



08 August 2012
EMA/PDCO/521483/2012
Human Medicines Development and Evaluation

Paediatric Committee (PDCO)

Provisional agenda of the 15-17 August 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 e-DoI	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-001196-PIP01-11
Adriana Ceci	Restriction level 3	EMEA-001258-PIP01-11
Adriana Ceci	Restriction level 3	EMEA-001039-PIP02-12
Adriana Ceci	Restriction level 3	EMEA-001071-PIP02-12
Gerard Pons	Restriction level 3	EMEA-000116-PIP01-07-M05
Gérard Pons	Restriction level 3	EMEA-001258-PIP01-11
Igor Francetic	Restriction level 3	EMEA-000439-PIP02-11
Michal Odermarsky	Restriction level 3	EMEA-000222-PIP01-08-M06



Member, alternate, expert name	Outcome restriction following evaluation of e-DoI	Topics on the current Committee Agenda for which this restriction applies
Michal Odermarsky	Restriction level 3	EMEA-001288-PIP01-12
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-001249-PIP01-11
Marek Migdal	Restriction level 4	EMEA-000205-PIP02-11
Paolo Rossi	Restriction level 4	EMEA-001289-PIP01-12
Peter Szitanyi	Restriction level 4	EMEA-000054-PIP01-07-M03
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-000302-PIP01-08-M03
Peter Szitanyi	Restriction level 4	EMEA-001300-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

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

69 current procedures in total¹, of which:

- 27 paediatric investigation plan applications;
- 10 product-specific waiver applications;
- 32 compliance check procedures (interim and final);
- 7 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 October 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 August are published in the same month's meeting report published on the [EMA website](#)

VI DISCUSSION OF THE APPLICABILITY OF CLASS WAIVER

Class waiver number	Active substance	Condition
EMA-27-2012	MEGF0444A	Treatment of adenocarcinoma of the colon and rectum
EMA-28-2012	MEGF0444A	Treatment of lung carcinoma (small cell and non-small cell carcinoma)
EMA-29-2012	Prasterone (Dehydroepiandrosterone, DHEA)	Treatment of climacteric symptoms associated with decreased oestrogen levels as occurring at menopause

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
EMA-30-2012	canakinumab	Treatment of coronary atherosclerosis
EMA-31-2012	Rucaparib	Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)
EMA-32-2012	BAY 1000394	Treatment of chronic lymphocytic leukaemia
EMA-33-2012	BAY 1000394	Treatment of lung carcinoma (small cell and non-small cell carcinoma)
EMA-34-2012	BAY 1000394	Treatment of epithelial ovarian carcinoma
EMA-35-2012	BAY 1000394	Treatment of mesothelioma
EMA-36-2012	Lenalidomide (Revlimid)	Treatment of follicular lymphoma

VII Other topics

Guidelines	
Concept paper on the involvement of Children and Young People*	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 ⁷	For discussion
Working groups	
Paediatric Inventory working group	For information
Formulation	For information
Non-Clinical	For information
Extrapolation	For information
Other topics	
Enpr-EMA : PDCO to identify areas in which close collaboration with Enpr-EMA members is warranted either through development of standard paediatric investigation plans (PIPs) or by providing expert advice	For discussion
Inventory of paediatric therapeutic needs : List of products in the therapeutic area of cardiovascular diseases* to be adopted by the Committee and	For adoption

released for public consultation	
Brief report on the workshop on clinical development and scientific advice in ophthalmology	For information
Nomination to the EMA Pandemic Task Force (ETF)	For nomination of PDCO members to the ETF

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.