18 June 2014
EMA/PDCO/324947/2014 Rev.3
Human Medicines Research & Development Support Division

Paediatric Committee (PDCO)

Draft agenda of June (18-20) 2014 meeting

Chair: Dirk Mentzer - Vice-chair: Koenraad Norga

18 June 2014, 08:30 – 19:00, room 2A

19 June 2014, 08:30 – 19:00, room 2A

20 June 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 the Agency's Health and Safety policy, delegates are to be briefed on health & safety and emergency information and procedures prior to the start of the meeting.

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.

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Oral explanation meetings:

Wednesday 18 June 2014, 11:00 - 12:00

Wednesday 18 June 2014, 14:00 - 15:00

Thursday 19 June 2014, 11:00 – 12:00 (tbc)

Thursday 19 June 2014, 16:00 – 17:00

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 18-20 June 2014.
See June 2014 minutes (to be published post July 2014 PDCO meeting)

I.4 External attendance

Jaroslav Sterba, University Hospital Brno, Czech Republic
Juliana Min, Medicines and Healthcare Products Regulatory Agency, UK
Parastoo Karoon, Medicines and Healthcare Products Regulatory Agency, UK
Nasir Hussain, Medicines and Healthcare Products Regulatory Agency, UK
Eleni Gaki, Medicines and Healthcare Products Regulatory Agency, UK

I.5 Leaving/New Members and Alternates

The PDCO welcome Peter Szitanyi in his new role as member and Marina Fertek in her new role as alternate, nominated to represent Czech Republic.

The PDCO would like to thank Jaroslav Sterba for his work following the end of his mandate.

II Opinions

II.1 Opinions on Products

II.2 Opinions on Compliance Check♦

♦ 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

II.3 Silent adoption of 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 August 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
• Sildenafil: Call for interest for a TC to discuss the possibility for an interim report for the PPHN study.	For adoption

IV.2 Nominations for other activities

Translator list for EC guideline	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-18-2014	Emixustat Hydrochloride	Treatment of geographic atrophy associated with age-related macular degeneration.	Treatment of age-related macular degeneration
EMEA-19-2014	Rituximab	In combination with chemotherapy for the treatment of adult patients with previously untreated and relapsed/refractory chronic lymphocytic leukaemia.	Treatment of chronic lymphocytic leukaemia

EMEA-20-2014	DNIB0600A (company code)	Treatment of patients with non-small cell lung cancer	Treatment of lung carcinoma (small cell and non-small cell carcinoma)
EMEA-21-2014	DNIB0600A (company code)	Treatment of patients with ovarian cancer	Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)
EMEA-22-2014	Topsalysin, PRX302	Treatment and control of benign prostatic hyperplasia (BPH) in patients with enlarged prostate	Treatment of Benign Prostatic Hyperplasia

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

No requests were received for the month of June.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000583-PIP01-09	boceprevir	Victrelis	No	Yes
EMEA-000342-PIP01-08	Sunitinib malate	Sutent	Yes	Yes
EMEA-001095-PIP02-12	Natalizumab	Tysabri	No	No
EMEA-001332-PIP01-12	Estetrol & Drospirenone	Estelle	No	Yes
EMEA-000235-PIP02-10	Aripiprazole	Abilify	No	No
EMEA-000308-PIP02-11	Rituximab	MabThera	No	No
EMEA-000373-PIP02-09	Ferumoxytol	Rienso	No	Yes

IX Other topics

Guidelines	
Guideline on Influenza vaccines	For discussion Friday morning as Paediatric Coordinator has TC with VWP on Thursday afternoon
Presentation of the Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections	For discussion
Working groups	
Formulation	Documents tabled for information
Non-Clinical	Documents tabled for information
Paediatric inventory	13:00-14:00 - Breakout session lunch break Wednesday – Function room
Extrapolation	13:00-14:00 - Breakout session lunch break Wednesday 2E
Paediatric oncology	13:00-14:00 - Breakout session lunch break Thursday 1H
Other topics	
PIP on DTaP-containing combination vaccine: feedback from VWP	For information Friday morning as Paediatric Coordinator has TC with VWP on Thursday afternoon
CoI policy	For information 16:45 – 17:05
Update on Enpr-EMA activities	For information 17:05 – 17-10
Guideline on asthma	For information 17:10 – 17-15
Initial consultation on paediatric development Dirk Mentzer	For discussion 17:15 – 18:15
PDCO Meeting Dates 2016, 2017, 2017	For adoption

Chlorhexidine cutaneous solutions and chemical skin burns in neonates Angelika Siapkara	For discussion
Funds - Horizon 2020	For discussion
Paediatric inventory	For discussion
Draft Agenda for Informal PDCO/SAWP, 16-17 October 2014, Rome Paolo Rossi	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 05 May 2014 with paediatric questions	For discussion Friday 20 June 2014 **09:30 - 10:30**
SA on the quality, preclinical and clinical (PK, statistics, safety/efficacy) development	Helena Fonseca
FU PA on the quality and clinical (PK, manufacturing changes) development	Immanuel Barth
PA on the quality, preclinical and clinical (PK, statistics, safety/efficacy) development and Significant benefit	Helena Fonseca
FU on the clinical (statistics, safety/efficacy) development	Paolo Rossi
SA on the clinical (statistics, safety/efficacy) development	Maria Jesus Fernandez Cortizo
SA on the nonclinical and clinical (PK, safety/efficacy) development	Maria Jesus Fernandez Cortizo
SA on the clinical (safety/efficacy) development	Maria Jesus Fernandez Cortizo
SA on the clinical (statistics, safety/efficacy) development	Fernando de Andrés Trelles

Any other business