



6 June 2013
EMA/PDCO/349551/2013
Human Medicines Development and Evaluation

Paediatric Committee (PDCO)

Provisional agenda of the 12-14 June 2013 meeting

Chair: Daniel Brasseur

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 Declaration of Interests	Topics on the current Committee Agenda for which this restriction applies
Adriana Ceci	Restriction level XR	EMA-001315-PIP01-12
Adriana Ceci	Restriction level XR	EMA-000019-PIP09-13
Alexandra Compagnucci	Restriction level XR	EMA-001464-PIP01-13
Alexandra Compagnucci	Restriction level XR	EMA-000019-PIP09-13
Alexandra Compagnucci	Restriction level XR	EMA-001457-PIP01-13
Alexandra Compagnucci	Restriction level XR	EMA-001469-PIP01-13
Alexandra Compagnucci	Restriction level XR	EMA-000117-PIP01-07-M05
Alexandra Compagnucci	Restriction level XR	EMA-000689-PIP01-09-M04
Carine de Beaufort	Restriction level XR	EMA-001464-PIP01-13



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-001053-PIP02-13
Carine de Beaufort	Restriction level XR	EMEA-000430-PIP01-08-M04
Carine de Beaufort	Restriction level XR	EMEA-001425-PIP01-13
Carine de Beaufort	Restriction level XR	EMEA-001469-PIP01-13
Carine de Beaufort	Restriction level XR	EMEA-001441-PIP01-13
Carine de Beaufort	Restriction level XR	EMEA-001434-PIP01-13
Christoph Male	Restriction level XP	EMEA-000430-PIP01-08-M04
Christoph Male	Restriction level XP	EMEA-001456-PIP01-13
Christoph Male	Restriction level XP	EMEA-001114-PIP01-10-M01
Christoph Male	Restriction level XP	EMEA-000914-PIP01-10-M01
Dobrin Konstantinov	Restriction level DP	EMEA-000019-PIP09-13
Gerard Pons	Restriction level DP	EMEA-000467-PIP01-08-M03
Jaroslav Sterba	Restriction level XP	EMEA-001429-PIP01-13
Jaroslav Sterba	Restriction level XP	EMEA-000019-PIP09-13
Jean-Pierre Aboulker	Restriction level XR	EMEA-001464-PIP01-13
Jean-Pierre Aboulker	Restriction level XR	EMEA-000019-PIP09-13
Jean-Pierre Aboulker	Restriction level XR	EMEA-001457-PIP01-13
Jean-Pierre Aboulker	Restriction level XR	EMEA-001469-PIP01-13
Jean-Pierre Aboulker	Restriction level XR	EMEA-000117-PIP01-07-M05
Jean-Pierre Aboulker	Restriction level XR	EMEA-000689-PIP01-09-M04
Kolbeinn Gudmundsson	Restriction level DP	EMEA-001348-PIP01-12
Matthias Keller	Restriction level DP	EMEA-001351-PIP01-12
Michal Odermarksky	Restriction level XP	EMEA-001460-PIP01-13
Michal Odermarksky	Restriction level XP	EMEA-001442-PIP01-13
Michal Odermarksky	Restriction level XP	EMEA-000317-PIP01-08-M04
Michal Odermarksky	Restriction level XP	EMEA-001368-PIP01-12
Michal Odermarksky	Restriction level XP	EMEA-000222-PIP01-08-M07
Paolo Rossi	Restriction level DP	EMEA-000830-PIP02-10-M01
Paolo Rossi	Restriction level XR	EMEA-001442-PIP01-13

Member, alternate, expert name	Outcome restriction following evaluation of electronic Declaration of Interests	Topics on the current Committee Agenda for which this restriction applies
Paolo Rossi	Restriction level XR	EMEA-001429-PIP01-13
Paolo Rossi	Restriction level XR	EMEA-001469-PIP01-13
Paolo Rossi	Restriction level XR	EMEA-001441-PIP01-13
Paolo Rossi	Restriction level XR	EMEA-001430-PIP01-13
Paolo Rossi	Restriction level DP	EMEA-000872-PIP02-13

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

1.4 External attendance

TBC

1.5 Leaving/New Members and Alternates

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

The PDCO would like to thank Johannes Taminiau for his work following the end of his mandate.

The PDCO would like to thank Vlasta Kakosova and Jan Mazag for their work following the end of their mandate.

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

89 current procedures in total¹, of which:

- 40 paediatric investigation plan applications;
- 12 product-specific waiver applications;
- 5 compliance check procedures (interim and final);
- 32 requests for modifications of an agreed paediatric investigation plan;
- 0 re-examination requests.

IV Nomination of Rapporteurs and Peer reviewers

- List of letters of intent received for submission of applications with start of procedure August 2013¹ for Nomination of Rapporteur and Peer reviewer
- Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver.

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).

V Finalisation and adoption of opinions

The opinions adopted during the Paediatric Committee meeting of June 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
EMA-23-2013	BAN2401	Treatment of Alzheimer's Disease	Treatment of Alzheimer's Disease
EMA-24-2013	RO5537381 (also known as GDC-0032)	Treatment of post-menopausal women with neoadjuvant or adjuvant breast cancer; treatment of postmenopausal women with advanced or metastatic breast cancer who have had recurrence or progression after treatment with an aromatase inhibitor	Treatment of breast carcinoma
EMA-25-2013	Alisertib	Treatment of relapsed/refractory small cell lung cancer	Treatment of lung carcinoma (small cell and non-small cell carcinoma)
EMA-26-2013	Alisertib	Treatment of relapsed/refractory epithelial ovarian cancer	Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)

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

There are no discussions on the inclusion of an indication within a condition in an agreed PIP/waiver during the June plenary of PDCO.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMA-001167-PIP02-11	Atomoxetine hydrochloride	Strattera	No	No
EMA-000183-PIP01-08	Apixaban	Eliquis	No	No
EMA-000183-PIP02-12	Apixaban	Eliquis	No	No
EMA-000365-PIP01-08	Oseltamivir phosphate	Tamiflu	No	Yes
EMA-000118-PIP02-10	Abatacept	ORENCIA	No	TBC

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMA-000470-PIP01-08	Sitagliptin phosphate monohydrate	Januvia	No	No
EMA-000713-PIP02-10	pixantrone dimaleate	Pixuvri	Yes	No
EMA-000429-PIP01-08	N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup W polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup C polysaccharide conjugated to tetanus toxoid / N. meningitidis serogroup A polysaccharide conjugated to tetanus toxoid	Nimenrix	No	Yes
EMA-000065-PIP01-07	Telbivudine	Sebivo	No	No
EMA-000116-PIP01-07	Retigabine	Trobalt	No	No
EMA-000412-PIP01-08	Insulin detemir	Levemir	No	No
EMA-000434-PIP01-08	Ambrisentan	Volibris	Yes	Yes
EMA-000145-PIP01-07	Denosumab		No	No
EMA-000145-PIP02-12	Denosumab	XGEVA (previously Amgiva), Prolia	No	No
EMA-000308-PIP01-08	Rituximab	MabThera	No	No
EMA-000157-PIP01-07	Belatacept		No	No
EMA-000235-PIP02-10	Aripiprazole	Abilify	No	No
EMA-000568-PIP01-09	C1 Inhibitor	Cinryze	Planned	Yes
EMA-000601-PIP01-09	Pazopanib		Yes	No

IX Other topics

Guidelines	
Contribution of PDCO to guidelines	For information
Guideline on pharmaceutical development of medicines for paediatric use	For adoption
Working groups	
Formulation	Documents tabled for information
Paediatric oncology	Breakout session Thursday before plenary (08:00-08:30), Room 1E
Non-Clinical	Documents tabled for information
Other topics	
Summary of Opinion template and guidance*	For Information
Screening criteria for PIP Examples of key binding elements (quality) FWG best practice	For information and adoption
Paediatric Inventory: Discussion on therapeutic area nephro-urology	For discussion
Vaccine schedules in PIPs-Update	For information
Good Clinical Practice (GCP) inspections of paediatric clinical trials agreed in Paediatric Investigation Plans*	For discussion and adoption
Update on Enpr-EMA activities	For information
CHMP update on paediatric topics	For information
Reflection on class waiver revocation	For information and discussion
Discussion on role and benefit of PDCO informal meetings	For discussion
Candidature to the election of Chair and Vice-Chair	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.