EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 May 2014
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Human Medicines Research & Development Support Division

Paediatric Committee (PDCO)

Provisional agenda of the 23-25 April 2014 meeting

Chair: Dirk Mentzer - Vice-chair: Koenraad Norga

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
Alexandra Compagnucci	Restriction level XC	EMEA-001576-PIP01-13
Alexandra Compagnucci	Restriction level XC	EMEA-8-2014
Alexandra Compagnucci	Restriction level XR	EMEA-001593-PIP01-13
Alexandra Compagnucci	Restriction level XR	EMEA-000310-PIP03-10-M01
Alexandra Compagnucci	Restriction level XR	EMEA-000118-PIP02-10-M02
Alexandra Compagnucci	Restriction level XR	EMEA-000601-PIP01-09-M02
Alexandra Compagnucci	Restriction level XR	EMEA-001600-PIP01-13
Jaroslav Sterba	Restriction level DP	EMEA-001372-PIP02-13
Jean Pierre Aboulker	Restriction level XC	EMEA-001576-PIP01-13

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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
Jean-Pierre Aboulker	Restriction level XR	EMEA-001593-PIP01-13
Jean-Pierre Aboulker	Restriction level XR	EMEA-000310-PIP03-10-M01
Jean-Pierre Aboulker	Restriction level XR	EMEA-000118-PIP02-10-M02
Jean-Pierre Aboulker	Restriction level XR	EMEA-000601-PIP01-09-M02
Jean-Pierre Aboulker	Restriction level XR	EMEA-8-2014
Jean-Pierre Aboulker	Restriction level XR	EMEA-001600-PIP01-13
Marek Migdal	Restriction level DP	EMEA-000525-PIP01-08-M02
Michal Odermarsky	Restriction level XP	EMEA-000279-PIP01-08-M02
Paolo Rossi	Restriction level XR	EMEA-000120-PIP01-07-M04
Romaldas Maciulaitis	Restriction level XR	EMEA-000310-PIP03-10-M01
Romaldas Maciulaitis	Restriction level XR	EMEA-001425-PIP01-13-M01

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 European Commission attendance / External attendance

Florian Schmidt, European Commission.

I.5 Leaving/New Members and Alternates

The PDCO welcomes Michaela Meciakova in her new role as member and Karol Kralinsky in his new role as alternate, nominated to represent Slovakia.

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

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

- 26 paediatric investigation plan applications;
- 9 product-specific waiver applications;
- 5 compliance check procedures (interim and final);
- 32 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 2014[1]for Nomination of Rapporteur and Peer reviewer

[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).

- 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 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
(18F)-Fluoromethylcholine	Initial staging of prostate cancer: regional nodal disease and distant metastases	Treatment of prostate carcinoma (excluding rhabdomyosarcoma)
Cediranib (AZD2171)	Cediranib, in combination with platinum-based chemotherapy, followed by monotherapy maintenance, is indicated for the treatment of adult patients with platinum sensitive relapsed (PSR) ovarian cancer (including fallopian tube or primary peritoneal)	Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)
S 47445	Symptomatic treatment of mild to moderate Alzheimer's disease in patients with depressive symptoms	Treatment of Alzheimer's Disease
Pimavanserin tartrate	Treatment of Alzheimer's disease psychosis (ADP) Treatment of Parkinson's disease psychosis (PDP)	Treatment of Alzheimer's disease Treatment of Parkinson's disease (non-juvenile)
Bavituximab	Treatment of previously treated non-squamous non-small cell lung cancer	Treatment of lung carcinoma (small cell and non-small cell carcinoma)
Doxorubicin hydrochloride	Treatment of unresectable hepatocellular carcinoma (HCC) after sorafenib	Treatment of liver and intrahepatic bile duct carcinoma (excluding hepatoblastoma)
E2609[2]	Treatment of Alzheimer's Disease	Treatment of Alzheimer's Disease

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

[2] Deleted chemical name

PIP number	Active substance	Proposed indication	Condition
EMEA-000019-PIP03-08	Everolimus	Treatment of adult patients with progressive neuroendocrine tumours of gastrointestinal or lung origin[3]	Treatment of carcinoid tumours
EMEA-000329-PIP02-09	Darbepoetin alfa (Aranesp)	Treatment of anaemia due to myelodysplastic syndromes (MDS)	Treatment of anaemia due to chronic disorders

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000153-PIP01-07	Piperaquine phosphate anhydride / Dihydroartemisinin	Eurartesim	Yes	Yes
EMEA-000347-PIP01-08	Bilastine	Bilaxten	No	No
EMEA-000713-PIP02-10	pixantrone dimaleate	Pixuvri	Yes	No
EMEA-000777-PIP01-09	Artemether (20mg) and lumefantrine (120mg)	RIAMET (in all EU), Coartem in some countries such as US, Switzerland, Australia, African countries...	No	Yes
EMEA-000178-PIP01-07	Purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/0...	Pumarix	No	No
EMEA-000128-PIP02-09	Liraglutide	The intention is to not retain the invented name (Victoza). The invented name has not been decided yet.	No	No
EMEA-000309-PIP01-08	Tocilizumab	Tocilizumab Roche	No	No

[3] Corrected indication and condition

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000673-PIP01-09	Pneumococcal polysaccharide serotype 23F conjugated to Protein D (derived from n...	Synflorix	No	Yes
EMEA-000054-PIP01-07	Pitavastatin calcium		No	No
EMEA-000065-PIP01-07	telbivudine	Sebivo	No	No
EMEA-000300-PIP01-08	Pitavastatin calcium		No	No
EMEA-000301-PIP01-08	Pitavastatin calcium		No	No
EMEA-000436-PIP01-08	Mannitol	Bronchitol	Yes	No
EMEA-001201-PIP01-11	Haemophilus influenzae type b polysaccharide conjugated to tetanus protein / Hep...	Hexaxim	No	No
EMEA-001261-PIP01-11	Eribulin	Halaven	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 adoption
Guideline on the clinical development of medicinal products intended for the treatment of chronic primary immune thrombocytopenia* (Adopted by CHMP)	For information
Guideline on the clinical investigation of human normal immunoglobulin for subcutaneous and/or intramuscular administration (SCIg/IMIg)* - Draft revised guideline and overview of comments	For comments
Guideline on clinical investigation of hepatitis B immunoglobulin (updated with comments after public consultation)*	For comments
Working groups	
White paper drafting group: The paediatric regulation beyond 2017	For discussion

Paediatric inventory	For discussion
Paediatric oncology	For discussion
Extrapolation	For discussion
Formulation	For information
Non-Clinical	For information
Other topics	
Update on Enpr-EMA activities	For information
CHMP update on paediatric topics	For information
Draft inventory of paediatric therapeutic needs - Ophthalmology for public consultation*	For adoption
Vaccine standard PIP	For discussion
Inclusion of young adults into paediatric type 2 diabetes studies: FDA and EMA views	For information
Comments from NcWG/SWP on the ICH Juvenile Draft Concept Paper	For adoption
Definition of the condition(s) for the PIP/waiver opinions	For discussion
Revision of class waivers	For discussion
Advanced Therapy Medicinal Products (ATMPs) at the PDCO, collaboration CAT-PDCO	For discussion
Experts nomination for the Paediatric Formulary Group	For discussion
ISO IDMP standards: These standards cover the identification of medicinal products, substances and related controlled vocabularies.	For information and discussion
Project 2014 - Move to Churchill Place	For information
Experts nomination for SAG Psychiatry (Dexamed for ADHD)	For adoption

Any other business

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).