29 September 2012
EMA/PDCO/563185/2012
Human Medicines Development and Evaluation

# Paediatric Committee (PDCO)

Provisional agenda of the 05-07 September 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 3 | EMEA-C2-000548-PIP01-09-M03 |
| Adriana Ceci | Restriction level 3 | EMEA-000366-PIP01-08-M05 |
| Adriana Ceci | Restriction level 3 | EMEA-001322-PIP01-12 |
| Adriana Ceci | Restriction level 3 | EMEA-001321-PIP01-12 |
| Adriana Ceci | Restriction level 3 | EMEA-001315-PIP01-12 |
| Adriana Ceci | Restriction level 3 | EMEA-001258-PIP01-11 |
| Adriana Ceci | Restriction level 3 | EMEA-001196-PIP01-11 |
| Adriana Ceci | Restriction level 3 | EMEA-001071-PIP02-12 |
| Alexandra Compagnucci | Restriction level 3 | EMEA-C1-001181-PIP01-11 |

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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 |
|---|---|---|
| Carine de Beaufort | Restriction level XR | EMEA-001178-PIP01-11 |
| Dobrin Konstantinov | Restriction level 3 | EMEA-001301-PIP01-12 |
| Dobrin Konstantinov | Restriction level 3 | EMEA-001301-PIP02-12 |
| Gerard Pons | Restriction level 3 | EMEA-001258-PIP01-11 |
| Igor Francetic | Restriction level DP | EMEA-000439-PIP02-11 |
| Marek Migdal | Restriction level 4 | EMEA-001211-PIP01-11 |
| Marek Migdal | Restriction level 4 | EMEA-000205-PIP02-11 |
| Matthias Keller | Restriction level 4 | EMEA-001305-PIP01-12 |
| Matthias Keller | Restriction level 4 | EMEA-001302-PIP01-12 |
| Michal Odermarsky | Restriction level XP | EMEA-001307-PIP01-12 |
| Michal Odermarsky | Restriction level XP | EMEA-001219-PIP01-11 |
| Kolbeinn Gudmundsson | Restriction level DP | Confirmation of applicability of class waiver EMEA-45-2012 |
| Kolbeinn Gudmundsson | Restriction level DP | Confirmation of applicability of class waiver EMEA-44-2012 |

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).

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:<br>- 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. |

| Evaluation of the conflict of interest – Previous code | |
|---|---|
| 4 | Where Individual product involvement is declared:<br>- 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:<br>- 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.<br>- Cannot act as Rapporteur for these products<br>- [Cannot act as Rapporteur for development of guidelines in concerned therapeutic area]. |
| XC | Where cross product / general involvement is declared - COMPANY:<br>- No involvement (as outlined above) with respect to products from the specified company.<br>- Cannot act as Rapporteur for products from the relevant company(ies). |
| DP | Where Individual product involvement is declared - PRODUCT INDICATION:<br>- Involvement in discussions only with respect to procedures involving the relevant product or a competitor product<br>i.e. no part in final deliberations and voting as appropriate as regards these medicinal products.<br>- Cannot act as Rapporteur for these products. |
| DC | Where cross product / general involvement is declared - COMPANY:<br>- Involvement in discussions only with respect to products from the specified company.<br>- 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*

The PDCO welcomes the new alternate from Slovenian, Dr Tadej Avcin, who has been nominated by Slovenian Ministry of Health.

## 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

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

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

## IV Nomination of Rapporteurs and Peer reviewers

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

## V Finalisation and adoption of opinions

The opinions adopted during the Paediatric Committee meeting of September 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-37-2012 | BI 836845 | Treatment of lung carcinoma (small cell and non-small cell carcinoma) |
| EMEA-38-2012 | BI 836845 | Treatment of liver and intrahepatic bile duct carcinoma (excluding hepatoblastoma) |
| EMEA-39-2012 | BI 836845 | Treatment of breast carcinoma |
| EMEA-40-2012 | BI 836845 | Treatment of prostate carcinoma (excluding rhabdomyosarcoma) |

[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).

| | | |
|---|---|---|
| EMEA-41-2012 | Lisuride Hydrogenmaleate (LHM) | Treatment of Parkinson's disease (non juvenile) |
| EMEA-42-2012 | MEHD7945A | Adenocarcinoma of the colon and rectum |
| EMEA-43-2012 | MEHD7945A | Oropharyngeal, laryngeal or nasal epithelial carcinoma (excluding nasopharyngeal carcinoma or lymphoepithelioma) |
| EMEA-44-2012 | Nicotinic Acid / Laropiprant | Treatment of coronary atherosclerosis |
| EMEA-45-2012 | Perindopril tosilate/Amlodpine besilate | Treatment of coronary atherosclerosis |

## 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 and adoption |
| Concept paper on the involvement of Children and Young People* | For adoption |
| Guideline on the clinical development of medicinal products intended for the treatment of chronic primary immune thrombocytopaenia* | For discussion |
| **Working groups** | |
| Breakout for the revision of the standard allergen PIP | For information |
| Breakout for the revision of the standard asthma PIP | For information |
| Paediatric Inventory working group | For information |
| Formulation | For information |
| Non-Clinical | For information |
| Extrapolation | For information |
| **Other topics** | |
| Brief report on the workshop on clinical development and scientific advice in ophthalmology | For information |
| Validation of marketing authorisation / variation / line extensions applications when the PIP / waiver was granted to a different applicant | For information |

## 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.