2 October 2013
EMA/PDCO/592362/2013
Human Medicines Research & Development Support Division

Paediatric Committee (PDCO)

Provisional agenda of the 09-11 October 2013 meeting

Chair: Dirk Mentzer

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
Marina Dimov	Restriction level XR	EMEA-001094-PIP01-10-M01
Adriana Ceci	Restriction level DP	EMEA-001071-PIP02-12-M01
Tadej Avcin	Restriction level XP	EMEA-001071-PIP02-12-M01
Carine de Beaufort	Restriction level XR	EMEA-001489-PIP01-13
Michal Odermarsky	Restriction level XP	EMEA-001418-PIP01-13
Adriana Ceci	Restriction level XR	EMEA-000599-PIP01-09-M03
Jean-Pierre Aboulker	Restriction level XR	EMEA-000599-PIP01-09-M03
Alexandra Compagnucci	Restriction level XR	EMEA-000599-PIP01-09-M03

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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

I.5 Leaving/New Members and Alternates

The PDCO welcomes Birka Lehmann in her new role as a member nominated to represent Germany.

The PDCO welcomes Immanuel Barth in his new role as an alternate nominated to represent Germany.

The PDCO welcomes Stefan Grosek in his new role as a member nominated to represent Slovenia.

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

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

- 28 paediatric investigation plan applications;
- 13 product-specific waiver applications;
- 11 compliance check procedures (interim and final);
- 30 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 December 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 October 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-57-2013	Darapladib	Treatment of visual impairment due to diabetic macular oedema	Treatment of diabetic macular oedema
EMEA-58-2013	RO4602522	Adjunctive therapy for the treatment of patients with moderate severity Alzheimer's disease	Treatment of Alzheimer's disease
EMEA-59-2013	Bevacizumab	Avastin in combination with chemotherapy (paclitaxel plus topotecan or paclitaxel plus cisplatin) is indicated for the treatment of	Treatment of cervix and corpus uteri carcinoma

[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).

		persistent, recurrent or Stage IVB carcinoma of the cervix	
EMEA-60-2013	Momelotinib	1. Treatment of Primary Myelofibrosis (PMF) 2. Treatment of Post-Polycythemia Vera or Post-Essential Thrombocythemia Myelofibrosis (Post-PV/ET MF)	Treatment of primary myelofibrosis

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

No requests were received for the month of October

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?	PIP coordinator
EMEA-000468-PIP02-12	Posaconazole	Noxafil	No	Yes	Irmgard Eichler
EMEA-001071-PIP02-12	Certolizumab pegol	Cimzia	No	No	Richard Vesely
EMEA-000035-PIP02-09	Tiotropium bromide (monohydrate)	Spiriva Respimat	No	Yes	Irmgard Eichler
EMEA-000265-PIP01-08	Golimumab	Simponi	No	Yes	Richard Vesely
EMEA-000265-PIP02-11	Golimumab	Simponi	No	Yes	Richard Vesely
EMEA-000671-PIP01-09	Sildenafil citrate	Revatio	Yes	Yes	Sophie Olivier
EMEA-000452-PIP02-10	Tadalafil	Cialis, Adcirca	No	No	Gunter Egger
EMEA-000627-PIP01-09	Ivabradine hydrochloride	Corlentor	No	No	Peter Karolyi
EMEA-000628-PIP01-09	Ivabradine hydrochloride	Procoralan	No	No	Peter Karolyi
EMEA-000200-PIP01-08	Saxagliptin	Onglyza	No	Yes	Janina Karres
EMEA-000367-PIP01-08	Human recombinant C1 inhibitor	Rhucin	Yes	Yes	Dobromir Penkov

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?	PIP coordinator
EMEA-000827-PIP01-09	Aztreonam	Cayston	Yes	No	Ralph Bax

IX Other topics

Guidelines	
Revision of the EC guideline on excipients	For information
Working groups	
Paediatric inventory	For discussion
Paediatric oncology	For discussion
Extrapolation	For discussion
Formulation	Documents tabled for information
Non-Clinical	Documents tabled for information
Other topics	
PDCO/COMP workshop on conditions in rare diseases	The agenda of the workshop has been attached to this document.
Draft inventory of paediatric therapeutic needs Therapeutic area neurology	For adoption
Reorganisation communication to the PDCO	For information
Nomination of PDCO representative in SAWP	For adoption
Request of nomination of PDCO representative as core member of Oncology WP	For adoption
CHMP update on paediatric topics	For information
Update on Enpr-EMA activities Dates for the 2014 annual workshop	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.

2 October 2013
EMA/586210/2013
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Agenda - First PDCO/COMP workshop on conditions in rare diseases 9 October 2013, 16:00 – 18:00 Room 2A

Chair: Zaide Frias

Objectives:

Bringing two committees together to discuss scientific and regulatory aspects on conditions for rare diseases

Item	Preliminary draft agenda	Presenter	Mins
1.	Welcome and introduction	Zaide Frias	5’
2.	“Conditions in the crossroads” – background and context	Jordi Llinares	25’
3.	Case studies (Epilepsy, Cholestatic syndrome, B-cell lymphomas)	Ralph Bax Sophie Olivier Chrissi Pallidis Segundo Mariz Ralf Herold	10’
4.	Experience with medical conditions in the context of the orphan designation	Bozenna Dembowska-Baginska (TBC)	15’
5.	Experience with medical conditions in the context of the paediatric investigation plans	Koenraad Norga	15’
6.	Discussion	All	40’
7.	Conclusions and next steps	Zaide Frias Dirk Mentzer Bruno Sepodes	10’

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