



06 February 2014
EMA/PDCO/56818/2014
Human Medicines Research & Development Support Division

Paediatric Committee (PDCO)

Provisional agenda of the 12-14 February 2014 meeting

Chair: Dirk Mentzer

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-001333-PIP02-13
Alexandra Compagnucci	Restriction level XC	EMA-001575-PIP01-13
Alexandra Compagnucci	Restriction level XC	EMA-001570-PIP01-13
Alexandra Compagnucci	Restriction level XC	EMA-000520-PIP02-13
Alexandra Compagnucci	Restriction level XC	EMA-001545-PIP01-13
Alexandra Compagnucci	Restriction level XC	EMA-000804-PIP01-09-M02
Alexandra Compagnucci	Restriction level XC	EMA-000117-PIP01-07-M06
Alexandra Compagnucci	Restriction level XC	EMA-000117-PIP02-10-M03
Alexandra Compagnucci	Restriction level XC	EMA-000653-PIP01-09-M04



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	Restriction level XC	EMA-001569-PIP01-13
Alexandra Compagnucci	Restriction level XR	EMA-001465-PIP01-13
Christoph Male	Restriction level DP	EMA-001114-PIP01-10-M02
Jean Pierre Aboulker	Restriction level XC	EMA-001575-PIP01-13
Jean Pierre Aboulker	Restriction level XC	EMA-001570-PIP01-13
Jean Pierre Aboulker	Restriction level XC	EMA-000520-PIP02-13
Jean Pierre Aboulker	Restriction level XC	EMA-001545-PIP01-13
Jean Pierre Aboulker	Restriction level XC	EMA-000804-PIP01-09-M02
Jean Pierre Aboulker	Restriction level XC	EMA-000117-PIP01-07-M06
Jean Pierre Aboulker	Restriction level XC	EMA-000117-PIP02-10-M03
Jean Pierre Aboulker	Restriction level XC	EMA-000653-PIP01-09-M04
Jean Pierre Aboulker	Restriction level XC	EMA-001569-PIP01-13
Jean Pierre Aboulker	Restriction level XR	EMA-001465-PIP01-13
Kolbeinn Gudmundsson	Restriction level DP	EMA-001578-PIP01-13
Marek Migdal	Restriction level DP	EMA-001581-PIP01-13
Marek Migdal	Restriction level DP	EMA-000486-PIP01-08-M03
Marek Migdal	Restriction level DP	EMA-000485-PIP01-08-M03
Marek Migdal	Restriction level DP	EMA-000325-PIP01-08-M03
Marina Dimov Di Giusti	Restriction level DC	EMA-001545-PIP01-13
Matthias Keller	Restriction level XR	EMA-000366-PIP05-12
Matthias Keller	Restriction level DP	EMA-000486-PIP01-08-M03
Matthias Keller	Restriction level DP	EMA-000485-PIP01-08-M03
Matthias Keller	Restriction level DP	EMA-000325-PIP01-08-M03
Michal Odermarsky	Restriction level XP	EMA-000775-PIP01-09-M01
Michal Odermarsky	Restriction level XP	EMA-001577-PIP01-13
Michal Odermarsky	Restriction level XP	EMA-000804-PIP01-09-M02
Michal Odermarsky	Restriction level XP	EMA-001465-PIP01-13
Paolo Rossi	Restriction level XR	EMA-001458-PIP01-13
Paolo Rossi	Restriction level XR	EMA-001430-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
Romaldas Maciulaitis	Restriction level XR	EMEA-001570-PIP01-13
Violeta Iotova	Restriction level XP	EMEA-001030-PIP01-10-M02

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

Florian Schmidt, European Commission.

I.5 Leaving/New Members and Alternates

The PDCO would like to thank Julia Dunne for her work as she has resigned from the Committee.

The PDCO welcomes Angeliki Siapkara in her new role as member and Martina Riegl in her new role as alternate, nominated to represent United Kingdom.

The PDCO would like to thank Tadej Avcin for his work as he has 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

96 current procedures in total¹, of which:

- 44 paediatric investigation plan applications;
- 4 product-specific waiver applications;
- 8 compliance check procedures (interim and final);
- 39 requests for modifications of an agreed paediatric investigation plan;
- 1 re-examination request.

IV Nomination of Rapporteurs and Peer reviewers

- List of letters of intent received for submission of applications with start of procedure April 2014¹ 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 February are published in the same month's meeting report published in the [EMA website](#)

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).

VI Discussion on the applicability of class waiver

Active substance	Proposed indication	Condition
TV-45070	Treatment of pain in patients with osteoarthritis	Treatment of primary and secondary osteoarthritis
vemurafenib	Treatment of adult patients with metastatic colorectal cancer positive for the BRAFV600 mutation in combination with an anti-EGFR agent	Treatment of adenocarcinoma of the colon and rectum

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

No requests were received for the month of February.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMA-000978-PIP01-10	(Propane-1-sulfonic acid { 3-[5-(4-chlorophenyl)-1H-pyrrolo[2,3-b]pyridine-3-carb...	Zelboraf	No	Yes
EMA-000052-PIP01-07	Vandetanib	Caprelsa	Yes	No
EMA-000653-PIP01-09	Romiplostim	Nplate	Yes	Yes
EMA-000469-PIP01-08	anidulafungin	ECALTA	No	Yes
EMA-000994-PIP01-10	gadobutrol	Gadovist	No	No
EMA-000816-PIP02-10	Potassium sulphate / Magnesium sulphate, heptahydrate / Sodium sulphate, anhydro...	Izinova	No	No
EMA-000306-PIP01-08	corifollitropin alfa	Elonva	No	No
EMA-001115-PIP01-10	Loxapine	Adasuve	No	No
EMA-000533-PIP01-08	Tenofovir disoproxil (as fumarate)	Viread	No	No
EMA-000553-PIP01-09	Lisdexamfetamine dimesylate	Venvanse	No	No

IX Other topics

Guidelines	
Draft guideline on the clinical development of medicinal products for the treatment of human-immunodeficiency-virus (HIV) infection (public consultation until 31/03/2014)	For discussion
Draft guideline on the clinical development of medicinal products for the treatment of Autism Spectrum Disorder (ASD)*	For discussion
Draft Guideline on clinical investigation of medicinal products for the treatment of Multiple Sclerosis*	For discussion
Working groups	
Paediatric inventory	For discussion
Paediatric oncology	For discussion
Extrapolation	For discussion
Formulation	For information
Non-Clinical	For information
Other topics	
CHMP update on paediatric topics	For information
Update on Enpr-EMA activities	For information
Project 2014 - Move to Churchill Place	For information
Extrapolation Group – working program for 2014*	For information
Debriefing on meetings related to the draft guideline on format and content of PIPs*	For information
Proposal for communicating on measures to prevent medication errors*	For discussion
Election/designation of the new FWG Chair	For discussion
Opening Managing Meeting Documents (MMD) access to members across committees	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.