EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

8 May 2013
EMA/PDCO/285727/2013
Human Medicines Development and Evaluation

Paediatric Committee (PDCO)

Provisional agenda of the 15-17 May 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
Jaroslav Sterba	Restriction level XP	EMEA-000227-PIP02-12
Jaroslav Sterba	Restriction level XP	EMEA-001397-PIP01-12
Adriana Ceci	Restriction level DP	EMEA-001039-PIP02-12
Adriana Ceci	Restriction level DP	EMEA-001366-PIP01-12
Matthias Keller	Restriction level DP	EMEA-001305-PIP01-12
Dobrin Konstantinov	Restriction level XP	EMEA-001301-PIP01-12
Paolo Rossi	Restriction level XR	EMEA-000469-PIP01-08-M04
Jaroslav Sterba	Restriction level XP	EMEA-000469-PIP01-08-M04
Dobrin Konstantinov	Restriction level DP	EMEA-000469-PIP01-08-M04

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
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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
Tadej Avcin	Restriction level XP	EMEA-000366-PIP02-09-M02
Adriana Ceci	Restriction level DP	EMEA-000366-PIP02-09-M02
Matthias Keller	Restriction level XR	EMEA-000366-PIP02-09-M02
Christoph Male	Restriction level XP	EMEA-000480-PIP01-08-M05
Paolo Rossi	Restriction level XR	EMEA-001430-PIP01-13
Carine de Beaufort	Restriction level XR	EMEA-001441-PIP01-13
Paolo Rossi	Restriction level XR	EMEA-001441-PIP01-13
Carine de Beaufort	Restriction level XR	EMEA-001464-PIP01-13
Jean-Pierre Aboulker	Restriction level XR	EMEA-001464-PIP01-13
Alexandra Compagnucci	Restriction level XR	EMEA-001464-PIP01-13
Paolo Rossi	Restriction level XR	EMEA-000576-PIP03-12
Christoph Male	Restriction level XP	EMEA-000430-PIP01-08-M04
Carine de Beaufort	Restriction level XR	EMEA-000430-PIP01-08-M04
Gerard Pons	Restriction level DP	EMEA-000467-PIP01-08-M03
Michal Odermarsky	Restriction level XP	EMEA-000222-PIP01-08-M07
Paolo Rossi	Restriction level DP	EMEA-000830-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).

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: - 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. - Cannot act as Rapporteur for these products - [Cannot act as Rapporteur for development of guidelines in concerned therapeutic area].

XC	Where cross product / general involvement is declared - COMPANY: - No involvement (as outlined above) with respect to products from the specified company. - Cannot act as Rapporteur for products from the relevant company(ies).
DP	Where Individual product involvement is declared - PRODUCT INDICATION: - 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 products. - Cannot act as Rapporteur for these products.
DC	Where cross product / general involvement is declared - COMPANY: - Involvement in discussions only with respect to products from the specified company. - 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

Silvia Girotto, HMPC member, Italy

I.5 Leaving/New Members and Alternates

The PDCO would like to thank Andreas Teloudes for his work following the end of his mandate.

The PDCO would like to thank Dorthe Meyer for her work as she has resigned from the Committee.

The PDCO welcomes the new member George Savva, nominated to represent Cyprus.

The PDCO welcomes Karl-Heinz Huemer in his new role as member and Christoph Male in his new role as alternate, nominated to represent Austria.

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

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

- 38 paediatric investigation plan applications;
- 13 product-specific waiver applications;
- 5 compliance check procedures (interim and final);
- 26 requests for modifications of an agreed paediatric investigation plan;

[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).

IV Nomination of Rapporteurs and Peer reviewers

- List of letters of intent received for submission of applications with start of procedure July 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 May 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	Proposed indication	Condition
EMEA-18-2013	Alpha-1 antitrypsin (AAT)	Treatment of individuals with congenital deficiency of alpha-1-proteinase inhibitor (API) with clinically demonstrable panacinar emphysema	Treatment of chronic obstructive pulmonary disease (COPD)
EMEA-19-2013	RO5509554, RG7155, CSF-1R	Treatment of breast carcinoma	Treatment of breast carcinoma
EMEA-20-2013	RO5509554, RG7155, CSF-1R	Treatment of ovarian carcinoma	Treatment of ovarian carcinoma
EMEA-21-2013	Ganetespib	Ganetespib is indicated in combination with docetaxel for the treatment of patients with locally advanced or metastatic non-small cell adenocarcinoma of the lung after failure of prior platinum-based chemotherapy or other therapy for advanced disease	Non-small cell lung carcinoma

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

PIP number	Active substance	Proposed indication	Condition
EMEA-000699-PIP01-09	linagliptin (base)/ metformin (hydrochloride)	In combination with insulin (i.e. triple combination therapy) as an adjunct to diet and exercise to improve glycaemic control in adult patients when insulin and meformin alone do not provide adequate gylcaemic control.	Diabetes type 2

VIII Annual reports on deferrals

There are no reports for discussion during the May plenary of the PDCO.

IX Other topics

Guidelines	
Guideline on clinical investigation of medicinal products for the treatment of juvenile idiopathic arthritis	For information/discussion
Guideline on clinical investigation of medicinal products in the treatment of depression	For information
Working groups	
Paediatric inventory	For discussion
Paediatric oncology	For discussion
Formulation	For information
Non-Clinical	For information
Extrapolation	For information
Other topics	
Update on H7N9 influenza activities, Revision* of the influenza standard PIP	For information
Summary of Opinion template and guidance*	For information
Reflexion* on the revocation of the EMA decision on the list of class waiver	For discussion
CHMP update on paediatric topics and	For information
PDCO news at CHMP	For information
Proposals for topics for a suggested common informal meeting of PDCO-SAWP* in November 2013	For discussion
PRAC List of outstanding issues to be addressed by the marketing authorisation holder(s) for codeine containing medicinal products used for pain in children	For discussion
HMPC Monographs: Overview of recommendations for the use of herbal medicinal products in the paediatric population*.	For discussion
Mandate, objectives and rules of procedure for the European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP)*	For adoption
Mandate, objectives and rules of procedure for the European Medicines Agency Human Scientific Committees' Working Party	For adoption

with Patients' and Consumers' Organisations (HCPWP)*	
Draft agenda PCWP/ HCPWP joint meeting 5 June 2013*	For information
Draft Agenda - PCWP meeting 6 June 2013*	For information

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.