



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 September 2014
EMA/PDCO/509779/2014
Procedure Management and Business Support Division

Paediatric Committee (PDCO)

Draft agenda of the 10-12 September 2014 meeting

Chair: Dirk Mentzer - Vice-chair: Koenraad Norga

10 September 2014, 08:30 – 19:00, room 2A

11 September 2014, 08:30 – 19:00, room 2A

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



Oral explanation meetings:

Wednesday 10 September 2014, 14:00 - 15:00, room 2A

Wednesday 10 September 2014, 16:00 - 17:00, room 2A

Thursday 11 September 2014, 11:00 – 12:00, 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 10 - 12 September 2014.
See September 2014 minutes (to be published post October 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

TBC

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

II.4 Opinions on Re-examination

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

<ul style="list-style-type: none">List of letters of intent received for submission of applications with start of procedure October 2014 for Nomination of Rapporteur and Peer reviewerNomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver.	For adoption
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IV.2 Nominations for other activities

Call for volunteers for joint PDCO/ SAWP membership Pre-requisites: <ul style="list-style-type: none">Member or alternate in the PDCO with ability to regularly and actively participate in the SAWP;Expertise in paediatric clinical medicine/ paediatric pharmacology/ paediatric clinical trial investigation;Provide feedback to PDCO during the joint PDCO/SAWP session during PDCO plenary.	For adoption
Election/designation of the new FWG Chair	For adoption

V Finalisation of opinions

VI Discussion on the applicability of class waiver

Class waiver number	Active substance	Proposed indication	Condition
EMEA-29-2014	ABT-199 (or GDC-0199)	1. As a single agent, for the treatment of patients with 17p deletion mutation positive Chronic Lymphocytic Leukaemia who have received at least one prior therapy 2. In combination with rituximab, for the treatment of patients with Chronic Lymphocytic Leukaemia who have received at least one prior therapy	Treatment of chronic lymphocytic leukaemia
EMEA-30-2014	LEE011	In combination with letrozole, for the treatment of postmenopausal women with hormone receptor positive, HER-2 negative, advanced breast cancer who received no prior therapy for advanced disease	Treatment of breast carcinoma
EMEA-31-2014	2-(18F)Fluor-N-(2-hydroxyethyl)-N,N dimethylethan aminiumchlorid	To be used in oncological diagnostic procedures with PET-scans in patients with a valid suspicion of prostate cancer	Treatment of prostate carcinoma (excluding rhabdomyosarcoma)
EMEA-32-2014	Losmapimod	To reduce the rate of major adverse cardiovascular events in patients during and following acute coronary syndrome (ACS) when added to standard of care	Treatment of Coronary Atherosclerosis
EMEA-33-2014	Everolimus	Treatment of adult patients with advanced non-functional neuroendocrine tumours of gastrointestinal origin	Treatment of gastroenteropancreatic neuroendocrine tumors (excluding neuroblastoma, neuroganglioblastoma, phaeochromocytoma)
EMEA-34-2014	Tremelimumab	Treatment of unresectable pleural and peritoneal malignant mesothelioma that has progressed following 1 or 2 prior platinum-based systemic lines of therapy	Treatment of mesothelioma
EMEA-35-2014	Lucitanib	Treatment of metastatic breast cancer	Treatment of breast carcinoma

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

No requests were received for the month of September.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug
EMA-001094-PIP01-10-M02	teriflunomide	Aubagio	No
EMA-000228-PIP01-08-M03	asenapine melete	Sycrest	No
EMA-000160-PIP01-07	Purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/...	Pandemrix, Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) (referring to Informed Consent for Prepandrix), Prepandrix	No
EMA-001072-PIP01-10	alemtuzumab	Lemtrada	No
EMA-000827-PIP01-09	Aztreonam	Cayston	Yes
EMA-000019-PIP02-07	Everolimus	Afinitor, Certican and associated names	Yes
EMA-000019-PIP08-12	Everolimus	Votubia	Yes
EMA-000402-PIP02-11	lacosamide	Vimpat	No
EMA-000555-PIP01-09	decitabine	Dacogen	Yes
EMA-000020-PIP01-07	maraviroc	Celsentri	No
EMA-000018-PIP01-07	Tapentadol Hydrochloride	Palexia	No

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug
EMA-000325-PIP01-08	Tapentadol hydrochloride	Palexia	No
EMA-000485-PIP01-08	Tapentadol hydrochloride	Palexia	No
EMA-000486-PIP01-08	Tapentadol hydrochloride	Palexia	No
EMA-000494-PIP01-08	Tapentadol hydrochloride	Palexia	No
EMA-000495-PIP01-08	Tapentadol hydrochloride	Palexia	No
EMA-000239-PIP01-08	Telavancin	Vibativ	No
EMA-000222-PIP01-08	Etravirine	Intence	No

IX Other topics

Guidelines	
Revision of the asthma guideline Marek Migdal	For adoption
Working groups	
Paediatric inventory	Breakout session lunch break, room 2C
Extrapolation	Breakout session lunch break, room 2H
Paediatric oncology	Breakout session lunch break, room 2C
Neonatology group	Breakout session Thursday lunch break (room tbc)
Formulation	Documents tabled for information
Non-Clinical	Documents tabled for information
Other topics	
CMDh request for PDCO advice on contraindication of medicines used for the treatment of cough and cold in children below 6 years of age Angeliki Siapkara	For discussion

Revision of class waiver (updated proposal) Koenraad Norga	For discussion
CHMP update on paediatric topics	For information
Oncology inventory of paediatric therapeutic needs for public consultation	For adoption
Submission of applications by Eudralink only to PDCO members/alternates	For discussion
Gastrointestinal development Jan Taminiau	For discussion
PECCO/ESPGHAN: Placebo without active medication in trials of paediatric IBD Jan Taminiau	For discussion
EMA policy on DoI	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 (16 September 2014)	Document tabled for information
D30 Products identified for the Non-Clinical Working Group Jacqueline Carleer	For information
Outcome of Scientific Advice / Protocol Assistance with Start of Procedure September 2014 with paediatric questions	For discussion

Any other business