



7 January 2012
EMA/PDCO/820062/2012
Human Medicines Development and Evaluation

Paediatric Committee (PDCO)

Provisional agenda of the 09-11 January 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 DP	EMA-001371-PIP01-12
Adriana Ceci	Restriction level DP	EMA-001366-PIP01-12
Adriana Ceci	Restriction level DP	EMA-001045-PIP01-10
Adriana Ceci	Restriction level DP	EMA-001220-PIP01-11
Adriana Ceci	Restriction level DP	EMA-001089-PIP01-10
Adriana Ceci	Restriction level XR	EMA-000019-PIP06-09-M03
Alexandra Compagnucci	Restriction level XC	EMA-000733-PIP02-12
Carine de Beaufort	Restriction level XR	EMA-001045-PIP01-10
Carine de Beaufort	Restriction level XR	EMA-001207-PIP01-11



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	Restriction level DP	EMEA-001296-PIP01-12
Gerard Pons	Restriction level DP	EMEA-000332-PIP01-08-M06
Gerard Pons	Restriction level DP	EMEA-000116-PIP01-07-M06
Jaroslav Sterba	Restriction level XP	EMEA-001372-PIP01-12
Jaroslav Sterba	Restriction level XP	EMEA-001350-PIP01-12
Jaroslav Sterba	Restriction level XP	EMEA-001033-PIP02-11
Jaroslav Sterba	Restriction level XP	EMEA-001207-PIP01-11
Kolbeinn Gudmundsson	Restriction level DP	EMEA-001348-PIP01-12
Matthias Keller	Restriction level XR	EMEA-000366-PIP05-12
Michal Odermarsky	Restriction level XP	EMEA-001280-PIP01-12
Michal Odermarsky	Restriction level XP	EMEA-000968-PIP02-11-M01
Michal Odermarsky	Restriction level XP	EMEA-000533-PIP01-08-M04
Paolo Rossi	Restriction level DP	EMEA-001289-PIP01-12
Peter Bauer	Restriction level DP	EMEA-001327-PIP01-12
Peter Bauer	Restriction level DP	EMEA-000733-PIP02-12
Peter Szitanyi	Restriction level DP	EMEA-001364-PIP01-12
Peter Szitanyi	Restriction level DP	EMEA-001100-PIP01-10
Romaldas Maciulaitis	Restriction level XR	EMEA-001207-PIP01-11
Tadej Avcin	Restriction level XP	EMEA-001371-PIP01-12
Tadej Avcin	Restriction level XP	EMEA-001045-PIP01-10
Tadej Avcin	Restriction level XP	EMEA-001220-PIP01-11
Tadej Avcin	Restriction level XP	EMEA-001089-PIP01-10

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

Nao Tsuchida, National Center for Child Health and Development, Japan

1.5 Leaving/New Members and Alternates

N/A

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

87 current procedures in total¹, of which:

- 38 paediatric investigation plan applications;
- 16 product-specific waiver applications;
- 25 compliance check procedures (interim and final);
- 8 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 March 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.

V Finalisation and adoption of opinions

The opinions adopted during the Paediatric Committee meeting of January 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	Condition	Proposed indication
EMA-63-2012	N-{3-[(2-{[4-(4-acetylpiperazin-1-yl)-2-methoxyphenyl]amino}-5-(trifluoromethyl)pyrimidin-4-yl)amino]phenyl}prop-2-enamide	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Treatment of patients with mutant epidermal growth factor receptor (EGFR ^{mut}) non-small cell lung cancer who have received prior EGFR-directed therapy
EMA-64-2012	RO5137382 (GC33, RG7686)	Treatment of liver and intrahepatic bile duct carcinoma (excluding	Treatment of glypican 3 (GPC3) expressing

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).

		hepatoblastoma)	hepatocellular carcinoma
EMA-65-2012	Strontium succinate (Protelos)	Treatment of primary and secondary osteoarthritis	Treatment of osteoarthritis of the knee and hip to reduce the progression of the cartilage damage.

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

No requests were received for review during the January PDCO plenary

VIII Other topics

Guidelines	
Paediatric Addendum* to Note for guidance on clinical investigation of medicinal products in the treatment of hypertension	For discussion
Guideline on the clinical investigation of medicinal products to prevent development/slow progression of chronic renal insufficiency* (Concept paper on the need for the guidance on the clinical investigation of medicinal products to slow progression of renal insufficiency)	For discussion
Working groups	
Paediatric inventory	For discussion
Paediatric oncology	For discussion
Formulation	For information
Non-Clinical	For information
Extrapolation	For discussion
Other topics	
CHMP List of Questions to be addressed by PDCO: Privigen	For discussion / adoption
CHMP List of Questions to be addressed by PDCO: Votubia	For discussion / adoption
Overview of comments received on the concept paper on the involvement of Children and Young People	For information
Model oncology PIP acute myeloid leukaemia* Ralph Herold	For discussion
Work plan for the European Medicines Agency Human	For adoption

Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) 2013* Work plan for the European Medicines Agency/ CHMP Working Group with Healthcare Professionals' Organisations (HCP WG) 2013*	
Annual reports on deferrals	For information / discussion
Article 6.1(J) of the Paediatric Regulation (Communication on paediatric clinical research)	For information
Launch of the revised EudraSmPC webpage http://eudrasmpc.eudra.org/	For information
Reflection on revocation of the EMA decision on the list of class waivers	For discussion
Summary of PDCO Opinion: new document and guidance*	For information / discussion
Meeting dates for 2015*	For adoption

IX 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.