EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

31 July 2013
EMA/PDCO/472742/2013
Human Medicines Development and Evaluation

Paediatric Committee (PDCO)

Provisional agenda of the 07-09 August 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
Christoph Male	XP	EMEA-000778-PIP02-12
Adriana Ceci	XR	EMEA-000880-PIP02-11-M02
Paolo Rossi	XR	EMEA-000731-PIP01-09-M01
Carine de Beaufort	XR	EMEA-000731-PIP01-09-M01
Adriana Ceci	XR	EMEA-000527-PIP03-13
Jean-Pierre Aboulker	XR	EMEA-000527-PIP03-13
Alexandra Compagnucci	XR	EMEA-000527-PIP03-13
Adriana Ceci	XR	EMEA-000527-PIP04-13
Jean-Pierre Aboulker	XR	EMEA-000527-PIP04-13

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Alexandra Compagnucci	XR	EMEA-000527-PIP04-13
Adriana Ceci	XR	EMEA-001454-PIP01-13
Jean-Pierre Aboulker	XR	EMEA-001454-PIP01-13
Alexandra Compagnucci	XR	EMEA-001454-PIP01-13
Marek Migdal	XR	EMEA-001455-PIP01-13
Michal Odermanski	XP	EMEA-001465-PIP01-13
Jean-Pierre Aboulker	XR	EMEA-001465-PIP01-13
Alexandra Compagnucci	XR	EMEA-001465-PIP01-13
Adriana Ceci	XR	EMEA-001333-PIP02-13
Paolo Rossi	XR	EMEA-001458-PIP01-13
Christoph Male	DP	EMEA-001382-PIP01-12
Carine de Beaufort	XR	EMEA-001395-PIP01-12
Romaldas Mačiulaitis	XR	EMEA-001395-PIP01-12
Carine de Beaufort	XR	EMEA-001053-PIP01-10-M02
Adriana Ceci	XR	EMEA-000362-PIP01-08-M03
Christoph Male	DP	EMEA-001064-PIP01-10-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

To be confirmed.

I.5 Leaving/New Members and Alternates

The PDCO welcomes Maaike van Dartel in her new role as an alternate nominated to represent The Netherlands.

The PDCO would like to thank Dobrin Konstantinov for his work as he resigned from the Committee.

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

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

- 38 paediatric investigation plan applications;
- 11 product-specific waiver applications;
- 6 compliance check procedures (interim and final);
- 35 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 October 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 August 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-33-2012	TH-302	Treatment of locally advanced unresectable or metastatic pancreatic adenocarcinoma	Treatment of adenocarcinoma of the pancreas
EMEA-34-2013	Neratinib	Treatment of HER2-Positive metastatic breast cancer	Treatment of breast carcinoma
EMEA-35-2013	Neratinib	Treatment of HER2-Mutant non-small cell lung cancer	Treatment of lung carcinoma (non-small cell carcinoma)
EMEA-36-2013	Tiotropium + Olodaterol	Maintenance bronchodilator treatment in patients with chronic obstructive pulmonary disease (COPD)	Chronic obstructive pulmonary disease (COPD)
EMEA-37-2013	ODM-201	Treatment of patients with non-metastatic castration resistant prostate cancer with a high risk of developing metastases	Treatment of prostate carcinoma (excluding rhabdomyosarcoma)
EMEA-38-2013	Lu AE58054	Treatment of mild to moderate dementia of the Alzheimer's Type as adjunctive therapy to Acetylcholinesterase Inhibitors	Treatment of Alzheimer's Disease
EMEA-39-2013	Buparlisib (BKM120)	Treatment of breast cancer	Treatment of breast carcinoma
EMEA-40-2013	Buparlisib (BKM120)	Treatment of castration resistant prostate cancer	Treatment of prostate carcinoma (excluding rhabdomyosarcoma)
EMEA-41-2013	Buparlisib (BKM120)	Treatment of non-small cell lung cancer	Treatment of lung carcinoma (small cell and non-small cell carcinoma)

Class waiver number	Active substance	Proposed indication	Condition
EMEA-42-2013	Ticagrelor (Brilique)	Prevention of atherothrombotic events in patients with established lower extremity arterial disease	Treatment of peripheral atherosclerosis
EMEA-43-2013	Ticagrelor (Brilique)	Prevention of atherothrombotic events in adult patients with a history of myocardial infaction and a high risk of developing an atherothrombotic event	Treatment of coronary atherosclerosis
EMEA-44-2013	AZD5363	Treatment of patients with hormone-receptor positive advanced breast cancer receiving their first exposure to chemotherapy, as a combination with paclitaxel	Treatment of breast carcinoma
EMEA-45-2013	AZD5363	Treatment of patients with metastatic castration resistant prostate cancer (CRPC) in whom maximum androgen blockade has failed	Treatment of prostate carcinoma
EMEA-46-2013	BAY 80-6946	Treatment of relapsed/refractory follicular lymphoma alone or in combination with rituximab	Treatment of follicular lymphoma
EMEA-47-2013	rilimogene galvacirepvec / rilimogene glafolivec	Treatment of metastatic, castrate-resistant prostate cancer	Treatment of prostate carcinoma (excluding shabdomyosarcoma)

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

There were no requests for the August agenda of the PDCO

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000019-PIP02-07	Everolimus	Afinitor, Certican and associated names	Yes	Yes
EMEA-000019-PIP08-12	Everolimus	Votubia	Yes	No
EMEA-000498-PIP01-08	linagliptin	Ondero	No	Yes
EMEA-000222-PIP01-08	Etravirine	Intelence	No	Yes

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000174-PIP01-07	Plerixafor	Mozobil	Yes	No
EMEA-000556-PIP01-09	velaglucerase alfa	N/A	No	Yes
EMEA-000362-PIP01-08	Aliskiren	Rasilez	No	Yes
EMEA000-769-PIP01-09-M03	Ceftaroline fosamil	Zinforo	No	No

IX Other topics

Working groups	
Paediatric inventory	For discussion
Paediatric oncology	For discussion
Formulation	For information
Non-Clinical	For information
Extrapolation	No meeting in August
Other topics	
Involvement from Children and Young people – feedback from EMPATHY	For discussion
A Standard PIP for Gaucher disease*	For adoption
Paediatric inflammatory bowel disease – update on ongoing activities	For information and discussion
CHMP update on paediatric topics	For information
Connectra keys and PedRA access – information for new members	For information
PRAC request of PDCO opinion on Numeta and hypermagnesemia	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.