9 January 2014
EMA/PDCO/801136/2013
Human Medicines Research & Development Support Division

Paediatric Committee (PDCO)

Provisional agenda of the 15-17 January 2014 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 evaluation form	Topics on the current Committee Agenda for which this restriction applies
Adriana Ceci	Restriction level DP	EMEA-001371-PIP01-12
Adriana Ceci	Restriction level DP	EMEA-70-2013 (EMEA-000978-PIP01-10)
Adriana Ceci	Restriction level DP	EMEA-71-2013 (EMEA-000978-PIP01-10)
Adriana Ceci	Restriction level DP	EMEA-72-2013 (EMEA-000978-PIP01-10)
Adriana Ceci	Restriction level DP	EMEA-73-2013 (EMEA-000978-PIP01-10)
Alexandra Compagnucci	Restriction level XC	EMEA-001371-PIP01-12

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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 XR	EMEA-68-2013 (EMEA-000978-PIP01-10)
Alexandra Compagnucci	Restriction level XR	EMEA-69-2013 (EMEA-000978-PIP01-10)
Alexandra Compagnucci	Restriction level XR	EMEA-70-2013 (EMEA-000978-PIP01-10)
Alexandra Compagnucci	Restriction level XR	EMEA-71-2013 (EMEA-000978-PIP01-10)
Alexandra Compagnucci	Restriction level XR	EMEA-72-2013 (EMEA-000978-PIP01-10)
Alexandra Compagnucci	Restriction level XR	EMEA-73-2013 (EMEA-000978-PIP01-10)
Carine de Beaufort	Restriction level XR	EMEA-000128-PIP03-13
Christoph Male	Restriction level DP	EMEA-001114-PIP01-10-M02
Jean Pierre Aboulker	Restriction level XC	EMEA-001371-PIP01-12
Jean-Pierre Aboulker	Restriction level XR	EMEA-68-2013 (EMEA-000978-PIP01-10)
Jean-Pierre Aboulker	Restriction level XR	EMEA-69-2013 (EMEA-000978-PIP01-10)
Jean-Pierre Aboulker	Restriction level XR	EMEA-70-2013 (EMEA-000978-PIP01-10)
Jean-Pierre Aboulker	Restriction level XR	EMEA-71-2013 (EMEA-000978-PIP01-10)
Jean-Pierre Aboulker	Restriction level XR	EMEA-72-2013 (EMEA-000978-PIP01-10)
Jean-Pierre Aboulker	Restriction level XR	EMEA-73-2013 (EMEA-000978-PIP01-10)
Matthias Keller	Restriction level XR	EMEA-000366-PIP05-12
Michal Odermarsky	Restriction level XP	EMEA-000775-PIP01-09-M01
Paolo Rossi	Restriction level DP	EMEA-000872-PIP02-13
Paolo Rossi	Restriction level XR	EMEA-000128-PIP03-13
Paolo Rossi	Restriction level XR	EMEA-001430-PIP01-13
Paolo Rossi	Restriction level XR	EMEA-001458-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
Romaldas Maciulaitis	Restriction level XR	EMEA-68-2013 (EMEA-000978-PIP01-10)
Romaldas Maciulaitis	Restriction level XR	EMEA-69-2013 (EMEA-000978-PIP01-10)
Romaldas Maciulaitis	Restriction level XR	EMEA-70-2013 (EMEA-000978-PIP01-10)
Romaldas Maciulaitis	Restriction level XR	EMEA-71-2013 (EMEA-000978-PIP01-10)
Romaldas Maciulaitis	Restriction level XR	EMEA-72-2013 (EMEA-000978-PIP01-10)
Romaldas Maciulaitis	Restriction level XR	EMEA-73-2013 (EMEA-000978-PIP01-10)
Tadej Avcin	Restriction level XP	EMEA-001371-PIP01-12

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

Johannes Taminiau, Dutch Medicines Evaluation Board, Netherlands;

John Hartley, Great Ormond Street Hospital for Children, UK;

Susanna Livadiotti, Bambino Gesù Children's Hospital, Italy (by teleconference);

Aina Øvrebust, Norwegian Medicines Agency, Norway;

Tove Lill Stendal, Norwegian Medicines Agency, Norway.

I.5 Leaving/New Members and Alternates

The PDCO welcomes Dana Gabriela Marin in her new role as a member nominated by the CHMP to represent Romania.

The PDCO welcomes Nela Vilceanu in her new role as an alternate nominated by the CHMP to represent Romania.

The PDCO would like to thank Peter Bauer for his work following his retirement.

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

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

- 44 paediatric investigation plan applications;

[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).

- 9 product-specific waiver applications;
- 5 compliance check procedures (interim and final);
- 34 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 2014[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 January 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
vemurafenib	Treatment of patients with BRAF V600 mutated hairy cell leukaemia	Treatment of hairy cell leukaemia
vemurafenib	Treatment of patients with BRAF V600 mutated non-small cell lung carcinoma	Treatment of lung carcinoma (small cell and non-small cell carcinoma)
vemurafenib	Treatment of patients with BRAF V600 mutated multiple myeloma	Treatment of multiple myeloma
vemurafenib	Treatment of patients with BRAF V600 mutated ovarian carcinoma	Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)
vemurafenib	Treatment of patients with BRAF V600 mutated breast carcinoma	Treatment of breast carcinoma
vemurafenib	Treatment of patients with BRAF V600 mutated cholangiocarcinoma/cancer of the biliary tract	Treatment of liver and intrahepatic bile duct carcinoma (excluding hepatoblastoma)
Selumetinib (AZD6244; ARRY-142886)	In combination with docetaxel, treatment of patients with locally advanced or metastatic KRAS mutation positive NSCLC after failure of one prior anticancer therapy	Treatment of lung carcinoma (small cell and non-small cell carcinoma)
AZD9291	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Treatment of lung carcinoma (small cell and non-small cell carcinoma)

Anti PD-L1 monoclonal antibody	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Treatment of lung carcinoma (small cell and non-small cell carcinoma)

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

PIP number	Active substance	Proposed indication	Condition
EMEA-001213-PIP02-12	Ferric citrate (KRX-0502)	Treatment/control of hyperphosphataemia in patients with end-stage renal disease on dialysis and the improvement (increase and maintenance) of iron stores	Treatment of hyperphosphataemia

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000279-PIP01-08	raltegravir	ISENTRESS	No	Yes
EMEA-000636-PIP01-09	3-[[[6-Deoxy-4-O-(3,5-dichloro-2-ethyl-4,6-dihydroxybenzoyl)-2-O-methyl-β-D- man...	Dificid	No	Yes
EMEA-000709-PIP01-09	rufinamide	Inovelon	Yes	Yes
EMEA-001194-PIP01-11	migalastat hydrochloride	The invented name "CONECTRIC" is proposed.	Yes	Yes
EMEA-000456-PIP01-08	Insulin degludec	Not available at present	No	No
EMEA-000479-PIP01-08	Insulin aspart / Insulin degludec	Not available at present	No	No
EMEA-000878-PIP02-11	Colestilan	BindRen	No	Yes
EMEA-001181-PIP01-11	AGOMELATINE	VALDOXAN, THYMANAX	No	Yes

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000139-PIP01-07	N.meningitidis 961c purified antigen / N.meningitidis 287-953 purified antigen /...	not available at present	No	No
EMEA-000311-PIP01-08	ustekinumab	STELARA	No	No
EMEA-000311-PIP03-11	ustekinumab	STELARA	No	No
EMEA-000480-PIP01-08	Ticagrelor	Not available at present	No	Yes
EMEA-000056-PIP01-07	Bevacizumab	Avastin®	No	No
EMEA-000056-PIP03-10	Bevacizumab	AVASTIN	No	Yes

IX Other topics

Guidelines	
Concept paper on the revision of the guideline on conduct of pharmacovigilance for medicines used by the paediatric population*	For discussion
Guideline on the clinical development of medicinal products for the treatment of Autism Spectrum Disorder (ASD)*	For discussion
Working groups	
Paediatric inventory	For discussion
Paediatric oncology	For discussion
Extrapolation	For discussion
Formulation	For information
Non-Clinical	For information
Other topics	
PDCO and Companies meeting on Paediatric trials in Clostridium difficile infections	For discussion
CHMP update on paediatric topics	For discussion
Outcome of PDCO/CAT informal meeting in Trieste	For information

Outcome of ECDC-EMA Workshop on Vaccine schedules in PIPs*	For discussion
Minutes of meeting on appropriate duration of the placebo controlled phase of the pivotal paediatric studies in type 2 diabetes*	For adoption
Reminder of copyright - Use of the slides, images and graphs produced by EMA	For information
Project 2014 - Move to Churchill Place	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.