7 September 2012
EMA/528504/2012
Human Medicines Development and Evaluation

Paediatric Committee (PDCO)

Minutes of the 15-17 August 2012 meeting

Chair: Daniel Brasseur

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 August 2012 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 August 2012 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 August 2012 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 69 procedures in total[1], of which:

- 27 paediatric investigation plan applications;
- 10 product-specific waiver applications;
- 32 compliance check procedures (interim and final);
- 7 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 October 2012 [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 August 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 OF THE APPLICABILITY OF CLASS WAIVER

Class waiver number	Active substance	Condition	Outcome (confirmed / not confirmed)
EMEA-27-2012	MEGF0444A	Treatment of adenocarcinoma of the colon and rectum	Confirmed
EMEA-28-2012	MEGF0444A	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Confirmed
EMEA-29-2012	Prasterone (Dehydroepiandrosterone, DHEA)	Treatment of climacteric symptoms associated with decreased oestrogen levels as occurring at menopause	Confirmed
EMEA-30-2012	canakinumab	Treatment of coronary atherosclerosis	Confirmed
EMEA-31-2012	Rucaparib	Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)	Confirmed
EMEA-32-2012	BAY 1000394	Treatment of chronic lymphocytic leukaemia	Confirmed
EMEA-33-2012	BAY 1000394	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Confirmed
EMEA-34-2012	BAY 1000394	Treatment of epithelial ovarian carcinoma	Confirmed
EMEA-35-2012	BAY 1000394	Treatment of mesothelioma	Confirmed

VII Other topics

Guidelines	
Concept paper on the involvement of Children and Young People*	The PDCO were informed that the first draft of the concept paper had been revised based on some of the comments received. It was re-emphasised that this was just a starting point for this activity, and therefore not meant to be exhaustive at this point. The PDCO were invited to add comments ahead of the September meeting, so that the paper could be adopted for publication at that point.
Advice to EC on the revision of the Guideline on the format and content of applications for agreement or modification of a paediatric investigation plan and	The PDCO has received a proposal for modification as drafted by the EMA Secretariat. The principles underlying the proposal have been endorsed by the PDCO, and are as follows: The guideline could benefit from incremental improvements, but

requests for waivers or deferrals and concerning the operation of the compliance check and on criteria for assessing significant studies☐	its general structure and content should not be completely rewritten. The following types of improvements should be carried out: Minor amendments and corrections: e.g. change “EMEA” to “EMA”, deletion of reference to applicants having to be located in the EEA, update of weblinks, changes on Risk Management Plans to reflect current legal advice, etc. Simplification: removal of duplicate, obsolete or unnecessary information/advice; simplification of the language and style; reduction of required level of detail to be provided by applicants in part B of the scientific document. Inclusion of additional/updated concepts: e.g. definition of key element, update of other definitions (condition), relationship between indication and condition, policy on multiple PIPs, etc. The “EC guideline working group” members and the other PDCO members will submit additional comments and proposals for discussion and possible adoption in September.
Working groups	
Paediatric Inventory working group	Discussion on the current therapeutic area (infectious diseases).
Formulation	No non-product related issues where reported to the Committee.
Non-Clinical	No non-product related issues where reported to the Committee
Extrapolation	N/A
Other topics	
Enpr-EMA: PDCO to identify areas in which close collaboration with Enpr-EMA members is warranted either through development of standard paediatric investigation plans (PIPs) or by providing expert advice	The PDCO discussed in April this year that collaboration with Enpr-EMA could focus on three areas: prioritisation, feasibility and elaboration of standard PIPs/guidelines. It was agreed to create an ad-hoc working group of PDCO members to implement the proposals made at the April PDCO meeting which, however, has not yet been established. To finally move forward, it was proposed to start with one area, i.e. asthma. A small subgroup of four to five PDCO members agreed to elaborate a first draft of standard PIP for asthma which will be discussed within this subgroup in September before circulating it to all PDCO members prior to sending it to Enpr-EMA for their comments. The Luxembourg PDCO member reported that the endocrinology group (emerging European network in paediatric endocrinology) will meet again in September. Their first goal is to establish a registry of adolescent type 2 Diabetes. They have circulated data on prevalence of t2dm in different countries and will discuss how to get better data on this subject. Following the PDCO proposal from April, the PDCO member will propose to also include in their discussions:

	1) to list high priority drugs and establish a need/ high priority list; 2) what kind of study/studies they would consider relevant/feasible for their high priority list.
Inventory of paediatric therapeutic needs: List of products in the therapeutic area of cardiovascular diseases to be adopted by the Committee and released for public consultation	The list of products in the therapeutic area of cardiovascular diseases was adopted by the Committee and released for public consultation.
Brief report on the workshop on clinical development and scientific advice in ophthalmology	Postponed to September.
Nomination of PDCO expert to ITF briefing Meeting Product/Technology: Minimal Residual Disease (MRD) diagnostics in haemato-oncology	Nomination took place.
Nomination to the EMA Pandemic Task Force (ETF)	Nomination took place.
Nomination of PDCO representative(s) for Rome Foundation initiative to develop diagnostic criteria for irritable bowel syndrome Richard Vesely	Nomination took place.

VIII Any other business

- Report to the European Commission: General report on the experience acquired as a result of the application of the Paediatric Regulation*.
- Clinical Trial regulation: The recent proposal of the European Commission was flagged and briefly discussed (http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm#rlctd)

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 August 2012

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 e-DoI	Topics on the current Committee Agenda for which this restriction applies
Adriana Ceci	Restriction level 3	EMEA-000145-PIP01-07-M05
Adriana Ceci	Restriction level 3	EMEA-001196-PIP01-11
Adriana Ceci	Restriction level 3	EMEA-001258-PIP01-11
Adriana Ceci	Restriction level 3	EMEA-001039-PIP02-12
Adriana Ceci	Restriction level 3	EMEA-001071-PIP02-12
Gérard Pons	Restriction level 3	EMEA-000116-PIP01-07-M05
Gérard Pons	Restriction level 3	EMEA-001258-PIP01-11
Igor Francetic	Restriction level 3	EMEA-000439-PIP02-11
Michal Odermarsky	Restriction level 3	EMEA-000222-PIP01-08-M06
Michal Odermarsky	Restriction level 3	EMEA-001288-PIP01-12
Christoph Male	Restriction level 4	EMEA-001024-PIP01-10-M01
Christoph Male	Restriction level 4	EMEA-001296-PIP01-12
Christoph Male	Restriction level 4	EMEA-001174-PIP02-12
Marek Migdal	Restriction level 4	EMEA-001249-PIP01-11
Marek Migdal	Restriction level 4	EMEA-000205-PIP02-11
Paolo Rossi	Restriction level 4	EMEA-001289-PIP01-12
Peter Szitanyi	Restriction level 4	EMEA-000054-PIP01-07-M03
Peter Szitanyi	Restriction level 4	EMEA-000300-PIP01-08-M03
Peter Szitanyi	Restriction level 4	EMEA-000301-PIP01-08-M03
Peter Szitanyi	Restriction level 4	EMEA-000302-PIP01-08-M03

Member, alternate, expert name	Outcome restriction following evaluation of e-DoI	Topics on the current Committee Agenda for which this restriction applies
Peter Szitanyi	Restriction level 4	EMEA-001300-PIP01-12

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**
1	**No involvement in activity**
2	**To be replaced for the discussions, final deliberations and voting** as appropriate in relation to the relevant product or a competitor product.
3	**Where Individual product involvement is declared:** - **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
4	**Where Individual product involvement is declared:** - **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

Annex II to the Minutes of the PDCO of August 2012

List of Participants

Chair

Daniel BRASSEUR

Vice-chair

Dirk MENTZER

Members appointed by Member States or CHMP

Jaroslav STERBA	Czech Republic
Marianne ORHOLM	Denmark
Irja LUTSAR	Estonia
Pirjo LAITINEN-PARKKONEN	Finland
Gerard PONS	France
Dirk MENTZER	Germany
Agnes GYURASICS	Hungary
Kevin CONNOLLY	Ireland
Dina APELE-FREIMANE	Latvia
Carine de BEAUFORT	Luxembourg
John Joseph BORG	Malta
Hendrik van den BERG	The Netherlands
Siri WANG	Norway
Marek MIGDAL	Poland
Fernando DE ANDRÉS TRELLES	Spain
Julia DUNNE	United Kingdom

Alternates appointed by Member States or CHMP

Karl Heinz HUEMER	Austria
Jacqueline CARLEER	Belgium
Peter SZITANYI	Czech Republic
Ann Marie KAUKONEN	Finland
Birka LEHMANN	Germany

Pending	Greece
Brian AYLWARD	Ireland
Pending	Latvia
Johannes TAMINIAU	The Netherlands
Ine Skottheim RUSTEN	Norway
Jolanda WITKOWSKA-OZOGOWSKA	Poland
Dana Gabriela MARIN	Romania
Tadej AVCIN	Slovenia
Viveca Lena ODLIND	Sweden

Members representing patients' organisations

Tsveta SCHYNS-LIHARSKA

Michal ODERMARSKY

Alternates representing patients' organisations

Gerard NGUYEN

Members representing health care professionals

Adriana CECI

Alternates representing health care professionals

None present

Experts

None present

Observers

None present

European Medicines Agency

Paolo TOMASI	Head of Section, Paediatric Medicines
Sophie OLIVIER	Scientific Administrator, Paediatric Medicines
Blanca QUIJANO RUIZ	Scientific Administrator, Paediatric Medicines
Dobromir PENKOV	Scientific Administrator, Paediatric Medicines
Elin Haf DAVIES	Scientific Administrator, Paediatric Medicines
Ermanno ZORZOLI	Scientific Administrator, Paediatric Medicines
Giovanni LESA	Scientific Administrator, Paediatric Medicines
Gunter EGGER	Scientific Administrator, Paediatric Medicines

Irmgard EICHLER	Scientific Administrator, Paediatric Medicines
Janina KARRES	Scientific Administrator, Paediatric Medicines
Julia SAPERIA	Scientific Administrator, Paediatric Medicines
Ralf HEROLD	Scientific Administrator, Paediatric Medicines
Ralph BAX	Scientific Administrator, Paediatric Medicines
Richard VESELY	Scientific Administrator, Paediatric Medicines
Thorsten OLSKI	Scientific Administrator, Paediatric Medicines
Aurelie HERVIEU	Assistant, Paediatric Medicines
Isabel PEREZ	Assistant, Paediatric Medicines
Anna MESTERHAZY	Assistant, Paediatric Medicines