30 January 2013
EMA/PDCO/60785/2013
Human Medicines Development and Evaluation

Paediatric Committee (PDCO)

Provisional agenda of the 06-08 February 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-001045-PIP01-10
Adriana Ceci	Restriction level DP	EMEA-001220-PIP01-11
Adriana Ceci	Restriction level XR	EMEA-000019-PIP06-09-M03
Adriana Ceci	Restriction level DP	EMEA-001371-PIP01-12
Adriana Ceci	Restriction level DP/XR	EMEA-C1-000118-PIP02-10-M01
Adriana Ceci	Restriction level XR	EMEA-001003-PIP01-10-M02
Alexandra Compagnucci	Restriction level DC	EMEA-000627-PIP01-09-M04
Alexandra Compagnucci	Restriction level DC	EMEA-000628-PIP01-09-M04
Carine de Beaufort	Restriction level XR	EMEA-001045-PIP01-10

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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-70-2012
Carine de Beaufort	Restriction level XR	EMEA-71-2012
Carine de Beaufort	Restriction level XR	EMEA-72-2012
Carine de Beaufort	Restriction level XR	EMEA-73-2012
Carine de Beaufort	Restriction level XR	EMEA-80-2012
Carine de Beaufort	Restriction level XR	EMEA-81-2012
Carine de Beaufort	Restriction level XR	EMEA-82-2012
Carine de Beaufort	Restriction level XR	EMEA-001395-PIP01-12
Christoph Male	Restriction level DP	EMEA-001296-PIP01-12
Christoph Male	Restriction level DP	EMEA-001382-PIP01-12
Dobrin Konstantinov	Restriction level XP	EMEA-C1-000468-PIP02-12
Gerard Pons	Restriction level.DP	EMEA-000116-PIP01-07-M06
Gerard Pons	Restriction level.DP	EMEA-000332-PIP01-08-M06
Jaroslav Sterba	Restriction level XP	EMEA-001372-PIP01-12
Jaroslav Sterba	Restriction level XP	EMEA-001392-PIP01-12
Jaroslav Sterba	Restriction level XP	EMEA-C1-000468-PIP02-12
Marek Migdal	Restriction level DP	EMEA-001309-PIP01-12
Matthias Keller	Restriction level XR	EMEA-000366-PIP05-12
Michal Odermarsky	Restriction level XP	EMEA-000968-PIP02-11-M01
Michal Odermarsky	Restriction level XP	EMEA-001368-PIP01-12
Michal Odermarsky	Restriction level XP	EMEA-001288-PIP01-12
Paolo Rossi	Restriction level DP	EMEA-001289-PIP01-12
Peter Bauer	Restriction level DP	EMEA-001327-PIP01-12
Peter Szitanyi	Restriction level DP	EMEA-001100-PIP01-10
Romaldas Maciulatis	Restriction level XR	EMEA-70-2012
Romaldas Maciulatis	Restriction level XR	EMEA-71-2012
Romaldas Maciulatis	Restriction level XR	EMEA-72-2012
Romaldas Maciulatis	Restriction level XR	EMEA-73-2012
Romaldas Maciulatis	Restriction level XR	EMEA-80-2012

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 Maciulatis	Restriction level XR	EMEA-81-2012
Romaldas Maciulatis	Restriction level XR	EMEA-82-2012
Tadej Avcin	Restriction level XP	EMEA-001045-PIP01-10
Tadej Avcin	Restriction level XP	EMEA-001220-PIP01-11
Tadej Avcin	Restriction level XP	EMEA-001371-PIP01-12
Jacqueline Haddad	Restriction level XR	EMEA-001394-PIP01-12
Jacqueline Haddad	Restriction level XR	EMEA-000279-PIP01-08-M01
Jacqueline Haddad	Restriction level XR	EMEA-C1-000468-PIP02-12
Jacqueline Haddad	Restriction level XR	EMEA-000144-PIP01-07-M04
Jacqueline Haddad	Restriction level XR	EMEA-001100-PIP01-10

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

Jacqueline Haddad, Agence nationale de sécurité du médicament et des produits de santé, France

I.5 Leaving / New Members and Alternates

N/A

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

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

- 38 paediatric investigation plan applications;
- 11 product-specific waiver applications;
- 6 compliance check procedures (interim and final);
- 38 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 April 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.

[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).

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

VI Discussion on the applicability of class waiver

Class waiver number	Active substance	Proposed indication	Condition
EMEA-66-2012	RO5314482	Treatment of advanced or metastatic breast cancer	Treatment of breast carcinoma
EMEA-67-2012	RO5314482	Treatment of non-small cell lung carcinoma	Treatment of lung carcinoma (small cell and non-small cell carcinoma)
EMEA-68-2012	RO5537381	Treatment of advanced or metastatic breast cancer	Treatment of breast carcinoma
EMEA-69-2012	Onartuzumab	treatment of patients with locally advanced or metastatic Met positive NSCLC after failure of at least one prior chemotherapy regimen	Treatment of lung carcinoma (small cell and non-small cell carcinoma)
EMEA-70-2012	Onartuzumab	First line treatment, in combination with chemotherapy, of patients with HER2 negative, Met-positive metastatic gastroesophageal cancer	Treatment of gastric adenocarcinoma
EMEA-71-2012	Onartuzumab	Treatment of breast carcinoma	Treatment of breast carcinoma
EMEA-72-2012	Onartuzumab	Treatment of adenocarcinoma of the colon and rectum	Treatment of adenocarcinoma of the colon and rectum
EMEA-73-2012	Onartuzumab	Treatment of hepatocellular carcinoma	Treatment of liver and intrahepatic bile duct carcinoma
EMEA-74-2012	Sulodexide	Treatment of peripheral arterial disease	Treatment of peripheral atherosclerosis
EMEA-75-2012	LY2886721	Slowing of disease progression in Patients with Prodromal Alzheimer's Disease and Mild Alzheimer's Disease	Treatment of Alzheimer's disease
EMEA-76-2012	Zoptarelin doxorubicin, company code is AEZS-108	Treatment with AEZS-108 in castration and taxane-resistant prostate cancer	Treatment of prostate cancer (excl. Rhabdomyeloma)
EMEA-77-2012	Zoptarelin doxorubicin, company code is AEZS-108	Treatment of localized unresectable pancreatic cancer with AEZS-108 and radiation	Treatment of adenocarcinoma of the pancreas
EMEA-78-2012	Zoptarelin doxorubicin, company code is AEZS-108	Treatment with AEZS-108 in chemotherapy refractory triple negative (ER/PR/HER2-negative) LHRH-R positive metastatic breast cancer	Treatment of breast carcinoma

Class waiver number	Active substance	Proposed indication	Condition
EMEA-79-2012	2-(6-(dimethylamino)benzo[d][1,3]dioxol-5-ylthio)-1-(2-(neopentylamino)ethyl)-1H-imidazo[4,5-c]pyridin-4-amine	Treatment of advanced metastatic renal cell carcinoma	Treatment of kidney and renal pelvis carcinoma (excluding nephroblastoma, nephroblastomatosis, clear cell sarcoma, mesoblastic nephroma, renal medullary carcinoma and rhabdoid tumour of the kidney)
EMEA-80-2012	MPDL3280A (Company code)	Treatment of patients with locally advanced or metastatic non-small cell lung cancer that is PD-L1-positive	Treatment of lung carcinoma (small cell and non-small cell)
EMEA-81-2012	MPDL3280A (Company code)	Treatment of patients with PD-L1 positive renal cell carcinoma	Treatment of renal cell carcinoma
EMEA-82-2012	GDC-0973 (Company code)	Treatment, in combination with vemurafenib, of patients with unresectable or metastatic melanoma with BRAFV600 mutations	Treatment of melanoma (from 0 to less than 12 years)

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

PIP number	Active substance	Proposed indication	Condition
EMEA-000978-PIP01-10	Vemurafenib	Indication in PIP Decision: Treatment of unresectable stage IIIc or stage IV melanoma in patients 12 to 18 y. old, positive for BRAF V600 mutation. Indication under investigation in adults: Adjuvant therapy in patients with surgically resected cutaneous BRAF-mutant melanoma at high risk of recurrence.	Treatment of melanoma
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

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties in progressing the PIP?
EMEA-000176-PIP01-07-M03	Colistimethate sodium	Colobreathe	Yes	Yes

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties in progressing the PIP?
EMEA-000994-PIP01-10	gadobutrol	Gadovist	No	No
EMEA-000052-PIP01-07	Vandetanib	Caprelsa	Yes	Yes
EMEA-000978-PIP01-10	Vemurafenib	Zelboraf	No	Yes
EMEA-000306-PIP01-08-M01	Corifollitropin alfa	Elonva	No	No
EMEA-000469-PIP01-08-M03	Anidulafungin	Ecalta	No	Yes
EMEA-000191-PIP01-08-M04	Voriconazole	Vfend	No	No
EMEA-000311-PIP01-08-M02	Ustekinumab	Stelara	No	No
EMEA-000311-PIP03-11-M01	Ustekinumab	Stelara	No	No
EMEA-000056-PIP01-07-M01	Bevacizumab	Avastin	No	Yes
EMEA-000056-PIP03-10-M01	Bevacizumab	Avastin	No	Yes

IX Other topics

Guidelines	
Paediatric Addendum to the guideline on clinical investigation of medicinal products to prevent development / slow progression of chronic renal insufficiency (CRI)*	For discussion
Guideline on the evaluation of Medicinal Products for the treatment of Irritable Bowel Syndrome*	For discussion
Paediatric Addendum* to Note for guidance on clinical investigation of medicinal products in the treatment of hypertension	For discussion and adoption
Concept paper on the development of Medicinal products for the treatment of Autism*	For discussion
Reflection paper on the use of methyl- and propylparaben as excipients in human medicinal products for oral use*	For information
Working groups and breakout sessions	
Paediatric inventory	For discussion
Paediatric oncology	For discussion
Indicators of public health effects of Paediatric Regulation	For discussion

Breakout group	
Revision of the standard allergen PIP	For discussion
Formulation	For information
Non-Clinical	For information
Extrapolation	For information
Other topics	
Changes to the rules of reimbursement for delegates	For information
Indicators of public health effects of Paediatric Regulation	For information
CHMP List of Questions to be addressed by PDCO: Everolimus (Votubia)	For discussion and adoption
Model oncology PIP acute myeloid leukaemia*	For discussion and adoption
Revision of the standard allergen PIP	For discussion
Article 6.1(J) of the Paediatric Regulation (Communication on paediatric clinical research)	For discussion and adoption
Summary of PDCO Opinion: new document and guidance*	For discussion and adoption
Reflection on revocation of the EMA decision on the list of class waivers	For discussion
Letter from European Haemophilia Consortium to Daniel Brasseur	For information
Enpr-EMA-Pharma Paediatric Type 2 diabetes mellitus meeting on 25 February 2013	For information
How to best evaluate effect of inhaled corticosteroids on HPA axis?	For discussion
Introduction to principles of bioequivalence and bioavailability demonstration	For information and discussion
Report from CHMP on paediatric topics	For information
Oseltamivir in infants	For discussion
PDCO survey on preferred submission method	For discussion

X 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.