EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

26 September 2012
EMA/PDCO/622209/2012
Human Medicines Development and Evaluation

Paediatric Committee (PDCO)

Provisional agenda of the 03-05 October 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 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

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 Declaration of Interests	Topics on the current Committee Agenda for which this restriction applies
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

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).

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

I.4 External attendance

To be confirmed

I.5 Leaving/New Members and Alternates

None

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

- 82 current 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 procedure 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.

V Finalisation and adoption of opinions

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

VI DISCUSSION OF THE APPLICABILITY OF CLASS WAIVER

Class waiver number	Active substance	Condition
EMEA-44-2012	Nicotinic Acid / Laropiprant	Treatment of coronary atherosclerosis
EMEA-46-2012	AZD8931	Treatment of breast carcinoma
EMEA-47-2012	glycopyrronium bromide (glycopyrrolate)	Chronic Obstructive Pulmonary Disease (COPD)

VII Other topics

Guidelines	
Guideline on the clinical development of medicinal products intended for the treatment of chronic primary immune thrombocytopaenia*	For discussion and adoption of PDCO comments.
Guideline on Clinical Medicinal Products Intended For The Treatment Of Pain	For discussion and adoption of PDCO comments.
Working groups	
Breakout for the revision of the standard asthma PIP	For discussion

[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).

Paediatric oncology	For discussion
Paediatric Inventory	For discussion
Formulation	For information
Non-Clinical	For information
Extrapolation	For information
Other topics	
Training for PDCO on new pharmacovigilance legislation	For information
ITF briefing Meeting Product/Technology: Minimal Residual Disease (MRD) diagnostics in haemato-oncology	For information
Revision of the standard asthma PIP*	For discussion
Revision of the standard PIP on allergen	For adoption
Model oncology PIPs*	For discussion
Review of the EMA decision on the list of class waivers	For discussion

VIII 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.