



06 June 2012
EMA/PDCO/483938/2012
Human Medicines Development and Evaluation

Paediatric Committee (PDCO) Agenda of the 06-08 June 2012 meeting

Chair: Daniel Brasseur

I Introduction

1.1 Adoption of the minutes from previous meeting

1.2 Adoption of the Agenda

1.3 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
Peter Szitanyi	Restriction level 4	EMA-000006-PIP03-12
Peter Szitanyi	Restriction level 4	EMA-000007-PIP04-12
Peter Szitanyi	Restriction level 4	EMA-000063-PIP02-12
Adriana Ceci	Restriction level 3	EMA-000715-PIP02-11
Adriana Ceci	Restriction level 3	EMA-000118-PIP02-10-M01
Adriana Ceci	Restriction level 3	EMA-001222-PIP01-11
Adriana Ceci	Restriction level 3	EMA-001217-PIP01-11
Adriana Ceci	Restriction level 3	EMA-C1-000431-PIP01-08-M04
Adriana Ceci	Restriction level 3	EMA-000309-PIP01-08-M04



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-000548-PIP01-09-M03
Christoph Male	Restriction level 3	EMEA-000183-PIP02-12
Dobrin Konstantinov	Restriction level 3	EMEA-000191-PIP01-08-M04
Dobrin Konstantinov	Restriction level 3	EMEA-000468-PIP02-12
Gerard Pons	Restriction level 3	EMEA-000347-PIP01-08-M02
Gerard Pons	Restriction level 3	EMEA-000630-PIP02-09-M02
Gerard Pons	Restriction level 3	EMEA-000662-PIP02-09-M02
Jaroslav Sterba	Restriction level 3	EMEA-000468-PIP02-12
Jaroslav Sterba	Restriction level 3	EMEA-001033-PIP02-11
Jaroslav Sterba	Restriction level 3	EMEA-001274-PIP01-12
Marek Migdal	Restriction level 3	EMEA-000184-PIP01-08-M01
Michal Odermarsky	Restriction level 3	EMEA-000774-PIP01-09-M01
Michal Odermarsky	Restriction level 3	EMEA-001005-PIP01-10-M01
Andreas Teloudes	Restriction level 4	EMEA-000006-PIP03-12
Andreas Teloudes	Restriction level 4	EMEA-000007-PIP04-12
Andreas Teloudes	Restriction level 4	EMEA-000063-PIP02-12
Andreas Teloudes	Restriction level 4	EMEA-000144-PIP01-07-M03
Andreas Teloudes	Restriction level 4	EMEA-000406-PIP01-08-M03
Andreas Teloudes	Restriction level 4	EMEA-001275-PIP01-12
Andreas Teloudes	Restriction level 4	EMEA-000468-PIP02-12
Christoph Male	Restriction level 4	EMEA-001139-PIP01-11-M01
Christoph Male	Restriction level 4	EMEA-000428-PIP01-08-M01
Christoph Male	Restriction level 4	EMEA-000312-PIP01-08-M04
Marek Migdal	Restriction level 4	EMEA-000525-PIP01-08-M01
Matthias Keller	Restriction level 4	EMEA-001279-PIP01-12
Matthias Keller	Restriction level 4	EMEA-001281-PIP01-12
Paolo Rossi	Restriction level 4	EMEA-000872-PIP01-10-M01
Paolo Rossi	Restriction level 4	EMEA-001110-PIP01-10-M01
Paolo Rossi	Restriction level 4	EMEA-000558-PIP01-09-M01

Member, alternate, expert name	Outcome restriction following evaluation of electronic declaration of interest	Topics on the current Committee Agenda for which this restriction applies
Peter Szitanyi	Restriction level 4	EMEA-001268-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
Igor Francetic	Restriction level 4	EMEA-001185-PIP01-11
Igor Francetic	Restriction level 4	EMEA-001230-PIP01-11
Igor Francetic	Restriction level 4	EMEA-000235-PIP02-10-M01

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

101 current procedures in total¹, of which:

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

IV Nomination of Rapporteurs and Peer reviewers

- List of letters of intent received for submission of applications with start of procedure August 2012¹ 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 June are published in the same month's meeting report published in the [EMA website](#)

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 OF THE APPLICABILITY OF CLASS WAIVER

Class waiver number	Active substance	Condition
EMA-16-2012	Levodopa, carbidopa, entacapone	Treatment of Parkinson's disease (non-juvenile)
EMA-18-2012	lisinopril dihydrate (link to EMA-001291-PIP01-12)	Treatment of coronary atherosclerosis and peripheral atherosclerosis
EMA-19-2012	Gabapentin	Treatment of climacteric symptoms associated with decreased oestrogen levels, as occurring at menopause
EMA-20-2012	Trastuzumab emtansine	Treatment of gastric adenocarcinoma
EMA-21-2012	6-ethynyl-1-(pentan-3-yl)-1H-imidazo[4,5-b]pyrazin-2(3H)-one (CK-2017357, Tirasemtiv)	Treatment of amyotrophic lateral sclerosis
EMA-22-2012	HLA class I/II binding tumour associated peptides (ADF-APO-CCN-GUC-K67-MET- MMP-MUC-RGS) [Abbreviated Chemical Name] (IMA-RGS-001)	Treatment of kidney and renal pelvis carcinoma
EMA-23-2012	Dacomitinib	Treatment of lung carcinoma (small cell and non-small cell carcinoma)
EMA-24-2012	Solanezumab	Treatment of Alzheimer's disease

VII Other topics

Guidelines	
Guideline for clinical investigation of medicinal products for the treatment of cutaneous and systemic lupus erythematosus*	For discussion / adoption
Working groups	
Formulation: PDCO FWG list of criteria for screening PIPs*	For information
Non-Clinical	For information
Extrapolation	For information

Other topics	
Feedback on extrapolation at FDA	For information
Update on EMA Policy on conflict of interest	For information
Draft Reflection Paper on phthalates*	For information
Draft Reflection Paper on parabens*	For information
Revision of the EC guideline on excipients in the label and package leaflet of medicinal products for human use	For information / discussion
Report on the Innovative Task Force (ITF) Briefing meeting with Novartis	For information
Innovative Task Force (ITF) Briefing Meeting with Chiesi	For information
Update of the organisation in place to the delegates attending meetings abroad during the Olympics Games in London.	For information
Policy - Use of agency's information and communication technology by external organisations	For information
Dealing with uncertainties in PIP evaluations and PDCO opinions	For information / discussion

VIII Any other business

- Draft concept paper* on the participation of children / young people in PDCO activities
- EU Ombudsman's [press release](#) on recommendation for more transparency concerning medicines for children.
- Publication of agenda and minutes of the Paediatric Committee.

Note on access to documents

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