14 July 2014
EMA/PDCO/381665/2014 Rev.3
Procedure Management and Business Support Division

Paediatric Committee (PDCO)

Draft agenda of the 16 - 18 July meeting

Chair: Dirk Mentzer - Vice-chair: Koenraad Norga

16 July 2014, 08:30 – 19:00, room 2A

17 July 2014, 08:30 – 19:00, room 2A

18 July 2014, 08:30 – 13:00, room 2A

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).

Health & Safety information

In accordance with Agency policy, delegates are to be shown a slide show with health and safety and emergency information and procedures. This is to be displayed at the start of this meeting using the Crestron system as delegates are entering the meeting room. In addition, the chairperson or meeting secretariat is to draw the delegates' attention to the slideshow and point out the nearest fire exit(s), which are marked where the room has two or more exits. Should there be an evacuation during the meeting; staff will guide delegates out of the building via the nearest fire exit.

Disclaimers

Some of the information contained in this agenda is considered commercially confidential or sensitive and therefore not disclosed. With regards to therapeutic indications listed against products it must be noted that these may not reflect the full wording proposed by applicants and may also vary during the course of the review. The procedures discussed by the PDCO are on-going and therefore certain aspects of them are considered confidential. Additional details on these procedures will be published 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). Of note,

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this agenda is a working document primarily designed for PDCO members and the work the Committee undertakes.

Oral explanation meetings:

Wednesday 16 July 2014, 11:00 – 12:00, room 2A

Wednesday 16 July 2014, 14:00 – 15:00, room 2A

Thursday 17 July 2014, 14:00 – 15:00, room 2A

I Introduction

I.1 Adoption of the minutes from previous meeting

I.2 Adoption of the Agenda

I.3 Declaration of Conflict of Interest

PRE-MEETING LIST of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PDCO plenary session to be held 16-18 July 2014.
See July 2014 minutes (to be published post August 2014 PDCO meeting)

Members of the Committee are kindly requested to review the list and state any changes, omissions or errors to the already declared interests.

I.4 External attendance

Dr Parastoo Karoon, Medicines and Healthcare Products Regulatory Agency, U.K.

I.5 Leaving/New Members and Alternates

The PDCO welcomes Kristine Supe in her new role as alternate, nominated to represent Latvia.

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

III.1 List of Products by Therapeutic Area D90-D60-D30

III.2 Compliance Check – List of Products by Therapeutic Area♦

♦ The following compliance checks have been put up for discussion and the members of the PDCO have been invited to comment on issues of possible non-compliance.

III.3 Modification of an Agreed PIP – List of Products by Therapeutic Area

IV Nomination 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 September 2014 for Nomination of Rapporteur and Peer reviewer • Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver.	For adoption

IV.2 Nominations for other activities

To be confirmed	For adoption

V Finalisation and adoption of opinions

VI Discussion on the applicability of class waiver

Class waiver number	Active substance	Proposed indication	Condition
EMEA-23-2014	Fluticasone furoate/umeclidinium bromide	Treatment of patients with COPD, including those with an asthmatic component	Treatment of Chronic Obstructive Pulmonary Disease (COPD) (excluding chronic lung diseases associated with long-term airflow limitation, such as asthma, bronchopulmonary dysplasia, primary cilia dyskinesia, obstructive lung disease related to graft-versus-host disease after (bone-marrow) transplantation)

Class waiver number	Active substance	Proposed indication	Condition
EMEA-24-2014	SB-659032 (company code)	Adjunctive treatment of patients with mild Alzheimer's dementia with neuroimaging evidence of cerebral small vessel disease to slow cognitive and functional decline	Treatment of Alzheimer's disease
EMEA-25-2014	Tiprelestat	Prevention of postoperative complications after resection of oesophageal cancer	Treatment of adenocarcinoma of the colon and rectum Treatment of gastric adenocarcinoma Treatment of oropharyngeal, laryngeal or nasal epithelial carcinoma Treatment of gastric carcinoids

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

No requests were received for the month of July.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000117-PIP01-07	ipilimumab	Strentarga	No	Yes
EMEA-000117-PIP02-10	ipilimumab	Yervoy (subject to change during MAA procedure)	No	No
EMEA-000548-PIP01-09	Beclometasone dipropionate plus formoterol fumarate dihydrate	Foster and Kantos and associated names, Kantos Master and Inuvair and associated names	No	No

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000979-PIP01-10	autologous cartilage derived cultured chondrocytes	MACI Implant	No	No
EMEA-000727-PIP01-09	Bosutinib (SKI-606)	Bosulif	Planned	Yes
EMEA-000916-PIP01-10	Lixisenatide	Lyxumia	No	Yes
EMEA-000408-PIP01-08	Icatibant acetate	Firazyr	Yes	No
EMEA-000876-PIP01-10	eculizumab	Soliris	Yes	No
EMEA-000876-PIP02-11	Eculizumab	Soliris	Yes	No
EMEA-000128-PIP01-07	Liraglutide	Victoza	No	Yes
EMEA-000128-PIP02-09	Liraglutide	Victoza	No	No
EMEA-000157-PIP01-07	belatacept	Nulojix	No	No
EMEA-000335-PIP01-08	N-(2,4-Di-tert-butyl-5-hydroxyphenyl)-1,4-dihydro-4- oxoquinoline-3-carboxamide	Kalydeco	Yes	No
EMEA-000520-PIP01-08	belimumab	Benlysta	No	Yes
EMEA-001186-PIP01-11	ponatinib	Iclusig	Yes	Yes
EMEA-000467-PIP01-08	Perampanel	Not available	No	Yes

IX Other topics

Guidelines	
Guideline on asthma Marek Migdal	For discussion

Working groups	
Paediatric consultation meeting – update and way forward	Breakout session Wednesday lunch break
Paediatric oncology	Breakout session Thursday lunch break
Paediatric inventory	Breakout session Thursday lunch break
Formulation	Documents tabled for information
Non-Clinical	Documents tabled for information
Other topics	
Optimisation of PDCO plenary Dirk Mentzer	For discussion
Training of new PDCO members	For information
EMA road map, EMA work programme and development of PDCO work plan	For discussion
Art.31 referral of Hydroxyzine, PRAC List of Questions to be addressed by the PDCO Sylvie Benchetrit	For discussion
Update on Enpr-EMA activities	For information
CHMP update on paediatric topics	For information
Serious adverse events and safety concerns for clofarabine combined with chemotherapy in children with acute lymphoblastic leukaemia Sylvie Benchetrit	For discussion
Paediatric formulary Anthony Nunn, Siri Wang	For discussion
DTaP Vaccine PIP (VWP feedback)	For discussion
PDCO response to the questions from PRAC on the Chlorhexidine procedure Angeliki Siapkara, Dina Apele	For adoption
Compliance report for Cobicistat / atazanavir sulphate EMEA-C1-001465-PIP01-13 Adopted on 1 July 2014	For information
Compliance report for asfotase alfa EMEA-C2-000987-PIP01-10-M02 Adopted on 11 July 2014	For information
Visit to 30 Churchill Place Wednesday 16 July 2014, 19:00	For information

Paediatric consultation meeting – update and way forward	For discussion
PAH – PPHN PIPs: PDCO overview	For discussion
D30 Products identified for the Non-Clinical Working Group Jacqueline Carleer	For information
Outcome of Scientific Advice / Protocol Assistance with Start of Procedure 2 June 2014 with paediatric questions	For discussion

IX Any other business

EFGCP-DIA-EMA Paediatric Conference (30 Sep-01 Oct 2014)