azacitidine	Vidaza	Yes	No	The PDCO noted the report.
EMA-000282-PIP01-08	clevidipine butyrate	Cleviprex TM (clevidipine butyrate injectable emulsion)	No	Yes	The PDCO noted the report. No action is necessary.
EMA-000927-PIP01-10	Linacotide	Constella	No	Yes	The PDCO was informed about the delay of the PIP due to ongoing discussions with the FDA. The applicant plans to submit a request for modification of the agreed PIP in June 2015.
EMA-000237-PIP01-08	Azilsartan medoxomil	Ipreziv	No	No	The PDCO noted the report.

IX Other topics

Guidelines	
Note for guidance on clinical investigation of medicinal products for treatment of asthma Marek Migdal	The PDCO was informed about the changes implemented into the paediatric part of the guideline following 6 months public consultation. The Committee adopted the paediatric part of the Note for guidance on clinical investigation of medicinal products for treatment of asthma.
Working groups	
Paediatric inventory	The group started discussing the first draft of the gastroenterology list of paediatric needs.

Paediatric oncology	The prepared topics included medicines with anti-angiogenic mechanism of action and presentations at forthcoming meetings.
Formulation	The PDCO was informed that a mandate for the FWG has been drafted and will be presented to the Committee in one of the next meetings.
Non-Clinical	No non-product related issues were reported to the Committee.
Neonatology	Discussions related to the neonatal guideline, planning of internal outcome research as well as the scope of this group.
PDCO Improvement exercise	The drafting group met in the margins of the PDCO December 2014 plenary meeting. The outcome of the meeting will be presented to the Committee in January 2015.
Product-related topics	
Waivers for fixed-dose combinations in HIV Maria Fernandez Cortizo	The PDCO noted the presentation. PDCO discussed whether fixed-dose combinations should be systematically considered for children younger than 6 years of age and also discussed the use of WHO weight bands. This issue will need further discussions involving also external stakeholders.
Art.31 Referral of Codeine to PRAC: presentation and request for PDCO advice Angeliki Siapkara	This Art.31 referral of Codeine and the PRAC questions to be addressed by the PDCO were presented. Following the presentation, the PDCO members were asked to provide written comments to each question by 7 January 2015. The comments received will be compiled and the PDCO general response/recommendations will be presented for endorsement at next PDCO meeting.
Signal of sodium-containing medicines and cardiovascular risk: PDCO responses to PRAC questions Angeliki Siapkara	The PDCO conclusions and recommendations to the PRAC questions were endorsed by the PDCO members and will be sent to the PRAC.

Questions from applicants on studies Paolo Paolucci, Birka Lehmann	The PDCO discussed questions concerning paediatric studies with certain non-authorised medicines that are part of an agreed PIP.
CHMP update on paediatric topics	The PDCO members were informed about one medicinal product with paediatric indication adopted by CHMP in November 2014.
Other topics	
Debriefing on the White Paper Drafting Group	The Chair of the DG informed the PDCO about progress and outlined further steps.
Debriefing on PDCO work plan	Draft objectives and activities for the PDCO work plan 2015-2016 were presented to the Committee. The first version of the draft work plan will be circulated to members post December 2014 plenary meeting for comments by 9 January 2015.
Involvement of children and members' representing patients' organisation in the PDCO activities: outcomes of the questionnaire to PDCO	The results of the questionnaire on involvement of children, parents and members representing patients' organisation in the PDCO activities were presented and the next steps for 2015 were outlined to the Committee.
Agenda - EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting with all eligible organisations – 26 November (EMA/632557/2014)	Document tabled for information
Agenda - Training session for patients and consumers involved in EMA activities – 25 November (EMA/632556/2014)	Document tabled for information
Minutes of the EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting – 16 September (EMA/563152/2014)	Document tabled for information
Benefit-risk communication to medicines users - How can regulators best meet the information needs of patients and healthcare professionals? - Workshop report (EMA/581546/2014)	Document tabled for information

<p>Annual reports on deferred measures: to be sent routinely to PDCO Rapporteur</p>	<p>The PDCO discussed the need to receive annual reports on deferred measures routinely and supported current practice.</p>
<p>Art. 46 studies submitted to EMA: to be evaluated by PDCO or CHMP</p>	<p>The PDCO considered that information should be collected regarding centralised procedures of assessment of studies under Art 46, and that a PDCO representative should be involved in these procedures, for the potential consequences that may arise regarding potential modifications of the agreed PIP. The CHMP will be informed of this PDCO proposal for possible discussion at CHMP ORGAM meeting.</p>
<p>Accessibility of full paediatric applications to PDCO members</p>	<p>PDCO members discussed the possibility of not requiring the submission of all complete applications to all PDCO members (in addition to the Rapporteur and Peer Reviewer) after validation is confirmed. However, for the time being it was felt that most committee members were in favour of the current working arrangements.</p>
<p>EMA's activities as part of the global response against the Ebola outbreak and strategy of investigating paediatric patients in Ebola development programs</p>	<p>The PDCO was informed about the EMA's activities as part of the global response against the Ebola outbreak. In particular, the paediatric part of recent scientific advices for Ebola related products was elucidated. The PDCO Chair, being a member of the EMA's ad-hoc group on Ebola, ensures that the needs of the paediatric population are being taken into account at an early stage of the discussions. In addition, applicants are currently being reminded that the paediatric requirements apply and that they have to come to the PDCO with a PIP if they consider submitting a centralised procedure MAA. The overview given at the PDCO plenary was intended to form the basis for developing a concise view of the requirements and to prepare the PDCO to be able to make an informed decision on development plans when they will be presented as PIPs.</p>

Adaptive pathway – update on pilot phase	Postponed to the January 2015 PDCO plenary.
Revision of class waiver Hendrik van den Berg, Koen Norga	PDCO and EMA continued the discussion, progressing the proposal for the revision of the EMA Decision on class waivers.

Any other business

None.

The Chair thanked all participants and closed the meeting.

Annex to the Minutes of the PDCO of December 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.

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.

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	
Violeta Iotova	Bulgaria	No participation in discussions, final deliberations and voting	EMA-000479-PIP01-08-M03 EMA-001175-PIP01-11-M02 EMA-000916-PIP01-10-M04
Marina Dimov Di Giusti	Croatia	Full involvement	
Georgios Savva	Cyprus	Full involvement	
Jaroslav Sterba	Czech Republic	No participation in final deliberations and voting	EMA-001627-PIP01-14
Marianne Orholm	Denmark	Full involvement	
Irja Lutsar	Estonia	Full involvement	
Pirjo Laitinen-Parkkonen	Finland	Full involvement	
Sylvie Benchetrit	France	Full involvement	
Birka Lehmann	Germany	Full involvement	
Grigorios Melas	Greece	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
Agnes Gyurasics	Hungary	Full involvement	
Gylfi Oskarsson	Iceland	Full involvement	
Brian Aylward	Ireland	Full involvement	
Paolo Rossi	Italy	Full involvement	
Dina Apele-Freimane	Latvia	Full involvement	
Carola de Beaufort	Luxembourg	Full involvement	
Hendrik van den Berg	Netherlands	Full involvement	
Siri Wang	Norway	Full involvement	
Marek Migdal	Poland	Full involvement	
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	
Ninna Gullberg	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
Jacqueline Carleer	Belgium	Full involvement	
Peter Szitanyi	Czech Republic	Full involvement	
Marta Granström	Denmark	Full involvement	
Immanuel Barth	Germany	Full involvement	
Francesca Rocchi	Italy	Full involvement	
Kristine Supe	Latvia	Full involvement	
Herbert Lenicker	Malta	Full involvement	
Ine Skottheim Rusten	Norway	Full involvement	
Jolanta Witkowska-Ożogowska	Poland	Full involvement	
Hugo Tavares	Portugal	Full involvement	
Anna-Karin Hamberg	Sweden		
Maria Jesús Fernández Cortizo	Spain	Full involvement	
Martina Riegl	United Kingdom	Full involvement	

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
Johannes Taminiau	Member	Representative of doctors' organisations	Full involvement	
Riccardo Riccardi	Member	Representative of doctors' organisations	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
Tsveta Schyns-Liharska	Member	Representative of patients' organisations	Full involvement	
Gunther Auerswald	Member	Representative of patients' organisations	No participation in discussions, final deliberations and voting	EMA-001203-PIP02-14
Paola Baiardi	Alternate	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.			
Jana Schweigertova	Slovakia	Full involvement	

PDCO Expert By phone	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.			
Adrienn Horváth	Hungary	Full involvement	

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