10 July 2013
EMA/PDCO/425226/2013
Human Medicines Development and Evaluation

Paediatric Committee (PDCO)

Provisional agenda of the 17-19 July 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
Jean-Pierre Aboulker	XR	EMEA-001457-PIP01-13
Jean-Pierre Aboulker	XR	EMEA-000117-PIP01-07-M05
Jean-Pierre Aboulker	XR	EMEA-000689-PIP01-09-M04
Jean-Pierre Aboulker	XR	EMEA-001469-PIP01-13
Jean-Pierre Aboulker	XR	EMEA-001465-PIP01-13
Jean-Pierre Aboulker	XR	EMEA-000019-PIP09-13
Adriana Ceci	XR	EMEA-001315-PIP01-12
Adriana Ceci	XR	EMEA-000019-PIP09-13
Adriana Ceci	XR	EMEA-000880-PIP02-11-M02

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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
Alexandra Compagnucci	XR	EMEA-001457-PIP01-13
Alexandra Compagnucci	XR	EMEA-000689-PIP01-09-M04
Alexandra Compagnucci	XR	EMEA-001469-PIP01-13
Alexandra Compagnucci	XR	EMEA-001465-PIP01-13
Alexandra Compagnucci	XR	EMEA-000019-PIP09-13
Alexandra Compagnucci	XR	EMEA-000117-PIP01-07-M05
Carine de Beaufort	XR	EMEA-001469-PIP01-13
Carine de Beaufort	XR	EMEA-000731-PIP01-09-M01
Kolbeinn Gudmundsson	DP	EMEA-001348-PIP01-12
Dobrin Konstantinov	DP	EMEA-000019-PIP09-13
Christoph Male	XP	EMEA-001114-PIP01-10-M01
Christoph Male	XP	EMEA-000914-PIP01-10-M01
Christoph Male	XP	EMEA-000778-PIP02-12
Christoph Male	XP	EMEA-001456-PIP01-13
Michal Odermarsky	XP	EMEA-000317-PIP01-08-M04
Michal Odermarsky	XP	EMEA-001465-PIP01-13
Michal Odermarsky	XP	EMEA-001460-PIP01-13
Michal Odermarsky	XP	EMEA-001442-PIP01-13
Paolo Rossi	DP	EMEA-000872-PIP02-13
Paolo Rossi	XR	EMEA-001469-PIP01-13
Paolo Rossi	XR	EMEA-001458-PIP01-13
Paolo Rossi	XR	EMEA-001429-PIP01-13
Paolo Rossi	XR	EMEA-001442-PIP01-13
Paolo Rossi	XR	EMEA-000731-PIP01-09-M01
Jaroslav Sterba	XP	EMEA-001429-PIP01-13
Jarolsav Sterba	XP	EMEA-000019-PIP09-13

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

I.5 Leaving/New Members and Alternates

The PDCO would like to thank Gerard Pons for his work following the end of his mandate.

The PDCO welcomes Sylvie Benchetrit in her new role as a member nominated to represent France.

The PDCO welcomes Marta Granström in her new role as an alternate nominated to represent Denmark.

The PDCO welcomes Marina Dimov Di Giusti in her new role as a member nominated to represent Croatia.

The PDCO welcomes Melinda Sobor in her new role as a CHMP alternate nominated to represent Hungary.

The PDCO welcomes Jana Lass in her new role as an alternate nominated to represent Estonia.

The PDCO welcomes Ninna Gullberg in her new role as an alternate nominated to represent Sweden

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

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

- 37 paediatric investigation plan applications;
- 10 product-specific waiver applications;
- 3 compliance check procedures (interim and final);
- 36 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 September 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 July 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-22-2013	(E)-4-[(5-Phenyl-1,3,4-thiadiazol-2-yl)oxy]-1-azoniatricyclo[3.3.1.13,7]decane 3,4-	Symptomatic treatment of mild to moderately severe Alzheimer's dementia	Treatment of Alzheimer's disease

[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).

	dicarboxy-3-hydroxybutanoate hydrate		
EMEA-27-2013	RO5479599, RG7116, GE-huMab-HER3	Treatment of non-small cell lung carcinoma	Treatment of lung carcinoma (small cell and non-small cell)
EMEA-28-2013	RO5479599, RG7116, GE-huMab-HER3	Treatment of breast cancer	Treatment of breast carcinoma
EMEA-29-2013	Gantenerumab - RO4909832	Disease modifying in prodromal (early) and mild stages of Alzheimer's disease Disease modifying in individuals at risk for and with dominantly inherited Alzheimer's disease	Treatment of Alzheimer's Disease
EMEA-30-2013	CC-223	Treatment of adult patients with unresectable hepatocellular carcinoma who have failed sorafenib	Treatment of liver and intrahepatic bile duct carcinoma (excluding hepatoblastoma)
EMEA-31-2013	CC-223	Treatment of adult patients with neuroendocrine tumour (NETs) of non-pancreatic origin	Treatment of gastroenteropancreatic neuroendocrine tumours (excluding neuroblastoma, neuroganglioblastoma, phaeochromocytoma)
EMEA-32-2013	BMN 673 [Poly (ADP-ribose) Polymerase (PARP) Inhibitor]	BMN 673 is intended as a monotherapy for treatment of patients with locally advanced or metastatic breast cancer with a BRCA 1 and/or BRCA 2 mutation	Treatment of breast carcinoma

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
	Ipilimumab	Strentarga	No	Other(s)
EMEA-000117-PIP02-10	Ipilimumab	YERVOY (subject to change during MAA procedure)	No	No
EMEA-000335-PIP01-08-M07	Ivacaftor	Kalydeco	No	No
EMEA-000467-PIP01-08	Perampanel		No	No
EMEA-001095-PIP02-12	Natalizumab	Tysabri	No	No
EMEA-000015-PIP01-07	Doripenem monohydrate		No	Yes
EMEA-000876-PIP01-10	Eculizumab	Soliris	Yes	

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000876-PIP02-11	Eculizumab	Soliris	Yes	No
EMEA-000339-PIP02-09	Entecavir (monohydrate)	Baraclude	No	No
EMEA-000548-PIP01-09	Beclometasone dipropionate plus formoterol fumarate dihydrate	Foster and associated names, Kantos and associated names, Kantos Master and associated names, Inuvair and associated names	No	Yes
EMEA-000520-PIP01-08	Belimumab	Benlysta™	No	No
EMEA-000342-PIP01-08	Sunitinib malate	Sutent	Yes	Yes
EMEA-000019-PIP06-09	Everolimus	Certican and associated names	No	Yes

IX Other topics

Guidelines	
Revision of Pharmacovigilance guideline for paediatric medicines: rapporteur nomination	
Guideline on Pharmaceutical Development of Medicines for Paediatric Use	For information
Working groups	
Paediatric inventory	Breakout session Wednesday lunch break, Room 1C
Paediatric oncology	Breakout session Thursday before plenary (08:00-08:30), Room 1E
Formulation	Documents tabled for information
Non-Clinical	Documents tabled for information
Extrapolation	Thursday lunch break, Room 2B
Other topics	
Scope of PIP (condition/indication), 10-year report, Paediatric-use marketing authorisations (PUMAs)	For discussion
Update on Enpr-EMA activities	For information

A Standard PIP for Gaucher disease May 2013*	For discussion
Paediatric needs for nephro-urology*	For adoption
Ambrisentan – final report on 8-week toxicity study in juvenile rat.	For discussion
Standard PIP for Influenza pandemic vaccine	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.