



12 March 2014
EMA/PDCO/134041/2014
Human Medicines Research & Development Support Division

Paediatric Committee (PDCO)

Provisional agenda of the 19-21 March 2014 meeting

Chair: Dirk Mentzer - Vice-chair: Koenraad Norga

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 evaluation form	Topics on the current Committee Agenda for which this restriction applies
Adriana Ceci	Restriction level XR	EMEA-001333-PIP02-13
Alexandra Compagnucci	Restriction level XC	EMEA-001575-PIP01-13
Alexandra Compagnucci	Restriction level XR	EMEA-001465-PIP01-13
Alexandra Compagnucci	Restriction level XC	EMEA-000117-PIP01-07-M06
Alexandra Compagnucci	Restriction level XC	EMEA-000117-PIP02-10-M03
Alexandra Compagnucci	Restriction level XC	EMEA-000653-PIP01-09-M04
Alexandra Compagnucci	Restriction level XC	EMEA-000804-PIP01-09-M02
Alexandra Compagnucci	Restriction level XC	EMEA-001569-PIP01-13
Alexandra Compagnucci	Restriction level XC	EMEA-001593-PIP01-13



Member, alternate, expert name	Outcome restriction following evaluation of electronic evaluation form	Topics on the current Committee Agenda for which this restriction applies
Alexandra Compagnucci	Restriction level XC	EMA-001576-PIP01-13
Alexandra Compagnucci	Restriction level XR	EMA-000019-PIP10-13
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 XR	EMA-000310-PIP03-10-M01
Alexandra Compagnucci	Restriction level XR	EMA-000601-PIP01-09-M02
Alexandra Compagnucci	Restriction level XR	EMA-000118-PIP02-10-M02
Alexandra Compagnucci	Restriction level XC	EMA-1-2014
Jaroslav Sterba	Restriction level DP	EMA-001372-PIP02-13
Jaroslav Sterba	Restriction level DP	EMA-000019-PIP10-13
Jean-Pierre Aboulker	Restriction level XC	EMA-001575-PIP01-13
Jean-Pierre Aboulker	Restriction level XR	EMA-001465-PIP01-13
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-000804-PIP01-09-M02
Jean-Pierre Aboulker	Restriction level XC	EMA-001569-PIP01-13
Jean-Pierre Aboulker	Restriction level XC	EMA-001593-PIP01-13
Jean-Pierre Aboulker	Restriction level XC	EMA-001576-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 XR	EMA-000019-PIP10-13
Jean-Pierre Aboulker	Restriction level XR	EMA-000310-PIP03-10-M01
Jean-Pierre Aboulker	Restriction level XR	EMA-000601-PIP01-09-M02
Jean-Pierre Aboulker	Restriction level XR	EMA-000118-PIP02-10-M02
Jean-Pierre Aboulker	Restriction level XR	EMA-1-2014
Kolbeinn Gudmundsson	Restriction level DP	EMA-001578-PIP01-13

Member, alternate, expert name	Outcome restriction following evaluation of electronic evaluation form	Topics on the current Committee Agenda for which this restriction applies
Marek Migdal	Restriction level DP	EMEA-000325-PIP01-08-M03
Marek Migdal	Restriction level DP	EMEA-000486-PIP01-08-M03
Marek Migdal	Restriction level DP	EMEA-000485-PIP01-08-M03
Marek Migdal	Restriction level DP	EMEA-001581-PIP01-13
Marek Migdal	Restriction level DP	EMEA-000525-PIP01-08-M02
Marina Dimov Di Giusti	Restriction level DC	EMEA-001545-PIP01-13
Matthias Keller	Restriction level DP	EMEA-000325-PIP01-08-M03
Matthias Keller	Restriction level DP	EMEA-000486-PIP01-08-M03
Matthias Keller	Restriction level DP	EMEA-000485-PIP01-08-M03
Michal Odermarsky	Restriction level XP	EMEA-001465-PIP01-13
Michal Odermarsky	Restriction level XP	EMEA-000804-PIP01-09-M02
Michal Odermarsky	Restriction level XP	EMEA-001577-PIP01-13
Michal Odermarsky	Restriction level XP	EMEA-000279-PIP01-08-M02
Romaldas Maciulaitis	Restriction level XR	EMEA-001570-PIP01-13
Romaldas Maciulaitis	Restriction level XR	EMEA-000310-PIP03-10-M01
Romaldas Maciulaitis	Restriction level XR	EMEA-001425-PIP01-13-M01
Romaldas Mačiulaitis	Restriction level XR	EMEA-1-2014
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

1.4 External attendance

Dr Katherine McGinn, Medicines and Healthcare Products Regulatory Agency, UK.

Fiona Bickell, Guy's and St Thomas' NHS Foundation Trust, UK.

1.5 Leaving/New Members and Alternates

The PDCO would like to thank Stefanos Christodoulou for his work as his mandate expired.

The PDCO welcomes Andreas Teloudes in his new role as an alternate to represent Cyprus.

II Opinions

11.1 Opinions on Products

11.2 Opinions on Compliance Check

11.3 Opinions on Modification of an Agreed Paediatric Investigation Plan

11.4 Opinions on Re-examination

III Discussion of applications

97 current procedures in total¹, of which:

- 39 paediatric investigation plan applications;
- 13 product-specific waiver applications;
- 4 compliance check procedures (interim and final);
- 40 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 May 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 March 2014 are published in the same month's meeting report published in the [EMA website](#)

VI Discussion on the applicability of class waiver

Active substance	Proposed indication	Condition
MPDL3280A	Treatment of patients with inoperable locally advanced or metastatic PD-L1 positive urothelial bladder cancer, after failure of a platinum-containing chemotherapy regimen	Treatment of ureter and bladder carcinoma
Patritumab	In combination with erlotinib, for the treatment of heregulin (HRG) high, EGFR inhibitor therapy naïve, EGFR wild type patients with locally advanced or metastatic non-small cell lung cancer after progression on at least one prior systemic therapy	Treatment of lung carcinoma (non-small cell carcinoma)
Bavituximab	Treatment of previously treated non-squamous non-small cell lung cancer	Treatment of lung carcinoma (small cell and non-small cell carcinoma)
GS-9973	Treatment of chronic lymphocytic leukaemia	Treatment of chronic lymphocytic leukaemia
GS-9973	Treatment of follicular lymphoma	Treatment of follicular lymphoma

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).

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

No requests were received for the month of March.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMA-000696-PIP02-10	Eslicarbazepine acetate	Exalief, Zebinix	No	Yes
EMA-000116-PIP01-07	Retigabine		No	No
EMA-000434-PIP01-08	ambrisentan	Volibris	Yes	Yes
EMA-000637-PIP02-10	Lanthanum carbonate hydrate	"Fosrenol" in the RMS (Sweden) and associated name "Foznol"	No	No
EMA-000817-PIP02-11	Purified antigen fractions of inactivated split virion Influenza manufactured in...	not available at present	No	No
EMA-000170-PIP01-07	Eltrombopag		Yes	No
EMA-000170-PIP02-10	Eltrombopag	Revolade	Yes	No
EMA-001066-PIP02-11	Aciclovir	Sitavir	No	No
EMA-000081-PIP01-07	dabigatran etexilate given as mesilate		No	Yes
EMA-000087-PIP01-07	Fingolimod hydrochloride	Not available at present	No	No

IX Other topics

Guidelines	
HIV guideline – feedback from PENTA	For discussion
Concept paper on the revision of the guideline on conduct of pharmacovigilance for medicines used by the paediatric population*	For adoption
Draft Guideline on clinical investigation of medicinal products for the treatment of Multiple Sclerosis* (PDCO comments by 21/02/2014)	For discussion
Guideline on the clinical investigation of medicinal products for the treatment of Duchenne and Becker muscular dystrophy*	For discussion
Working groups	
Paediatric inventory	For discussion

Paediatric oncology	For discussion
Formulation	For information
Non-Clinical	For information
Extrapolation	For information
Other topics	
CHMP update on paediatric topics	For information
Update on Enpr-EMA activities	For information
Revision of class waivers	For discussion
Edited revised draft of the Commission Guideline on the format and content of PIP applications	For discussion
Overview of waiver-requests and outcomes at PDCO/EMA and FDA (up to 2013)	For information
Inclusion of young adults into paediatric type 2 diabetes studies: FDA and EMA views	For information
PDCO nominations for Inter-committee Scientific Advisory Group Oncology (IC SAG-O)	For adoption
Questions from PDCO to PKWP - BA/BE demonstration for BCS II and IV compounds	For discussion
Excipient drafts for consultation on Benzalkonium chloride and Gluten*	For information
Plans for a juvenile animal ICH guideline	For information
Paracetamol exposure in pregnancy and risk of ADHD in children	For discussion
Debriefing on - Minutes of PDCO-COMP Working Group*	For information

Any other business

- Project 2014 - Move to Churchill Place;
- Access to D30 Summary Reports (PIPs only) of next PDCO meeting in MMD (time of postmail of previous meeting).

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present following a request for access to documents under Regulation (EC) No 1049/2001 as they are subject to on-going procedures for which a final decision has not yet been adopted. They will become public when adopted or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006).