



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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 | EMA-000145-PIP01-07-M05 |
| Adriana Ceci | Restriction level 3 | EMA-001196-PIP01-11 |
| Adriana Ceci | Restriction level 3 | EMA-001258-PIP01-11 |
| Adriana Ceci | Restriction level 3 | EMA-001039-PIP02-12 |
| Adriana Ceci | Restriction level 3 | EMA-001071-PIP02-12 |
| Gerard Pons | Restriction level 3 | EMA-000116-PIP01-07-M05 |
| Gérard Pons | Restriction level 3 | EMA-001258-PIP01-11 |
| Igor Francetic | Restriction level 3 | EMA-000439-PIP02-11 |
| Michal Odermarsky | Restriction level 3 | EMA-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.