



31 October 2013
EMA/PDCO/673586/2013
Human Medicines Research & Development Support Division

Paediatric Committee (PDCO)

Provisional agenda of the 06-08 November 2013 meeting

Chair: Dirk Mentzer

I Introduction

1.1 Adoption of the minutes from previous meeting

1.2 Adoption of the Agenda

1.3 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 evaluation form	Topics on the current Committee Agenda for which this restriction applies
Adriana Ceci	Restriction level XR	EMEA-000599-PIP01-09-M03
Jean-Pierre Aboulker	Restriction level XR	EMEA-000599-PIP01-09-M03
Alexandra Compagnucci	Restriction level XR	EMEA-000599-PIP01-09-M03
Michal Odermarsky	Restriction level XP	EMEA-001418-PIP01-13
Michal Odermarsky	Restriction level XP	EMEA-001460-PIP01-13
Michal Odermarsky	Restriction level XP	EMEA-001442-PIP01-13
Paolo Rossi	Restriction level XR	EMEA-001442-PIP01-13
Jaroslav Sterba	Restriction level XP	EMEA-001493-PIP01-13
Carine de Beaufort	Restriction level XR	EMEA-001489-PIP01-13



Member, alternate, expert name	Outcome restriction following evaluation of electronic evaluation form	Topics on the current Committee Agenda for which this restriction applies
Carine de Beaufort	Restriction level XR	EMEA-001425-PIP01-13
Carine de Beaufort	Restriction level XR	EMEA-001434-PIP01-13
Adriana Ceci	Restriction level DP	EMEA-000380-PIP02-09-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

Jenny Preston, Young Patient Group, Medicines for Children Research Network, U.K.

I.5 Leaving/New Members and Alternates

The PDCO welcomes Violeta Iotova in her new role as a member nominated to represent Bulgaria.

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 total¹, of which:

- 39 paediatric investigation plan applications;
- 6 product-specific waiver applications;
- 8 compliance check procedures (interim and final);
- 29 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 January 2014¹ 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 November are published in the same month's meeting report published in the [EMA website](#)

VI Discussion on the applicability of class waiver

Active substance	Proposed indication	Condition
Fluticasone Furoate / Umeclidinium / Vilanterol (GW685698/GSK57371 9/GW642444)	Treatment of chronic obstructive pulmonary disease (COPD)	Chronic Obstructive Pulmonary Disease (COPD)

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).

Regorafenib	Treatment of patients with advanced hepatocellular carcinoma (HCC) whose disease has progressed after prior treatment with sorafenib.	Treatment of liver and intrahepatic bile duct carcinoma (excluding hepatoblastoma)
MK-8931	1. Delay of disability in patients with mild-to-moderate Alzheimer's disease 2. Delay of progression to mild Alzheimer's disease in patients with amnesic mild cognitive impairment due to Alzheimer's disease	Treatment of Alzheimer's disease
Mepolizumab (SB240563) EMA-000069-PIP04-13	Treatment of chronic obstructive pulmonary disease (COPD)	Chronic Obstructive Pulmonary Disease (COPD)

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

No requests were received for the month of November.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMA-000185-PIP01-08	Catridecacog	NovoThirteen	Yes	No
EMA-000290-PIP01-08	Nilotinib	Tasigna	Yes	No
EMA-000237-PIP01-08	Azilsartan medoxomil	Edarbi	No	Yes
EMA-000430-PIP01-08	rivaroxaban	Xarelto	No	No
EMA-000694-PIP01-09	Dapagliflozin	Not available at present	No	Yes
EMA-000927-PIP01-10	Linaclotide	Not available at present	No	No
EMA-000980-PIP01-10	Brentuximab vedotin / Monoclonal antibody against human CD30 covalently linked t...	Not available at present	Yes	No
EMA-000060-PIP01-07	Recombinant human monoclonal antibody to human IL-1beta of the IgG1/K class (ACZ...		Yes	Yes
EMA-000060-PIP02-08	Canakinumab	ILARIS	Yes	No

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMA-000178-PIP01-07	Purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/0...	Pumarix	No	No
EMA-000160-PIP01-07	Purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/...	Pandemrix, Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) (referring to Informed Consent for Prepandrix), Prepandrix	No	No
EMA-000373-PIP02-09	Ferumoxytol	Not available at present	No	Yes
EMA-000583-PIP01-09	boceprevir	Not available at present	No	Yes

IX Other topics

Guidelines	
Revision of the EC guideline on excipients*	For discussion
Working groups	
Paediatric inventory	For discussion
Paediatric oncology	For discussion
Formulation	For information
Non-Clinical	For information
Extrapolation	For information
Other topics	
Election of the PDCO Vice-Chair	The election will take place on the first day of the November 2013 PDCO meeting.
Development of effective young people involvement strategies at PDCO	For discussion
7th DIA/EFGCP/EMA: Medicines for Children Conference	For information
CHMP update on paediatric topics	For information

Request of nomination of PDCO representative as core member of Oncology WP	For adoption
Impact of juvenile animal studies' results on paediatric anti-cancer medicine development – project presentation	For information
Report from Oncology pre-session: impediments to, and facilitation of early paediatric brain tumour studies	For adoption
Need for CD/DVD submission of applications to PDCO members	For discussion

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.