EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 October 2012
EMA/PDCO/701166/2012
Human Medicines Development and Evaluation

Paediatric Committee (PDCO)

Provisional agenda of the 07-09 November 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 XR	EMEA-000019-PIP08-12
Adriana Ceci	Restriction level XR	EMEA-001260-PIP01-11
Carine de Beaufort	Restriction level XR	EMEA-49-2012
Carine de Beaufort	Restriction level XR	EMEA-50-2012
Carine de Beaufort	Restriction level XR	EMEA-51-2012
Christoph Male	Restriction level DP	EMEA-000778-PIP02-12
Christoph Male	Restriction level DP	EMEA-001281-PIP01-12
Christoph Male	Restriction level XP	EMEA-000183-PIP02-12
Dobrin Konstantinov	Restriction level XP	EMEA-000468-PIP02-12

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Member, alternate, expert name	Outcome restriction following evaluation of electronic Declaration of Interests	Topics on the current Committee Agenda for which this restriction applies
Gerard Pons	Restriction level 3	EMEA-000019-PIP08-12
Jaroslav Sterba	Restriction level XP	EMEA-000468-PIP02-12
Jaroslav Sterba	Restriction level XP	EMEA-001259-PIP01-11
Matthias Keller	Restriction level DP	EMEA-000018-PIP01-07-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
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-001281-PIP01-12
Michal Odermarsky	Restriction level XP	EMEA-000804-PIP01-09-M01
Paolo Rossi	Restriction level 4	EMEA-001290-PIP01-12
Peter Szitanyi	Restriction level DP	EMEA-001353-PIP01-12
Romaldas Maciulatis	Restriction level XR	EMEA-000726-PIP01-09-M01
Romaldas Maciulatis	Restriction level XR	EMEA-49-2012
Romaldas Maciulatis	Restriction level XR	EMEA-50-2012
Romaldas Maciulatis	Restriction level XR	EMEA-51-2012

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:

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

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

- 27 paediatric investigation plan applications;
- 8 product-specific waiver applications;
- 5 compliance check procedures (interim and final);
- 26 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 January 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.

V Finalisation and adoption of opinions

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

VI Discussion on the applicability of class waiver and on the inclusion of an indication within a condition

Class waiver number	Active substance	Condition
EMEA-48-2012	Nanoliposomal irinotecan (MM-398)	Treatment of adenocarcinoma of the pancreas
EMEA-49-2012	RO5490249 (FCFD4514S)	Treatment of age-related macular degeneration (AMD)

[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).

Class waiver number	Active substance	Condition
EMEA-50-2012	Aleglitazar - RO0728804	Peroxisome proliferator-activated receptor (PPAR)-gamma modulators, including dual and multiple PPAR modulators (e.g., thiazolidinediones, glitazars, triple modulators), in the treatment of type II diabetes mellitus (EMEA/386453/2008)
EMEA-51-2012	Aleglitazar - RO0728804	Treatment of coronary atherosclerosis (EMA/973755/2011)

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	For discussion
Guideline on the clinical development of medicinal products intended for the treatment of chronic primary immune thrombocytopenia*	For discussion
Concept paper on the need for a paediatric addendum to the Draft guideline on clinical investigation of medicinal products for the treatment of acute heart failure (Release for public consultation)	For discussion
Guideline on Pharmaceutical Development of Medicines for Paediatric Use	For information
Guideline on autism*	For appointment of Rapporteur
Working groups	
Formulation	For information
Non-Clinical	For information
Extrapolation	For information
Other topics	
Inventory of paediatric medicines: Infectious diseases therapeutic area*	For discussion
Review of the EMA decision on the list of class waivers	For discussion
Revision of the standard PIP on allergen	For discussion

European Medicines Agency policy on changes in scope of paediatric investigation plan (PIP) decisions: Procedure to confirm the inclusion of an indication within a condition	For discussion
Feedback of the paediatric anticoagulatory therapy expert meeting held at the European Medicines Agency on 6 November 2012*	For information
Model oncology PIPs: Model rhabdomyosarcoma PIP* for adoption	For adoption
Update on Enpr-EMA activities: Feedback from coordinating group	For information
CHMP Safety Working Party's response to the PDCO regarding the use of PEGylated drug products in the paediatric population*	For information
Article 6.1(J) of the Paediatric Regulation: Communication of arrangements for paediatric research	For discussion
Strategy for development of medicinal products for the condition asthma*	For discussion
Good clinical practice (GCP) inspections in paediatric clinical trials	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.