13 August 2014
EMA/449773/2014 Rev 2 Corr. 1
Procedure Management and Business Support Division

Paediatric Committee (PDCO)

Draft agenda of the 13-15 August 2014 meeting

Chair: Dirk Mentzer - Vice-chair: Koenraad Norga

13 August 2014, 08:30 – 19:00, room 2A

14 August 2014, 08:30 – 19:00, room 2A

15 August 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

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work the Committee undertakes.

Oral explanation meetings:

Wednesday 13 August 2014, 14:00 – 15:00, room 2A

Thursday 14 August 2014, 14:00 – 15:00, room 2A

Wednesday 13 August 2014, 11:00 – 12:00, room 2A (tbc)

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 13-15 August 2014.
See August 2014 minutes (to be published post September 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

Katherine McGinn, Medicines and Healthcare Products Regulatory Agency, UK

I.5 Leaving/New Members and Alternates

The PDCO would like to thank Anthony Nunn, Adriana Ceci and Jean-Pierre Aboulker for their work at the end of their mandate.

The PDCO would like to thank Alexandra Compagnucci for her work at the end of her mandate.

The PDCO would like to thank Mathias Keller, Gerard Nguyen for their work at the end of their mandate.

The PDCO would like to thank Gerlind Bode for her work at the end of her mandate.

The PDCO welcomes Riccardo Riccardi, Antje Christin Neubert, Jan Taminiau in their new role as members, nominated to represent healthcare professionals.

The PDCO welcomes Maria Grazia Valsecchi and Doina Plesca in their new role as alternates, nominated to represent healthcare professionals.

The PDCO welcomes Günther Auerswald in his new role as member, nominated to represent patients' organisations.

The PDCO welcomes Paola Baiardi and Kerry Leeson-Beevers in their new role as alternates, nominated to represent patients' organisations.

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 October 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 of opinions

VI Discussion on the applicability of class waiver

Class waiver number	Active substance	Proposed indication	Condition
EMEA-26-2014	Elotuzumab	Treatment of multiple myeloma in combination with lenalidomide and dexamethasone in patients who have received one or more prior therapies.	Treatment of multiple myeloma fdc
EMEA-27-2014	Margetuximab	Treatment of advanced HER2-positive adenocarcinoma of the stomach or gastroesophageal junction	Treatment of gastric adenocarcinoma
EMEA-28-2014	Anti PD-L1 monoclonal antibody (MEDI4736)	Treatment of squamous cell cancer of head and neck	Treatment of oropharyngeal, laryngeal or nasal epithelial carcinoma (excluding nasopharyngeal carcinoma or lympho-epithelioma)

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

No requests were received for the month of August.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000498-PIP01-08	linagliptin	Trajenta[1]	No	Yes
EMEA-000556-PIP01-09	velaglucerase alfa	Vpriv	No	No
EMEA-001178-PIP01-11	Regorafenib	Stivarga	No	Yes
EMEA-000482-PIP01-08	Teduglutide ([gly2] recombinant human glucagon-like peptide)	Revestive	Yes	Yes

[1] Corrected product name for linagliptin

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-001019-PIP01-10	Poly(oxy-1,2-ethanediyl),alpha-hydro-omega-methoxy-133 ester with granulocyte co...	Lonquex	No	No
EMEA-000312-PIP01-08	Human coagulation Factor VIII (plus von Willebrand Factor) / Human coagulation F...	Biostate	No	Yes
EMEA-000362-PIP01-08	Aliskiren	Rasilez	No	Yes
EMEA-000174-PIP01-07	Plerixafor	Mozobil	Yes	No
EMEA-000185-PIP01-08	Catridecacog	NovoThirteen	Yes	No
EMEA-000019-PIP06-09	everolimus	Certican and associated names	No	No
EMEA-001147-PIP01-11	N-{3-[5-(2-Amino-4-pyrimidinyl)-2-(1,1-dimethylethyl)-1,3-thiazol-4-yl]-2-fluoro...	Tafinlar	No	No
EMEA-000145-PIP01-07	denosumab	Prolia, XGEVA (previously Amgiva)	No	Yes
EMEA-000145-PIP02-12	denosumab	Prolia, XGEVA (previously Amgiva)	No	No
EMEA-000769-PIP01-09	Ceftaroline fosamil (established INN)	Zinforo	No	No

IX Other topics

Guidelines	
Draft guideline on influenza vaccines: non-clinical and clinical module	For information

Working groups	
Extrapolation	Breakout session Wednesday lunch break, room 2H
Paediatric inventory	Breakout session Wednesday lunch break, room 2C
Paediatric oncology	Breakout session, Thursday lunch break 2C
Paediatric consultation meeting – update and way forward	Breakout session, Thursday lunch break 2H
Neonatal	Breakout session, Thursday lunch, meeting room 2J
Formulation	Documents tabled for information
Non-Clinical	Documents tabled for information
Other topics	
Induction to new EMA premises Wednesday, 13 August 2014, 08:45 – 09:00	For information
Art.31 referral of Hydroxyzine, PDCO responses to PRAC List of Questions Sylvie Benchetrit Wednesday 13 August 2014, 17:00	For adoption
Discussion on comments to the Questions and Answers draft document on the excipient Sodium (update of the Excipients guideline)	For discussion
Comparative analysis COMP Orphan Designation versus PDCO PIP condition	For information
CHMP update on paediatric topics	For information
PIP for DTaP-containing combination vaccine Marta Granström	For adoption
Organ maturation tables (lung, GI tract)	For adoption
Serious adverse events and safety concerns for clofarabine combined with chemotherapy in children with acute lymphoblastic leukaemia Sylvie Benchetrit	For information
Paediatric development life cycle	For information

D30 Products identified for the Non-Clinical Working Group Jacqueline Carleer	For information
PDCO response to the questions from PRAC on the Chlorhexidine procedure Angeliki Siapkara, Dina Apele-Freimane	Adopted at July PDCO[2]

Any other business

[2] Corrected timeline of adoption