06 February 2013
EMA/PDCO/9311/2013
Human Medicines Development and Evaluation

Paediatric Committee (PDCO)

Minutes of the 09-11 January 2013 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 January 2013 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 January 2013 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 January 2013 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 total[1], of which:

- 38 paediatric investigation plan applications;
- 15 product-specific waiver applications;
- 25 compliance check procedures (interim and final);
- 8 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 March 2013[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 January 2013 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 on the applicability of class waiver

Class waiver number	Active substance	Condition	Proposed indication	Outcome (confirmed / not confirmed)
EMEA-63-2012	N-{3-[(2-{[4-(4-acetylpiperazin-1-yl)-2-methoxyphenyl]amino}-5-(trifluoromethyl)pyrimidin-4-yl)amino]phenyl}prop-2-enamide	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Treatment of patients with mutant epidermal growth factor receptor ($EGFR^{mut}$) non-small cell lung cancer who have received prior EGFR-directed therapy	Confirmed
EMEA-64-2012	RO5137382 (GC33, RG7686)	Treatment of liver and intrahepatic bile duct carcinoma (excluding hepatoblastoma)	Treatment of glypican 3 (GPC3) expressing hepatocellular carcinoma	Confirmed
EMEA-65-2012	Strontium (succinate) (Protelos, Osseor)	Treatment of primary and secondary osteoarthrosis	Treatment of osteoarthritis of the knee and hip to reduce the progression of the cartilage damage.	Confirmed

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

No requests were received for review for the January PDCO plenary meeting.

VIII Other topics

Guidelines	
Paediatric Addendum* to the Note for guidance on clinical investigation of medicinal products in the treatment of hypertension	The first draft of the paediatric addendum, which has been prepared by the CHMP cardiovascular working party, was presented to the PDCO plenary. It was considered already quite mature. A few comments were raised by PDCO members regarding methods for blood pressure measurement, endpoints, long-term follow-up and lower age limit, which is scientifically difficult to determine since even children in the first year of live are affected by renal hypertension e g by congenital disorders. However, practicability considerations should be taken into account. The document will be circulated to all PDCO members in the postmail asking for further comments within 2 weeks.

	The document with all comments received will then be presented again to the PDCO plenary at the February meeting for discussion and final adoption.
Guideline on the clinical investigation of medicinal products to prevent development/slow progression of chronic renal insufficiency* (Concept paper on the need for the guidance on the clinical investigation of medicinal products to slow progression of renal insufficiency)	The draft of the paediatric paragraph of the proposed guideline was presented and discussed by the members. The document will be presented for adoption at the February meeting.
Working groups	
Paediatric inventory	The group continued with discussions on the therapeutic area of nephrology-urology.
Paediatric oncology	The group prepared product-related discussions in the PDCO and discussed a recent neuroblastoma meeting as well as tumour-biological and pharmacogenomic assessments.
Formulation	No non-product related issues where reported to the Committee.
Non-Clinical	No non-product related issues where reported to the Committee.
Extrapolation	The group continued discussions on external comments received on the concept paper, a specific PIP including extrapolation issues and organisation of future meetings.
Other topics	
CHMP List of Questions to be addressed by PDCO: Privigen	The PDCO adopted an opinion on a List of Question issued by the CHMP to the PDCO on an ongoing assessment of Privigen in the field of immunology.
CHMP List of Questions to be addressed by PDCO: Votubia	The PDCO had a preliminary discussion of the questions; the adoption of the PDCO opinion is scheduled for the February meeting.
Overview of comments received on the concept paper on the involvement of Children and Young People	PDCO members were presented the background need to this concept paper and informed of the comments received. Eight different stakeholders have sent in comments. All of whom were very supportive to the need of involving children and young people in the work of the PDCO. Three PDCO members volunteered to develop the concept paper into a reflection paper, and identify ways to implement the ideas into action plans.
Model oncology PIP acute	The model oncology PIP for acute myeloid leukaemia* was presented

myeloid leukaemia* Ralf Herold	in detail in the PDCO, inviting for final comments in view of an adoption and release for public consultation planned for the February 2013 PDCO meeting.
Work plan for the European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) 2013* Work plan for the European Medicines Agency/ CHMP Working Group with Healthcare Professionals' Organisations (HCP WG) 2013*	A presentation was made at the PDCO of the planned interactions between the EMA and Patients' and Consumer's organisations, and between EMA and Healthcare Professionals' organisations.
Annual reports on deferrals	From February 2013, PDCO members will be informed of Annual Deferral Reports received by the EMA on a monthly basis. Outcomes will be discussed during PDCO whenever needed.
Article 6.1(J) of the Paediatric Regulation (Communication on paediatric clinical research)	PDCO members were informed about the draft document on how communication should be improved on a European and national level in order to promote paediatric clinical research. Comments from the members are expected by 31 January 2013. It is aimed to adopt the document during the February PDCO plenary.
Launch of the revised EudraSmPC webpage: http://eudrasmpc.eudra.org/ How to prepare and review a summary of product characteristics	Colleagues from the Medical Information sector informed the PDCO about the upcoming public EudraSmPC webpage, and new information contained in the site.
Reflection on revocation of the EMA decision on the list of class waivers	The topic could not be discussed at this meeting. Postponed to February.
Summary of PDCO Opinion: new document and guidance*	The draft guidance and the draft Summary of PDCO Opinion were presented and discussed in the PDCO. The members will comment before the next PDCO meeting in February, when adoption is foreseen.
Meeting dates for 2015*	The meeting dates for 2015 were adopted.
Novartis proposal for PIPs for Lucentis: EMEA-000527-PIP01-08 EMEA-000527-PIP02-10	The applicant approached the chair od PDCO regarding their planned approach for submission of multiple paediatric investigation plans for several different conditions. The issue was discussed by the PDCO plenary. A letter summarising the conclusions will be sent to the applicant.

IX Any other business

- Guideline on the evaluation of Medicinal Products for the treatment of Irritable Bowel Syndrome*: The need for paediatric addendum to the guideline and preliminary proposal for it were presented. The addendum will be discussed / adopted during February meeting.

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 January 2013

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 DP	EMEA-001371-PIP01-12
Adriana Ceci	Restriction level DP	EMEA-001366-PIP01-12
Adriana Ceci	Restriction level DP	EMEA-001045-PIP01-10
Adriana Ceci	Restriction level DP	EMEA-001220-PIP01-11
Adriana Ceci	Restriction level DP	EMEA-001089-PIP01-10
Adriana Ceci	Restriction level XR	EMEA-000019-PIP06-09-M03
Alexandra Compagnucci	Restriction level XC	EMEA-000733-PIP02-12
Carine de Beaufort	Restriction level XR	EMEA-001045-PIP01-10
Carine de Beaufort	Restriction level XR	EMEA-001207-PIP01-11
Christoph Male	Restriction level DP	EMEA-001296-PIP01-12
Gerard Pons	Restriction level DP	EMEA-000332-PIP01-08-M06
Gerard Pons	Restriction level DP	EMEA-000116-PIP01-07-M06
Jaroslav Sterba	Restriction level XP	EMEA-001372-PIP01-12
Jaroslav Sterba	Restriction level XP	EMEA-001350-PIP01-12
Jaroslav Sterba	Restriction level XP	EMEA-001033-PIP02-11
Jaroslav Sterba	Restriction level XP	EMEA-001207-PIP01-11
Kolbeinn Gudmundsson	Restriction level DP	EMEA-001348-PIP01-12
Matthias Keller	Restriction level XR	EMEA-000366-PIP05-12
Michal Odermarsky	Restriction level XP	EMEA-001280-PIP01-12
Michal Odermarsky	Restriction level XP	EMEA-000968-PIP02-11-M01

Member, alternate, expert name	Outcome restriction following evaluation of electronic Declaration of Interests	Topics on the current Committee Agenda for which this restriction applies
Michal Odermarsky	Restriction level XP	EMEA-000533-PIP01-08-M04
Paolo Rossi	Restriction level DP	EMEA-001289-PIP01-12
Peter Bauer	Restriction level DP	EMEA-001327-PIP01-12
Peter Bauer	Restriction level DP	EMEA-000733-PIP02-12
Peter Szitanyi	Restriction level DP	EMEA-001364-PIP01-12
Peter Szitanyi	Restriction level DP	EMEA-001100-PIP01-10
Romaldas Maciulaitis	Restriction level XR	EMEA-001207-PIP01-11
Tadej Avcin	Restriction level XP	EMEA-001371-PIP01-12
Tadej Avcin	Restriction level XP	EMEA-001045-PIP01-10
Tadej Avcin	Restriction level XP	EMEA-001220-PIP01-11
Tadej Avcin	Restriction level XP	EMEA-001089-PIP01-10

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
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 January 2013

List of Participants

Chair

Daniel BRASSEUR

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-PARKONNEN	Finland
Gerard PONS	France
Stefanos MANTAGOS	Greece
Agnes GYURASICS	Hungary
Gylfi OSKARSSON	Iceland
Kevin CONNOLLY	Ireland
Paolo ROSSI	Italy
Dina APELE-FREMIANE	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
Pending	Greece
Brian AYLWARD	Ireland
Francesca ROCCHI	Italy
Rugile PILVINIENE	Lithuania
Herbert LENICKER	Malta
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
Angeliki SIAPKARA	United Kingdom

Members representing patients' organisations

Tsveta SCHYNS-LIHARSKA

Alternates representing patients' organisations

Gerlind BODE

Members representing health care professionals

Adriana CECI

Alternates representing health care professionals

Paolo PAOLUCCI

Experts

Peter BAUER	Medical statistician

Observers

Immanuel Barth	Paul Ehrlich Institut (Germany)

Nao Tsuchida	National Center for Child Health and Development (Japan)

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
Cecile OLLIVIER	Scientific Administrator, Paediatric Medicines
Chrissi Pallidis	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