5 September 2013
EMA/PDCO/512982/2013
Human Medicines Development and Evaluation

Paediatric Committee (PDCO)

Provisional agenda of the 11-13 September 2013 meeting

Chair: Paolo Tomasi, Paediatric Section Head till the election of the new Chair and Vice-Chair

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-001454-PIP01-13
Adriana Ceci	Restriction level XR	EMEA-000362-PIP01-08-M03
Adriana Ceci	Restriction level XR	EMEA-001333-PIP02-13
Adriana Ceci	Restriction level XR	EMEA-000527-PIP03-13
Adriana Ceci	Restriction level XR	EMEA-000527-PIP04-13
Adriana Ceci	Restriction level DP	EMEA-001071-PIP02-12-M01
Alexandra Compagnucci	Restriction level XR	EMEA-001454-PIP01-13
Alexandra Compagnucci	Restriction level XR	EMEA-000527-PIP03-13
Alexandra Compagnucci	Restriction level XR	EMEA-000527-PIP04-13

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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
Carine de Beaufort	Restriction level XR	EMEA-001395-PIP01-12
Carine de Beaufort	Restriction level XR	EMEA-001053-PIP01-10-M02
Christoph Male	Restriction level DP	EMEA-001382-PIP01-12
Christoph Male	Restriction level DP	EMEA-001064-PIP01-10-M01
Jean-Pierre Aboulker	Restriction level XR	EMEA-001454-PIP01-13
Jean-Pierre Aboulker	Restriction level XR	EMEA-000527-PIP03-13
Jean-Pierre Aboulker	Restriction level XR	EMEA-000527-PIP04-13
Marek Migdal	Restriction level DP	EMEA-001455-PIP01-13
Marina Dimov Di Gusti	Restriction level XR	EMEA-001094-PIP01-10-M01
Romaldas Mačiulaitis	Restriction level XR	EMEA-001395-PIP01-12
Romaldas Mačiulaitis	Restriction level XR	EMEA-50-2013
Romaldas Mačiulaitis	Restriction level XR	EMEA-51-2013
Tadej Avcin	Restriction level XP	EMEA-001071-PIP02-12-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

Dr Immanuel Barth, Paul-Ehrlich-Institut, Germany.

Dr Aina Ovrebust, Norwegian Medicines Agency, Norway.

Dr Tove Lill Stendal, Norwegian Medicines Agency, Norway.

I.5 Leaving/New Members and Alternates

To be confirmed.

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

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

- 32 paediatric investigation plan applications;
- 12 product-specific waiver applications;
- 8 compliance check procedures (interim and final);

[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).

- 42 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 November 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 September 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-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-48-2013	Trifuridine (FDA; a,a,a triflurothymidine) and tipiracil hydrochloride (TPI: 5-chloro-6[(2 iminopyrrolidin-1-yl)methyl]pyrimide-2,4-(1H,3H)-dione monohydrochloride	Treatment of patients with small cell lung cancer (SCLC) refractory or sensitive to first line platinum-based chemotherapy	Treatment of lung carcinoma (small cell and non-small cell)
EMEA-49-2013	Trifuridine (FDA; a,a,a triflurothymidine) and tipiracil hydrochloride (TPI: 5-chloro-6[(2 iminopyrrolidin-1-yl)methyl]pyrimide-2,4-(1H,3H)-dione monohydrochloride	Treatment of patients with metastatic colorectal cancer refractory to standard chemotherapies	Treatment of adenocarcinoma of the colon and rectum
EMEA-50-2013	(RO5520985)	Treatment of carcinoma of the colon or rectum	Treatment of adenocarcinoma of the colon and rectum

EMEA-51-2013	(RO5520985)	Treatment of epithelial ovarian cancer, fallopian tube or primary peritoneal cancer	Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)
EMEA-52-2013	Enobosarm (generic), GTx-024, ostarine (company code)	Prevention and treatment of muscle wasting in patients with non-small cell lung cancer	Treatment of lung carcinoma (small cell and non-small cell carcinoma)
EMEA-53-2013	estradiol (in form of estradiol hemihydrates)	Hormone replacement therapy (HRT) for estrogen deficiency symptoms in postmenopausal women (natural or surgical menopause, with or without a uterus). The experience in treating women older than 65 years is limited.	Treatment of climacteric symptoms associated with decreased oestrogen levels, as occurring at menopause
EMEA-54-2013	MORAb-004	Treatment of metastatic colo-rectal cancer	Treatment of adenocarcinoma of the colon and rectum
EMEA-55-2013	MORAb-004	Treatment of metastatic melanoma	Treatment of melanoma
EMEA-56-2013	Fasitibant Chloride	Symptomatic treatment of hip and knee osteoarthritis	Treatment of primary and secondary osteoarthrosis

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000228-PIP01-08	asenapine maleate		No	Yes
EMEA-000366-PIP01-08	Adalimumab	Humira	No	No
EMEA-000366-PIP02-09	Adalimumab	Humira	No	No
EMEA-000555-PIP01-09	decitabine	DACOGEN	Yes	No
EMEA-000020-PIP01-07	maraviroc	CELSENTRI	No	Yes

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000018-PIP01-07	Tapentadol Hydrochloride		No	No
EMEA-000325-PIP01-08	Tapentadol hydrochloride	not available at present	No	Yes
EMEA-000482-PIP01-08	Teduglutide ([gly2] recombinant human glucagon-like peptide)	Revestive	Yes	Yes
EMEA-000485-PIP01-08	Tapentadol hydrochloride	not available at present	No	Yes
EMEA-000486-PIP01-08	Tapentadol hydrochloride	not available at present	No	Yes
EMEA-000494-PIP01-08	Tapentadol hydrochloride	not available at present	No	No
EMEA-000495-PIP01-08	Tapentadol hydrochloride	not available at present	No	No
EMEA-000196-PIP01-08	Telaprevir		No	Yes

IX Other topics

Guidelines	
Revised draft guideline on clinical evaluation of medicinal products for the treatment of chronic hepatitis C*	For information
Guideline on the evaluation of Medicinal Products for the treatment of Chronic Constipation*	For discussion
Revision - Addendum on Paediatric Oncology to anti-cancer guideline*	For discussion
Working groups	
Paediatric inventory	For discussion
Paediatric oncology	For discussion
Paediatric extrapolation	For discussion
Formulation	For information
Non-Clinical	For information
Extrapolation	For discussion
Vaccine schedules in PIPs - Preparation of expert meeting	For discussion

Other topics	
Application and Opinion synopses for extrapolation and for modelling / simulation studies (measures 4 and 5 in document) - (Comments until 3 October 2013)	For information
Draft agenda PCWP/HCPWP joint meeting 25 September 2013	For information
Draft agenda workshop on patient's voice in the evaluation of medicines 26 September 2013	For information
CHMP update on paediatric topics	For information
PDCO/COMP workshop on the determination of the condition in rare diseases on 9th October 2013	For information
Election of PDCO Chair and Vice-Chair	The election will take place on the first day of the September 2013 PDCO meeting.
Revised PDCO rules of procedures: Inputs of the European Commission	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.