EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

07 November 2012
EMA/638304/2008
Human Medicines Development and Evaluation

Paediatric Committee (PDCO)

Minutes of the 03-05 October 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 October 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 October 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 October 2012 PDCO monthly report published in the EMA Website:

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III Discussion of applications

The PDCO discussed 82 procedures in total[1], of which:

- 37 paediatric investigation plan applications;
- 16 product-specific waiver applications;
- 8 compliance check procedures (interim and final);
- 21 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 December 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 October 2012 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-44-2012	Nicotinic Acid / Laropiprant	Treatment of coronary atherosclerosis	Confirmed
EMEA-46-2012	AZD8931	Treatment of breast carcinoma	Confirmed
EMEA-47-2012	glycopyrronium bromide (glycopyrrolate)	Chronic Obstructive Pulmonary Disease (COPD)	Confirmed

VII Other topics

Guidelines	
Advice to EC on revised* Guideline on the format and content of applications for agreement or modification of a paediatric investigation plan and requests for waivers or deferrals and concerning the operation of the compliance check and on criteria for assessing significant studies	The Committee was informed that a final draft of the proposed guideline has been prepared by the Secretariat, to include comments received by PDCO members in the last month and at the last PDCO. The final draft will be sent to PDCO members in the post-PDCO mail, for adoption in the November PDCO meeting.
Guideline on the clinical development of medicinal products intended for the treatment of chronic primary immune thrombocytopaenia*	Based on the comments received from PDCO members it was agreed that the changes could be done within the existing guideline and that there would not be the need to have a paediatric addendum. Changes will be made in the draft guideline in order to reflect PDCO opinions adopted for Chronic primary immune thrombocytopaenia PIPs. An overview of the comments received will be circulated in the postmail for information The version including PDCO comments will be discussed for adoption in the November PDCO.
Guideline on clinical medicinal products intended for the treatment of pain*	The draft guideline currently under development by the CNSWP was discussed in the PDCO. Comments were drafted and sent for consideration at the next CNSWP meeting.
ICH E11 guideline: Clinical Investigation of Medicinal Products in the Paediatric Population	The PDCO adopted a draft concept paper*, proposing updates to several sections of the ICH E11 guideline, in view of a possible discussion at the November ICH meeting.
Working groups	
Paediatric oncology	Discussion of participation in external meetings and of the evaluation of class waivers.

Paediatric Inventory	Discussion on the current therapeutic area (infectious diseases). The draft Inventory of Paediatric Medicines for the therapeutic area of Infectious Diseases* will be sent to the PDCO in the post-mail. The working group started discussing the new therapeutic area, Nephrology.
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	
Training for PDCO on new pharmacovigilance legislation	Peter Arlett, Head of Sector Pharmacovigilance, gave a presentation on the highlights of the new pharmacovigilance regulation and its implementation by the European Medicines Agency.
ITF briefing Meeting Product/Technology: Minimal Residual Disease (MRD) diagnostics in haemato-oncology	The PDCO was informed about a recent briefing meeting where the technology was discussed, in view of EMA guidelines for anti-cancer medicines and the role and procedures at EMA in developing and authorising medicines.
Work plan for the European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP) 2013*	Postponed
Work plan for the European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) 2013*	Postponed
Revision of the standard asthma PIP*	• The ad-hoc group of PDCO members presented the first draft development strategy for development of medicinal products for the condition asthma to the PDCO plenary for information. • The draft will be circulated in the post-mail to all PDCO members for comments until next PDCO meeting in November. • The strategy together with all comments received will then be discussed and finalised at the informal PDCO meeting in Rome, end of November 2012. • The final strategy will then be presented to the PDCO in the December meeting, for adoption.
Revision of the standard PIP on allergen	The PDCO reiterated the invitation to the European Allergen Manufacturers Group for submission of their proposals for

	alternate study designs which would allow generation of robust data demonstrating both short and long-term efficacy in children. It would enable the PDCO to start discussing potential revision of the current standard PIP on allergen products for specific immunotherapy.
Model oncology PIPs*	A "model PIP for the treatment of rhabdomyosarcoma"* was presented in detail and discussed by the PDCO. Another model PIP for the treatment of acute myeloid leukaemia* was also briefly described. Accordingly, comments are to be sought until the next meeting, when the draft for rhabdomyosarcoma* may be adopted, to be forwarded as a draft to the Oncology Working Party and the Scientific Advice Working Party at the EMA.
Review of the EMA decision on the list of class waivers	The PDCO appointed rapporteurs for the evaluation of the possible revocation of existing class waivers not aimed at a specific class of medicinal products.
Publication of full Annex I including key elements, and use of new template for opinions	The PDCO was informed that the Agency intends to proceed with inclusion of full Opinions, including the key binding elements contained in Annex I of the Opinions, in the Decisions that will be published in the EMA website from January 2013 (tentatively). This is one of the transparency measures being adopted by the Agency, also in line with the Draft Recommendation of the European Ombudsman on transparency in Paediatric medicines. The PDCO was also informed that the new, simplified template for Opinions, created in accordance with the recommendations of the specific PDCO working group, will be used starting from the Opinions adopted in November 2012.

VIII Any other business

- Ethical considerations for paediatric trials: How can Ethics Committees of the Member States and the Paediatric Committee at the European Medicines Agency work together? Draft report* provided to PDCO for further suggestions for working together.

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.

* Post meeting note: The report on the Ethical considerations form paediatrics trial was finalised and subsequently published on 25 October 2012:
http://www.ema.europa.eu/docs/en_GB/document_library/Report/2012/10/WC500134407.pdf

Annex I to the Minutes of the PDCO of October 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 electronic Declaration of Interests	Topics on the current Committee Agenda for which this restriction applies
Adriana Ceci	Restriction level 3	EMEA-001315-PIP01-12
Adriana Ceci	Restriction level XR	EMEA-001260-PIP01-11
Adriana Ceci	Restriction level 3	EMEA-000366-PIP01-08-M05
Alexandra Compagnucci	Restriction level 3	EMEA-C1-001181-PIP01-11
Andreas Teloudes	Restriction level 4	EMEA-001234-PIP01-11
Carine de Beaufort	Restriction level XR (Bayer)	EMEA-001178-PIP01-11
Dobrin Konstantinov	Restriction level 3	EMEA-001301-PIP01-12
Dobrin Konstantinov	Restriction level 3	EMEA-001301-PIP02-12
Dobrin Konstantinov	Restriction level XP	EMEA-000468-PIP02-12
Jaroslav Sterba	Restriction level XP	EMEA-001259-PIP01-11
Jaroslav Sterba	Restriction level XP	EMEA-000468-PIP02-12
Marek Migdal	Restriction level 4	EMEA-001211-PIP01-11
Michal Odermarsky	Restriction level 3	EMEA-001307-PIP01-12
Michal Odermarsky	Restriction level XP	EMEA-001219-PIP01-11
Paolo Rossi	Restriction level 4	EMEA-001290-PIP01-12
Paolo Rossi	Restriction level 4	EMEA-000454-PIP01-08-M02
Peter Szitanyi	Restriction level 4	EMEA-001344-PIP01-12
Tsveta Schyns-Liharska	Restriction level XR	EMEA-001260-PIP01-11
Tsveta Schyns-Liharska	Restriction level XR	EMEA-001276-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:

The European Medicines Agency recently reviewed and updated the coding used in the evaluation of the conflict of interest. There will be a short transition period when both codes will be in used until procedures evaluated under the previous code have been completed.

Evaluation of the conflict of interest – Previous code	
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 products.
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 product.
Evaluation of the conflict of interest – New code	
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 October 2012

List of Participants

Chair

Daniel BRASSEUR

Vice-chair

Dirk MENTZER

Members appointed by Member States or CHMP

Christoph MALE	Austria
Koenraad NORGA	Belgium
Dobrin KONSTANTINOV	Bulgaria
Jaroslav STERBA	Czech Republic
Marianne ORHOLM	Denmark
Irja LUTSAR	Estonia
Pirjo LAITINEN-PARKKONEN	Finland
Gerard PONS	France
Dirk MENTZER	Germany
Agnes GYURASICS	Hungary
Paolo ROSSI	Italy
Dina APELE-FREIMANE	Latvia
Carine de BEAUFORT	Luxembourg
Hendrik van den BERG	The Netherlands
Siri WANG	Norway
Marek MIGDAL	Poland
Helena FONSECA	Portugal
Vlasta KAKOSOVA	Slovak Republic
Janez JAZBEC	Slovenia
Fernando DE ANDRÉS TRELLES	Spain
Marta GRANSTRÖM	Sweden
Julia DUNNE	United Kingdom

Alternates appointed by Member States or CHMP

Karl Heinz HUEMER	Austria
Jacqueline CARLEER	Belgium
Ann Marie KAUKONEN	Finland
Sylvie BENCHETRIT	France
Birka LEHMANN	Germany
Brian AYLWARD	Ireland
Francesca ROCCHI	Italy
Johannes TAMINIAU	The Netherlands
Ine Skottheim RUSTEN	Norway
Jolanda WITKOWSKA-OZOGOWSKA	Poland
Hugo TAVARES	Portugal
Dana Gabriela MARIN	Romania
Maria Jesus FERNANDEZ CORTIZO	Spain
Viveca Lena ODLIND	Sweden

Members representing patients' organisations

Tsveta SCHYNS-LIHARSKA

Alternates representing patients' organisations

Members representing health care professionals

Adriana CECI

Anthony James NUNN

Alternates representing health care professionals

Paolo PAOLUCCI

Experts

Peter BAUER	Medical statistician

Observers

European Medicines Agency

Agnes SAINT RAYMOND	Head of Sector, Human Medicines Special Areas
Paolo TOMASI	Head of Section, Paediatric Medicines
Sophie OLIVIER	Scientific Administrator, Paediatric Medicines
Anne-Sophie HENRY-EUDE	Scientific Administrator, Paediatric Medicines

Almudena SAIZ HERRANZ	Scientific Administrator, Paediatric Medicines
Benjamin PELLE	Scientific Administrator, Paediatric Medicines
Blanca QUIJANO RUIZ	Scientific Administrator, Paediatric Medicines
Cecile OLLIVIER	Scientific Administrator, Paediatric Medicines
Dobromir PENKOV	Scientific Administrator, Paediatric Medicines
Elin Haf DAVIES	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
Peter KÁROLYI	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
Alessandro JENKNER	National Expert on Secondment, Paediatric Medicines
Cristina BEJNARIU	Trainee
Aurelie HERVIEU	Assistant, Paediatric Medicines
Isabel PEREZ	Assistant, Paediatric Medicines
Anna MESTERHAZY	Assistant, Paediatric Medicines