EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 May 2014
EMA/PDCO/276223/2014
Procedure Management & Business Support Division

Paediatric Committee (PDCO)

Provisional agenda of the 21-23 May 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
Adriana Ceci	Restriction level DP	EMEA-001619-PIP01-14
Alexandra Compagnucci	Restriction level XC	EMEA-000527-PIP03-13
Alexandra Compagnucci	Restriction level XC	EMEA-000527-PIP04-13
Alexandra Compagnucci	Restriction level XC	EMEA-001618-PIP01-14
Alexandra Compagnucci	Restriction level XC	EMEA-001613-PIP01-14
Alexandra Compagnucci	Restriction level XC	EMEA-001600-PIP01-13
Alexandra Compagnucci	Restriction level XC	EMEA-001191-PIP01-11-M01
Alexandra Compagnucci	Restriction level XC	EMEA-000689-PIP01-09-M05
Alexandra Compagnucci	Restriction level XC	EMEA-000184-PIP01-08-M02

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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
Alexandra Compagnucci	Restriction level XC	EMEA-000455-PIP02-10-M02
Alexandra Compagnucci	Restriction level XC	EMEA-000227-PIP03-13
Alexandra Compagnucci	Restriction level XC	EMEA-001452-PIP01-13
Alexandra Compagnucci	Restriction level XC	EMEA-001485-PIP01-13
Alexandra Compagnucci	Restriction level XC	EMEA-13-2014
Alexandra Compagnucci	Restriction level XC	EMEA-14-2014
Christoph Male	Restriction level XP/DP/XR	EMEA-001456-PIP01-13
Christoph Male	Restriction level XP/DP/XR	EMEA-000480-PIP01-08-M06
Christoph Male	Restriction level XP/DP/XR	EMEA-001215-PIP01-11-M01
Christoph Male	Restriction level XP/DP/XR	EMEA-000527-PIP03-13
Christoph Male	Restriction level XP/DP/XR	EMEA-000527-PIP03-14
Jaroslav Sterba	Restriction level DP	EMEA-000227-PIP03-13
Jaroslav Sterba	Restriction level DP	EMEA-001450-PIP01-13
Kolbeinn Gudmundsson	Restriction level DP/DC	EMEA-16-2014
Kolbeinn Gudmundsson	Restriction level DP/DC	EMEA-17-2014
Marina Dimov Di Giusti	Restriction level DC	EMEA-001501-PIP01-13
Paolo Rossi	Restriction level XR	EMEA-000576-PIP03-12
Violeta Iotova	Restriction level XP	EMEA-001527-PIP01-13

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

Dominik Karres, Medicines and Healthcare Products Regulatory Agency, U.K.

Nasir Hussain, Medicines and Healthcare Products Regulatory Agency, U.K.

Anastasia Mountaki, National Organization for Medicines, Greece

I.5 Leaving/New Members and Alternates

The PDCO welcome Grigorios Melas in his new role as member and Stefanos Mantagos in his new role as alternate, nominated to represent Greece.

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

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

- 34 paediatric investigation plan applications;
- 6 product-specific waiver applications;
- 5 compliance check procedures (interim and final);
- 31 requests for modifications of an agreed paediatric investigation plan.

IV. Nominations of Rapporteurs and Peer reviewers

IV.1 Nominations for paediatric procedures

- List of letters of intent received for submission of applications with start of procedure July 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.

IV.2 Nominations for other activities

- Nomination of PDCO representative in the establishment of a joint PDCO/PRAC Working Group

V Finalisation and adoption of opinions

The opinions adopted during the Paediatric Committee meeting of May 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
RO6867461	Treatment of wet age-related macular degeneration	Treatment of age-related macular degeneration
Talaporfin sodium & light activation therapy device	Treatment of the signs and symptoms of benign prostatic hyperplasia	Treatment of benign prostatic hyperplasia
AMG 337	Treatment of unresectable, locally advanced or metastatic gastric, gastro-oesophageal junction and oesophageal adenocarcinoma	Treatment of gastric adenocarcinoma
BI 691751	Reduction of major CV events in patients with established atherosclerotic disease in multiple vascular beds	Treatment of coronary atherosclerosis

[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).

BI 691751	Reduction of major CV events in patients with established atherosclerotic disease in multiple vascular beds	Treatment of peripheral atherosclerosis

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

No requests were received for the month of May.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000308-PIP01-08	rituximab	MabThera	No	No
EMEA-000118-PIP02-10	Abatacept	ORENCIA	No	No
EMEA-000412-PIP01-08	Insulin detemir	Levemir	No	No
EMEA-000601-PIP01-09	pazopanib	VOTRIENT	Yes	No
EMEA-001149-PIP01-11	Human Fibrinogen / Human Thrombin	EVARREST, EVICEL	No	Yes
EMEA-000970-PIP01-10	elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil (as fumarate)	Stribild	No	No
EMEA-000872-PIP01-10	Recombinant human hyaluronidase / Human normal immunoglobulin	HyQvia	No	Yes
EMEA-000183-PIP01-08	Apixaban	Eliquis	No	No
EMEA-000183-PIP02-12	apixaban	Eliquis	No	No
EMEA-000365-PIP01-08	Oseltamivir phosphate	Tamiflu®	No	Yes
EMEA-000429-PIP01-08	N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / N. men...	Nimenrix	No	Yes

IX Other topics

Guidelines	
Guideline on clinical investigation of hepatitis B immunoglobulin (updated with comments after public consultation)	For discussion
Working groups	
White paper drafting group: The paediatric regulation beyond 2017	For discussion
Paediatric oncology	For discussion
Extrapolation	For discussion
Paediatric inventory	For discussion
Formulation	For information
Non-Clinical	For information
Other topics	
Further debriefing on the workshop on paediatric PBPK	For information
Project 2014 - Move to Churchill Place	For information
ICH E11 Concept Paper	For discussion
Review and Reconnect: Rationalisation of Committees Secretariat	For information
Initial Paediatric Guidance TC: draft procedure	For discussion
Draft standard PIP on DTaP-containing combination vaccine & Letter to the VWP	For adoption
Gaucher disease – a Strategic Collaborative Approach from EMA and FDA Adopted via written procedure on 12 May 2014	For information
Opinion for Insulin degludec EMEA-000456-PIP01-08-M02 Adopted via written procedure on 15 May 2014	For information
PDCO dates for 2016	For adoption
Inventory of paediatric therapeutic needs - Infectious diseases (final adopted list) Draft inventory of paediatric therapeutic needs - Neurology (list open for public consultation) Draft inventory of paediatric therapeutic needs - Ophthalmology (list open for public consultation)	For information

Draft agenda of the EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting (3 June 2014)	Documents tabled for information

Any other business

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present within the framework of Regulation (EC) No 1049/2001 on access to documents because 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).