EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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EMA/PDCO/110302/2013
Human Medicines Development and Evaluation

# Paediatric Committee (PDCO)

## Provisional agenda of the 13-15 March 2013 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 XR | EMEA-001003-PIP01-10-M02 |
| Adriana Ceci | Restriction level DP | EMEA-C1-000118-PIP02-10-M01 |
| Alexandra Compagnucci | Restriction level XR | EMEA-001405-PIP01-12 |
| Alexandra Compagnucci | Restriction level DC | EMEA-000627-PIP01-09-M04 |
| Alexandra Compagnucci | Restriction level DC | EMEA-000628-PIP01-09-M04 |
| Carine de Beaufort | Restriction level XR | EMEA-001395-PIP01-12 |
| Christoph Male | Restriction level DP | EMEA-001382-PIP01-12 |
| Dobrin Konstantinov | Restriction level DP | EMEA-000713-PIP02-10-M02 |
| Jaroslav Sterba | Restriction level XP | EMEA-001392-PIP01-12 |

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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 |
|---|---|---|
| Jaroslav Sterva | Restriction level XP | EMEA-000713-PIP02-10-M02 |
| Marek Migdal | Restriction level DP | EMEA-001309-PIP01-12 |
| Michal Odermarsky | Restriction level XP | EMEA-001288-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).

**Restriction levels:**

| Evaluation of the conflict of interest | |
|---|---|
| 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*

N/A

### *I.5 Leaving/New Members and Alternates*

N/A

## 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

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

- 34 paediatric investigation plan applications;
- 7 product-specific waiver applications;
- 3 compliance check procedures (interim and final);
- 25 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 May 2013[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 March are published in the same month's meeting report published in the EMA website

## VI Discussion on the applicability of class waiver

| Class waiver number | Active substance | Condition | Proposed indication |
|---|---|---|---|
| EMEA-01-2013 | Panobinostat (LBH589) | Treatment of Multiple Myeloma | Treatment of Multiple Myeloma |

[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).

## VII Discussion on the inclusion of an indication within a condition in an agreed PIP/waiver

| PIP number | Active substance | Condition | Proposed indication |
|---|---|---|---|
| EMEA-000200-PIP01-08 | Saxagliptin | Treatment of patients with type 2 Diabetes Mellitus | Reduction of major CV events in patients with Type 2 diabetes who also have CV risk factors or established CV disease |
| EMEA-000467-PIP01-08 | Perampanel | Treatment of treatment-resistant epilepsies | 1) Adjunctive therapy in patients with PGTC seizures<br>2) Adjunctive therapy in the treatment of seizures associated with Lennox-Gastaut syndrome |

## VIII Annual reports on deferrals

| Annual report based on PIP decision for | Substances (abbrev.) | Product Name | Orphan drug | Difficulties progressing the PIP? |
|---|---|---|---|---|
| EMEA-000178-PIP01-07-M02 | purified antigen fractions of inactivated split virion… | Pumarix | No | No |
| EMEA-000087-PIP01-07-M02 | Fingolimod hydrochloride | Gilenya | No | No |
| EMEA-000673-PIP01-09-M06 | Pneumococcal polysaccharide serotype 23F conjugate… | Synflorix | No | Yes |
| EMEA-000347-PIP01-08-M02 | Bilastine | Bilaxten and associated names | No | Yes |
| EMEA-000637-PIP02-10-M02 | Lanthanum carbonate hydrate | "Fosrenol" in the RMS (Sweden) and associated name "Foznol" | No | Yes |
| EMEA-000081-PIP01-07-M05 | Dabigatran etexilate | Pradaxa | No | Yes |
| EMEA-000170-PIP02-10-M01 | Eltrombopag (eltrombopag olamine) | Revolade | Yes | No |
| EMEA-000170-PIP01-07-M03 | Eltrombopag (eltrombopag olamine) | Revolade | No | No |
| EMEA-000533-PIP01-08-M04 | Tenofovir disoproxil (as fumarate) | Viread | No | No |
| EMEA-000653-PIP01-09-M02 | Romiplostim | Nplate | Yes | Yes |
| EMEA-001181-PIP01-11 | Agomelatine | Valdoxan, Thymanax | No | No |

## IX Other topics

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|---|---|
| **Guidelines** | |
| Revision of the Reflection paper on Immune Tolerance Induction in haemophilia A patients with inhibitors | For adoption |
| Draft 'Letter to the Editor' of the journal Haemophilia responding to Mannucci article 'Evolution of the European guidelines for the clinical development of factor VIII products: little progress towards improved patient management' that is critical of revised European guidance for FVIII and FIX products)* | For adoption |
| **Working groups** | |
| Paediatric inventory | For information |
| Paediatric oncology | For information |
| Formulation | For information |
| Non-Clinical | For information |
| Extrapolation | For information |
| **Other topics** | |
| Revision of Rules of procedure of the Paediatric Committee (PDCO) | For adoption |
| Reflection on revocation of the EMA decision on the list of class waivers | For discussion |
| EMEA-000463-PIP01-08-M0x (Glivec) – PDCO opinion on design of follow-up study to evaluate the long-term safety of imatinib | For discussion and adoption |
| Analysis done for the purpose of the Annual Report 2012 to EC* | For discussion |
| Revision of the off-patent priority list | For discussion |
| Questionnaire for children and young people* | For discussion |
| Vaccine schedules in PIPs: action plan | For discussion |
| Rotavirus vaccine: size of clinical study to exclude an increased risk of intussusception | For information |
| CHMP update on paediatric topics | For information |
| Draft plan for indicators to be measured, benchmarked and interpreted on the question, what are the public health benefits of the Paediatric Regulation* | For discussion |
| Update on the Workshop on paediatric investigation plans in type-2 diabetes mellitus on 25 February 2013 | For information |

| | |
|---|---|
| Guidance for Summary of PDCO Opinion* | For adoption |
| PDCO survey on preferred submission method | For discussion |

## Any other business

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## *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.