3 April 2013
EMA/PDCO/208985/2013
Human Medicines Development and Evaluation

Paediatric Committee (PDCO)

Provisional agenda of the 10-12 April 2013 meeting

Chair: Daniel Brasseur

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
Adriana Ceci	Restriction level DP	EMEA-000366-PIP02-09-M02
Adriana Ceci	Restriction level XR	EMEA-000087-PIP01-07-M03
Adriana Ceci	Restriction level DP	EMEA-001039-PIP02-12
Adriana Ceci	Restriction level DP	EMEA-001366-PIP01-12
Adriana Ceci	Restriction level XR	EMEA-14-2013
Alexandra Compagnucci	Restriction level XR	EMEA-001405-PIP01-12
Alexandra Compagnucci	Restriction level XR	EMEA-14-2013
Alexandra Compagnucci	Restriction level XR	EMEA-15-2013
Carine de Beaufort	Restriction level XR	EMEA-02-2013

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Member, alternate, expert name	Outcome restriction following evaluation of electronic Declaration of Interests	Topics on the current Committee Agenda for which this restriction applies
Carine de Beaufort	Restriction level XR	EMEA-10-2013
Carine de Beaufort	Restriction level XR	EMEA-11-2013
Carine de Beaufort	Restriction level XR	EMEA-12-2013
Christoph Male	Restriction level XP	EMEA-000480-PIP01-08-M05
Dobrin Konstantinov	Restriction level DP	EMEA-000469-PIP01-08-M04
Dobrin Konstantinov	Restriction level XP	EMEA-001301-PIP02-12
Dobrin Konstantinov	Restriction level XP	EMEA-001301-PIP01-12
Gerard Pons	Restriction level DP	EMEA-000402-PIP02-11
Jaroslav Sterba	Restriction level XP	EMEA-000469-PIP01-08-M04
Jaroslav Sterba	Restriction level XP	EMEA-001397-PIP01-12
Jaroslav Sterba	Restriction level XP	EMEA-001259-PIP02-13
Jaroslav Sterba	Restriction level XP	EMEA-000227-PIP02-12
Jaroslav Sterba	Restriction level XP	EMEA-05-2013
Jean-Pierre Aboulker	Restriction level XR	EMEA-14-2013
Jean-Pierre Aboulker	Restriction level XR	EMEA-15-2013
Kolbeinn Gudmundson	Restriction level DP	EMEA-17-2013
Matthias Keller	Restriction level XR	EMEA-000366-PIP02-09-M02
Matthias Keller	Restriction level 4	EMEA-001305-PIP01-12
Paolo Rossi	Restriction level XR	EMEA-000576-PIP03-12
Paolo Rossi	Restriction level XR	EMEA-000469-PIP01-08-M04
Tadej Avcin	Restriction level XP	EMEA-000366-PIP02-09-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

I.5 Leaving/New Members and Alternates

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

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

- 33 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).

- 10 product-specific waiver applications;
- 3 compliance check procedures (interim and final);
- 20 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 June 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 April 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-02-2013	RO5424802	Treatment of non-small cell lung cancer	Treatment of lung carcinoma (small cell and non-small cell carcinoma)
EMEA-03-2013	Ixazomib citrate	1) Treatment of newly diagnosed multiple myeloma 2) Treatment of relapsed and/or refractory multiple myeloma	Treatment of multiple myeloma
EMEA-04-2013	Ibrutinib 1-[(3R)-3-[4-amino-3-(4-phenoxyphenyl)-1H-pyrazolo[3,4 d]pyrimidin-1-yl]-1-piperidinyl]-2-propen-1-one (EMEA-001397-PIP01-12)	Treatment of chronic lymphocytic leukaemia	Chronic lymphocytic leukaemia
EMEA-05-2013	Ibrutinib 1-[(3R)-3-[4-amino-3-(4-phenoxyphenyl)-1H-pyrazolo[3,4 d]pyrimidin-1-yl]-1-	Treatment of follicular lymphoma	Follicular lymphoma

Class waiver number	Active substance	Proposed indication	Condition
	piperidinyl]-2-propen-1-one (EMEA-001397-PIP01-12)		
EMEA-06-2013	Ibrutinib 1-[(3R)-3-[4-amino-3-(4-phenoxyphenyl)-1H-pyrazolo[3,4 d]pyrimidin-1-yl]-1-piperidinyl]-2-propen-1-one (EMEA-001397-PIP01-12)	Treatment of multiple myeloma	Multiple myeloma
EMEA-07-2013	simtuzumab (GS-6624)	Treatment of metastatic colorectal adenocarcinoma	Treatment of adenocarcinoma of the colon and rectum
EMEA-08-2013	simtuzumab (GS-6624)	Treatment of primary, Post-Polycythemia Vera, and Post-Essential Thrombocythemia Myelofibrosis	Treatment of Myelofibrosis
EMEA-09-2013	simtuzumab (GS-6624)	Treatment of Metastatic Pancreatic Adenocarcinoma	Treatment of adenocarcinoma of the pancreas
EMEA-10-2013	Bay 86-9766, RDEA 119 (S)-N-(3,4-difluoro-2-(2-fluoro-4-iodophenylamino)-6-methoxyphenyl)-1-(2,3-dihydroxypropyl) cyclopropane-1-sulfonamide INN: Refametinib	Treatment of unresectable hepatocellular carcinoma alone or in combination with sorafenib in first line patients with RAS mutations	Treatment of liver and intrahepatic bile duct carcinoma (excluding hepatoblastoma)
EMEA-11-2013	Bay 86-9766, RDEA 119 (S)-N-(3,4-difluoro-2-(2-fluoro-4-iodophenylamino)-6-methoxyphenyl)-1-	First line treatment of locally advanced, inoperable, or metastatic pancreatic cancer in combination with gemcitabine for those whom systemic palliative	Treatment of adenocarcinoma of the pancreas

Class waiver number	Active substance	Proposed indication	Condition
	(2,3-dihydroxypropyl) cyclopropane-1-sulfonamide INN: Refametinib	treatment with gemcitabine is indicated	
EMEA-12-2013	Aleglitazar - RO0728804	Delay of the onset of type 2 diabetes in patients with cardiovascular disease and pre-diabetes	Peroxisome proliferator-activated receptor (PPAR)-gamma modulators, including dual and multiple PPAR modulators (e.g., thiazolidinediones, glitazars, triple modulators), in the treatment of type II diabetes mellitus (EMEA/386453/2008)
EMEA-13-2013	HuMax-CD38 (Daratumumab)	Treatment of multiple myeloma	Treatment of multiple myeloma
EMEA-14-2013	5-Chloro-N2-[2-isopropoxy-5-methyl-4-(4-piperidinyl)phenyl]-N4-[2-(isopropylsulfonyl)phenyl]-2,4-pyrimidinediamine Company code: LDK378	treatment of anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC)	Treatment of lung carcinoma (small cell and non-small cell carcinoma)
EMEA-15-2013	Moxetumomab pasudotox	Treatment of relapsed or refractory hairy cell leukaemia	Hairy cell leukemia
EMEA-16-2013	Carfilzomib (Kyprolis)	Treatment of patients with relapsed and refractory multiple myeloma who have received at least two prior therapies that included bortezomib and an immunomodulatory agent.	Treatment of multiple myeloma
EMEA-17-2013	Sulodexide (DOVIDA 2700 UI Anti Xa capsule soft)	Treatment of peripheral arterial disease due to atherosclerosis	Treatment of peripheral atherosclerosis

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

PIP number	Active substance	Proposed indication	Condition
EMEA-000200-PIP01-08	Saxagliptin	Reduction of major CV events in patients with Type 2 diabetes who also have CV risk factors or established CV disease	Treatment of patients with type 2 Diabetes Mellitus
EMEA-000978-PIP01-10	Vemurafenib	Vemurafenib in combination with cobimetinib for the treatment of adult patients with unresectable or metastatic melanoma with BRAFV600 mutations	Treatment of melanoma

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000065-PIP01-07-M03	Telbivudine	Sebivo	No	No
EMEA-000116-PIP01-07-M05	Retigabine	Trobalt	No	No
EMEA-000470-PIP01-08-M06	Sitagliptin	Januvia (and related products)	No	No
EMEA-000696-PIP02-10-M02	Eslicarbazepine acetate	Exalief, Zebinix	No	Yes

IX Other topics

Guidelines	
Draft guideline on the clinical investigation of medicinal products for the treatment of urinary incontinence	For discussion
Guideline on the clinical development of medicinal products intended for the treatment of chronic primary immune thrombocytopenia (EMA/CHMP/153191/2013)	For information
Working groups	
Paediatric inventory	For discussion
Paediatric oncology	For discussion
Formulation	For information

Non-Clinical	For information
Extrapolation	For information
Other topics	
Questionnaire for children and young people*	For discussion
Update on the Workshop on paediatric investigation plans in type-2 diabetes mellitus on 25 February 2013	For information
Revision of the Priority list of off-patent medicines	For adoption
Reflexion on the revocation of the EMA decision on the list of class waiver	For discussion / adoption
Performance indicators and parameters for the 10-year report on the Paediatric Regulation	For adoption
Presentation of the Annual report on rewards and incentives 2012* to the European Commission (Art 50.1)	For information
Template and guidance for Summary of Opinion*	For discussion /adoption
Overview of CHMP Opinions	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.