28 November 2012
EMA/PDCO/764750/2012
Human Medicines Development and Evaluation

Paediatric Committee (PDCO)

Provisional agenda of the 05-07 December 2012 meeting

Chair: Daniel Brasseur

I Introduction

I.1 Adoption of the minutes from previous meeting

I.2 Adoption of the Agenda

I.3 Declaration of Conflict of Interest

Based on the Declaration of Interest submitted by the Committee members, alternates and experts, the Committee Secretariat identified, based on the topics listed in the Agenda of the current Committee meeting, the following restricted involvement of Committee members for the upcoming discussions:

Member, alternate, expert name	Outcome restriction following evaluation of electronic evaluation form	Topics on the current Committee Agenda for which this restriction applies
Michal Odermarsky	Restriction level XP	EMEA-000804-PIP01-09-M01
Matthias Keller	Restriction level DP	EMEA-000018-PIP01-07-M05
Matthias Keller	Restriction level DP	EMEA-000494-PIP01-08-M05
Matthias Keller	Restriction level DP	EMEA-000495-PIP01-08-M05
Matthias Keller	Restriction level DP	EMEA-000325-PIP01-08-M01
Matthias Keller	Restriction level DP	EMEA-000485-PIP01-08-M01
Matthias Keller	Restriction level DP	EMEA-000486-PIP01-08-M01
Peter Szitanyi	Restriction level DP	EMEA-001353-PIP01-12
Romaldas Maciulatis	Restriction level XR	EMEA-000726-PIP01-09-M01

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

Member, alternate, expert name	Outcome restriction following evaluation of electronic evaluation form	Topics on the current Committee Agenda for which this restriction applies
Carine de Beaufort	Restriction level XR	EMEA-000128-PIP01-07-M05
Jaroslav Sterba	Restriction level XP	EMEA-001033-PIP02-11
Adriana Ceci	Restriction level XR	EMEA-000019-PIP08-12
Gerard Pons	Restriction level DP	EMEA-000019-PIP08-12
Matthias Keller	Restriction level DP	EMEA-001281-PIP01-12
Christoph Male	Restriction level DP	EMEA-001281-PIP01-12
Christoph Male	Restriction level XP	EMEA-000183-PIP02-12

Members of the Committee are kindly requested to review the list and state any changes, omissions or errors to the already declared interests.

Note: the procedures identified in the table above are on-going and therefore considered confidential. Additional details on these procedures will be disclosed in the PDCO Committee meeting reports webpage (after the PDCO Opinion is adopted), and on the Opinions and decisions on paediatric investigation plans webpage (after the EMA Decision is issued).

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.

Evaluation of the conflict of interest	
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

I.4 External and EC attendance

Lisa Hampson, Lancaster University. See systematic review of designs of dose-finding studies in Paediatric Investigation Plans (2010-2012) under VIII Other topics

Florian Schmidt, European Commission. See EC consultation on the Paediatric Regulation – feed-back on comments received under VIII Other topics.

I.5 Leaving/New Members and Alternates

The PDCO welcomes the new alternate representing United Kingdom, Dr Angeliki Siapkara.

II Opinions

II.1 Opinions on Products

II.2 Opinions on Compliance Check

II.3 Opinions on Modification of an Agreed Paediatric Investigation Plan

III Discussion of applications

87 current procedures in total[1], of which:

- 35 paediatric investigation plan applications;
- 14 product-specific waiver applications;
- 5 compliance check procedures (interim and final);
- 33 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 February 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.

[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).

V Finalisation and adoption of opinions

The opinions adopted during the Paediatric Committee meeting of December are published in the same month's meeting report published in the EMA website

VI Discussion on the applicability of class waiver

Class waiver number	Active substance	Proposed indication	Condition
EMEA-52-2012	RO5083945 (GA201)	Treatment of adenocarcinoma of the colon and rectum	Adenocarcinoma of the colon and rectum
EMEA-53-2012	RO5083945 (GA201)	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Lung carcinoma (small cell and non-small cell carcinoma
EMEA-54-2012	RO5083945 (GA201)	Treatment of oropharyngeal, laryngeal or nasal epithelial carcinoma (excluding nasopharyngeal carcinoma or lymphoepithelioma)	Oropharyngeal, laryngeal or nasal epithelial carcinoma (excluding nasopharyngeal carcinoma or lymphoepithelioma)
EMEA-55-2012	Pertuzumab (Perjeta)	Treatment, in combination with trastuzumab, fluorouracil (5 fluorouracil or capecitabine), and cisplatin, of patients with HER2-positive metastatic adenocarcinoma of the stomach and/or gastroesophageal junction who have not had prior treatment for metastatic disease	Treatment of gastric adenocarcinoma
EMEA-56-2012	Pertuzumab (Perjeta)	Treatment, in combination with standard chemotherapy, of recurrent platinum resistant epithelial ovarian cancer and low HER3 mRNA expression	Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)
EMEA-57-2012	RO5490254	Treatment of mesothelioma	Treatment of mesothelioma
EMEA-58-2012	RO5490254	Treatment of renal cell carcinoma	Treatment of kidney and renal pelvis carcinoma (excluding nephroblastoma, nephroblastomatosis, clear cell sarcoma, mesoblastic nephroma, renal medullary

			carcinoma and rhabdoid tumour of the kidney)
EMEA-59-2012	RO5490254	Treatment of endometrial carcinoma	Treatment of endometrial carcinoma
EMEA-60-2012	linsitinib	Treatment of non-small cell lung carcinoma	Treatment of lung carcinoma (small cell and non-small cell carcinoma)
EMEA-61-2012	linsitinib	Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)	Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)
EMEA-62-2012	Olaparib (AZD2281, KU-0059436)	Maintenance monotherapy for the treatment of patients with relapsed gBRCA mutation positive ovarian cancer who have responded (complete response or partial response) to platinum-based chemotherapy Maintenance monotherapy for the treatment of patients with gBRCA mutation positive ovarian cancer who have responded (complete response or partial response) to first-line platinum-based chemotherapy.	Treatment of ovarian carcinoma

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

No requests were received for review during the December PDCO plenary.

VIII Other topics

Guidelines	
Proposal to EC 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	For discussion and adoption
Working groups	
Paediatric oncology	For discussion

Paediatric inventory	For discussion
Formulation	For information
Non-Clinical	For information
Extrapolation	For information
Other topics	
EC consultation on the Paediatric Regulation – feed-back on comments received	For information
Reflection on revocation of the EMA decision on the list of class waivers	For discussion
Systematic review of designs of dose-finding studies in Paediatric Investigation Plans (2010-2012)	For information and discussion
Annual reports on deferrals	For discussion
Development strategy for medicinal products targeting asthma in children*	For discussion
Overview of comments received on the concept paper on the involvement of Children and Young People	For information
Inventory of paediatric medicines: Infectious diseases therapeutic area* Cardiovascular diseases therapeutic area	 For adoption For review of comments received
Model oncology PIPs*	For discussion and adoption
PIP Application Summary*	For discussion

IX Any other business

Note on access to documents

Documents marked with an asterisk* in document cannot be released at present as they are currently in draft format. They will become public when adopted in their final form.