EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

04 July 2012
EMA/PDCO/488196/2012
Human Medicines Development and Evaluation

Paediatric Committee (PDCO)

Agenda of the 04-06 July 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 interest	Topics on the current Committee Agenda for which this restriction applies
Adriana Ceci	Restriction level 3	EMEA-000145-PIP01-07-M05
Adriana Ceci	Restriction level 3	EMEA-000548-PIP01-09-M03
Adriana Ceci	Restriction level 3	EMEA-000309-PIP01-08-M04
Adriana Ceci	Restriction level 3	EMEA-001222-PIP01-11
Adriana Ceci	Restriction level 3	EMEA-001217-PIP01-11
Adriana Ceci	Restriction level 3	EMEA-001039-PIP02-12
Dobrin Konstantinov	Restriction level 3	EMEA-000468-PIP02-12
Gerard Pons	Restriction level 3	EMEA-000116-PIP01-07-M05
Jaroslav Sterba	Restriction level 3	EMEA-001274-PIP01-12

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Member, alternate, expert name	Outcome restriction following evaluation of electronic declaration of interest	Topics on the current Committee Agenda for which this restriction applies
Jaroslav Sterba	Restriction level 3	EMEA-001033-PIP02-11
Jaroslav Sterba	Restriction level 3	EMEA-000468-PIP02-12
Michal Odermarsky	Restriction level 3	EMEA-000222-PIP01-08-M06
Michal Odermarsky	Restriction level 3	EMEA-001288-PIP01-12
Andreas Teloudes	Restriction level 4	EMEA-001275-PIP01-12
Andreas Teloudes	Restriction level 4	EMEA-000468-PIP02-12
Christoph Male	Restriction level 4	EMEA-001024-PIP01-10-M01
Christoph Male	Restriction level 4	EMEA-001296-PIP01-12
Christoph Male	Restriction level 4	EMEA-001174-PIP02-12
Marek Migdal	Restriction level 4	EMEA-000525-PIP01-08-M01
Marek Migdal	Restriction level 4	EMEA-001249-PIP01-11
Matthias Keller	Restriction level 4	EMEA-001281-PIP01-12
Matthias Keller	Restriction level 4	EMEA-001279-PIP01-12
Michal Odermarsky	Restriction level 4	EMEA-000774-PIP01-09-M01
Paolo Rossi	Restriction level 4	EMEA-000558-PIP01-09-M01
Paolo Rossi	Restriction level 4	EMEA-001289-PIP01-12
Peter Szitanyi	Restriction level 4	EMEA-000300-PIP01-08-M03
Peter Szitanyi	Restriction level 4	EMEA-000301-PIP01-08-M03
Peter Szitanyi	Restriction level 4	EMEA-000054-PIP01-07-M03
Peter Szitanyi	Restriction level 4	EMEA-000302-PIP01-08-M03
Peter Szitanyi	Restriction level 4	EMEA-001300-PIP01-12
Peter Szitanyi	Restriction level 4	EMEA-001291-PIP01-12
Peter Szitanyi	Restriction level 4	EMEA-001278-PIP01-12
Peter Szitanyi	Restriction level 4	EMEA-001275-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).

Evaluation of the conflict of interest	
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
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

I.4 External attendance

I.5 Leaving/New Members and Alternates

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

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

- 42 paediatric investigation plan applications;
- 12 product-specific waiver applications;
- 3 compliance check procedures (interim and final);
- 27 requests for modifications of an agreed paediatric investigation plan;
- 1 re-examination requests.

IV Nomination of Rapporteurs and Peer reviewers

- List of letters of intent received for submission of applications with start of procedure September 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.

[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 July 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-25-2012	(6R)-4, 5, 6, 7-tetrahydro-N6-propyl-2, 6-benzothiazolediamine dihydrochloride monohydrate (Dexpramipexole)	Treatment of amyotrophic lateral sclerosis
EMEA-26-2012	Perindopril tosilate/Amlodipine besilate	Treatment of coronary atherosclerosis
EMEA-17-2012	Autologous tumour-derived immunoglobulin idiotype coupled to keyhole limpet haemocyanin (EMEA-001274-PIP01-12)	Treatment of follicular lymphoma

VII Other topics

Guidelines	
Revision of the Note for Guidance on Clinical Investigation of Medicinal Products for Treatment of Asthma	For discussion
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 information
Paediatric addendum* to the Note for Guidance on clinical investigation of medicinal products in the treatment of lipid disorders (EMA/CHMP/213057/2010)	For discussion
Working groups	
Formulation	For information
Non-Clinical	For information
Extrapolation	For information
Other topics	
Draft reflection paper on biomarkers* - PDCO comments	For discussion
Harmonisation of vaccine schedules	For discussion

Improving D60 Requests for Modification	For discussion
Propylene glycol Art. 5(3) - Joint Assessment Report* for PDCO comments	For discussion
Update on committees interactions project	For information
Executive Summary on applications	For discussion

VIII Any other business

N/A

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.