



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

20 May 2015
EMA/PDCO/243363/2015
Procedure Management and Committees Support Division

Paediatric Committee (PDCO) Minutes of the 15 - 17 April 2015 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

I.1 Adoption of the minutes from previous meeting

The Minutes of the PDCO plenary session held on 18-20 March 2015 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

I.3 Declaration of Conflict of Interest

Please refer to the List of participants to be found at the end of this document.

I.4 External attendance

Please refer to the List of participants to be found at the end of this document.

I.5 Leaving/New Members and Alternates

Please refer to the April 2015 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

Please refer to the April 2015 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

III Discussion of applications

The PDCO discussed 79 procedures in total¹, of which:

- 30 paediatric investigation plan applications;
- 6 product-specific waiver applications;
- 9 compliance check procedures (interim and final);

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).

- 32 requests for modifications of an agreed paediatric investigation plan.
- 2 re-examination requests

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 June 2015¹ 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 for the month of April.
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V Update and finalisation of opinions and requests for modification

The opinions adopted during the Paediatric Committee meeting of April 2015 are published on 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	Applicant	Proposed indication	Condition	Outcome	Potential paediatric interest of this medicine suggested by PDCO
SYB01021	ETHYPHARM S.A.	Treatment of agitation and aggression in patients with Alzheimer's disease	Treatment of Alzheimer's disease	Not confirmed	Not applicable
Telotristat (etiprate)	IPSEN PHARMA	Treatment of patients with carcinoid syndrome	Treatment of gastroentero-pancreatic neuroendocrine tumours (excluding neuroblastoma, neuro-ganglioblastoma, phaeochromocytoma)	Postponed	

ACP-196	Acerta Pharma, BV	Treatment of chronic lymphocytic leukemia	Treatment of chronic lymphocytic leukemia	Confirmed	Burkitt lymphoma and diffuse large B cell lymphoma
Glycopyrronium Bromide/ Formoterol fumarate (Inhalation Aerosol)	Pearl Therapeutics, Inc.	Maintenance bronchodilator treatment in adult patients with COPD	Treatment of chronic obstructive pulmonary disease (COPD) (excluding chronic lung diseases associated with long-term airflow limitation, such as asthma, bronchopulmonary dysplasia, primary cilia dyskinesia, obstructive lung disease related to graft-versus-host disease after (bone-marrow) transplantation)	Confirmed	Asthma
Octreotide (hydrochloride)	Novartis Europharm Limited	Treatment of adult patients with functional neuroendocrine tumours of gastrointestinal origin	Treatment of gastroenteropancreatic neuroendocrine tumours (excluding neuroblastoma, neuroganglioblastoma, pheochromocytoma)	Postponed	
REGN2176-3 (REGN2176/ aflibercept)	Regeneron Pharmaceuticals, Inc.	Treatment of neovascular age-related macular degeneration	Treatment of neovascular age-related macular degeneration	Confirmed	Not applicable
Allogenic ex-vivo expanded placental mesenchymal-like adherent stromal cells	Pluristem Ltd. Voisin Consulting Sarl (on behalf of Pluristem)	Treatment of peripheral occlusive arterial disease due to atherosclerosis	Treatment of peripheral atherosclerosis	Confirmed	Muscle injury and muscle wasting

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

No requests were received for the month of April 2015.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Active substance	Applicant	Product Name	Orphan	Difficulties progressing the PIP?	Outcome
EMA-000973-PIP01-10	recombinant human N-acetylgalactosamine-6-sulfatase	BioMarin Europe Limited	Vimizim	Yes	Yes	The PDCO noted the report and the intention to submit a modification of an agreed PIP.
EMA-000116-PIP01-07	Retigabine	Valeant Pharmaceuticals Ltd.	Trobalt	No	Yes	The PDCO noted the report and the intention to submit a modification of an agreed PIP.
EMA-001113-PIP01-10	Delamanid	Otsuka Frankfurt Research Institute GmbH	Delyba	Yes	No	The PDCO noted the report.
EMA-001261-PIP01-11	Eribulin	Eisai Europe Ltd	Halaven	No	No	The PDCO noted the report.
EMA-000434-PIP01-08	ambrisentan	Glaxo Group Limited	Volibris	Yes	No	The PDCO noted the report.
EMA-000727-PIP01-09	Bosutinib (SKI-606)	Pfizer Limited	Bosulif	Planned	Yes	The PDCO noted the report and the intention to submit a modification of an agreed PIP.

IX Other topics

Working groups	
Formulation	Documents tabled for information
Public consultation of the inventories for gastroenterology and for endocrinology Birka Lehmann	The two inventories were adopted for public consultation.
D30 Products identified for the Non-Clinical Working Group Jacqueline Carleer	Report noted.
Product-related topics	
CHMP update on paediatric topics	The PDCO members were informed about two products with paediatric indication recommended by the CHMP at their March 2015 plenary meeting.
Signal Reduced bone density in children with long term use of warfarin – PRAC request for PDCO advice Christoph Male	The background information on the safety signal and questions from PRAC to PDCO were presented by the PRAC Rapporteur for the signal prioritisation and assessment. PDCO members were invited to send their written comments on the PRAC questions in advance of the PDCO May 2015 plenary meeting. A draft conclusion and recommendation will be presented for endorsement at PDCO May 2015 plenary meeting.
Commission requests EMA/PDCO opinion regarding a 7th Framework Programme project for a medicinal product	The PDCO discussed the current status of the PIP and provided the EC with comments on the relevance for EU stakeholders of a marketing authorisation in the proposed condition
Sodium-containing effervescent dispersible and soluble medicines – signal of cardiovascular events - PRAC recommendations	During the assessment by PRAC of this safety signal, the PDCO was consulted and provided advice related to the paediatric population. The PRAC recommendations (adopted in March 2015) were presented to the PDCO.

Other topics	
Draft PDCO work plan 2015	<p>The PDCO discussed the draft PDCO work plan 2015.</p> <p>PDCO members were invited to send additional comments to the PDCO secretariat in advance of PDCO May 2015 plenary meeting.</p>
Presentation of Workshop on Haemophilia Registries	<p>The PDCO was informed of the upcoming EMA Workshop on haemophilia registries (to be held on 1-2 July 2015), as a follow-up of the January 2015 expert meeting on haemophilia and under the umbrella of the global EMA initiative on registries. Two PDCO members are expected to be part of the Steering Committee and attend the workshop. The PDCO endorsed the revised outline (incorporating previous written comments), which will be forwarded to CHMP before publication.</p>
Outcome of Scientific Advice / Protocol Assistance with paediatric questions	<p>The PDCO discussed SAWP products with paediatric interest.</p>
Discussion of 1 st reports	
Breakout sessions	
Neonatology	<p>Neonatal aspects of submitted PIPs were discussed as well as general topics in preparation of the C-Path/EMA neonatal meeting in May 2015.</p>
Paediatric oncology	<p>The forthcoming EMA industry stakeholder meeting and plans for meetings on paediatric oncology prioritisation were discussed.</p>

Any other business

- Presentation of workshop 'Applying Regulatory Science to Neonates'; The draft agenda of the C-Path/EMA meeting on 18/19 May 2015 was presented. Further information will be circulated via post-mail.
- Presentation of the workshop on Extrapolation across age groups; The PDCO was informed that a first internal experts workshop on extrapolation will take place on 30th September 2015.

It will be a cross Committees and working parties. The outcome of the workshop should allow for progress in the drafting of the Extrapolation drafting paper by agreeing on a toolkit of methods available allowing for a better informed system data from every source according to the increasing

level of evidence across the life cycle. The draft agenda will be available end of May 2015 and published on EMA website.

The Chair thanked all participants and closed the meeting.

List of participants

including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 15-17 April 2015 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	
Christoph Male	Alternate	Austria	No participation in discussions, final deliberations and voting No participation in final deliberations and voting	EMEA-000183-PIP01-08-M03 EMEA-001215-PIP01-11-M03 EMEA-C-000312-PIP01-08-M07
Koenraad Norga	Member (Vice-Chair)	Belgium	To be replaced for discussions, final deliberations and voting when chairing the meeting	Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.
Jacqueline Carleer	Alternate	Belgium	No restrictions applicable to this meeting	
Violeta Iotova	Member	Bulgaria	No participation in discussions, final deliberations and voting	EMEA-000783-PIP01-09-M02 EMEA-000496-PIP01-08-M04 EMEA-001517-PIP02-14 EMEA-000828-PIP03-14 EMEA-C2-000694-PIP01-09-M04
Marina Dimov Di Giusti	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	
Ann Marie Kaukonen	Member	Finland	No interests declared	
Maija Pihlajamaki	Member	Finland	No interests declared	
Sylvie Benchetrit	Member	France	No interests declared	
Birka Lehmann	Member	Germany	No interests declared	
Immanuel Barth	Alternate	Germany	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Grigorios Melas	Member	Greece	No interests declared	
Ágnes Gyurasics	Member (CHMP member)	Hungary	No interests declared	
Gylfi Oskarsson	Member	Iceland	No interests declared	
Brian Aylward	Member	Ireland	No interests declared	
Paolo Rossi	Member	Italy	No restrictions applicable to this meeting	
Francesca Rocchi	Alternate	Italy	No restrictions applicable to this meeting	
Dina Apele-Freimane	Member	Latvia	No interests declared	
Carola de Beaufort	Member (CHMP alternate)	Luxembourg	No restrictions applicable to this meeting	
Herbert Lenicker	Alternate	Malta	No interests declared	
Hendrik van den Berg	Member	Netherlands	No interests declared	
Siri Wang	Member	Norway	No interests declared	
Ine Skottheim Rusten	Alternate	Norway	No interests declared	
Marek Migdal	Member	Poland	No restrictions applicable to this meeting	
Jolanta Witkowska-Ozogowska	Alternate	Poland	No interests declared	
Helena Fonseca	Member	Portugal	No interests declared	
Hugo Tavares	Alternate	Portugal	No restrictions applicable to this meeting	
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 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	
Maria Grazia Valsecchi	Alternate	Healthcare Professionals' Representative	No restrictions applicable to this meeting	
Paolo Paolucci	Alternate	Healthcare Professionals' Representative	No interests declared	
Johannes Taminiau	Member	Healthcare Professionals' Representative	No interests declared	
Günther Auerswald	Member	Patients' Organisation Representative	No participation in discussions, final deliberations and voting	EMA-001215-PIP01-11-M03 EMA-C-000312-PIP01-08-M07
Paola Baiardi	Alternate	Patients' Organisation Representative	Full involvement	
Tsvetana Schyns-Liharska	Member	Patients' Organisation Representative	No restrictions applicable to this meeting	
Eleni Gaki	Expert - in person*	United Kingdom	No interests declared	
Dominik Karres	Expert - in person*	United Kingdom	No restrictions applicable to this meeting	
Michael Lassmann	Expert - via telephone*	EMA	No restrictions applicable to this meeting	
Susanne Kaul	Expert - via telephone*	Germany	No interests declared	
Torbjorn Callreus	Expert - via telephone*	Denmark	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.