



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 January 2015
EMA/PDCO/779162/2014
Procedure Management and Business Support Division

Paediatric Committee (PDCO)

Public agenda of the 14-16 January 2015 meeting

Chair: Dirk Mentzer - Vice-chair: Koenraad Norga

14 January 2015, 08:30 – 19:00, room 3A

15 January 2015, 08:30 – 19:00, room 3A

16 January 2015, 08:30 – 13:00, room 3A

Note on access to documents

Some documents mentioned in the agenda 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 14 January 2015, 11:00 – 12:00

Thursday 15 January 2015, 11:00 – 12:00

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 on 14 - 16 January 2015.

See January 2015 Minutes (to be published post February 2015 PDCO meeting)

I.4 External attendance

I.5 Leaving/New Members and Alternates

The PDCO would like to thank Kolbeinn Gudmundsson for his work at the end of his mandate as alternate.

II Opinions

II.1 Opinions on Products

Oncology

Day 120 opinion

Infectious Diseases / Dermatology

Day 120 opinion

Immunology-Rheumatology-Transplantation

Day 120 opinion

Neurology

Day 120 opinion

Infectious Diseases

Day 120 opinion

Day 60 opinion

Haematology-Hemostaseology

Day 120 opinion

Other / Pain / Gastroenterology-Hepatology

Day 60 opinion

Diagnostic / Oncology

Day 60 opinion

Cardiovascular Diseases

Day 60 opinion

Other

Day 60 opinion

Pneumology – Allergology

Day 60 opinion

Psychiatry

Day 60 opinion

11.2 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

Oncology

Day 30 opinion

Day 60 opinion

Immunology/Rheumatology/Transplantation

Day 60 opinion

11.3 Opinions on Modification of an Agreed Paediatric Investigation Plan**Cardiovascular Diseases**

Day 60 opinion

Other / Haematology-Hemostaseology

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 60 opinion

Neurology

Day 60 opinion

Pneumology - Allergology

Day 60 opinion

Vaccines

Day 60 opinion

Other

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 60 opinion

Haematology-Hemostaseology

Day 60 opinion

Dermatology

Day 60 opinion

Infectious Diseases / Pneumology - Allergology

Day 30 opinion

III Discussion of applications

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

Gastroenterology-Hepatology

Day 30 discussion

Infectious Diseases

Day 60 discussion

Day 90 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 60 discussion

Day 90 discussion

Pain / Neonatology - Paediatric Intensive Care / Anaesthesiology

Day 60 discussion

Neonatology - Paediatric Intensive Care / Pneumology - Allergology

Day 30 discussion

Cardiovascular Diseases

Day 30 discussion

Day 60 discussion

Immunology-Rheumatology-Transplantation

Day 60 discussion

Day 90 discussion

Psychiatry

Day 90 discussion

Neurology

Day 90 discussion

Pain

Day 30 discussion

Oncology

Day 90 discussion

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.

Oncology

Day 30 discussion

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

Oncology

Day 30 discussion

Infectious Diseases

Day 30 discussion

Psychiatry

Day 30 discussion

Immunology-Rheumatology-Transplantation

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 30 discussion

Cardiovascular Diseases

Day 30 discussion

Haematology-Hemostaseology

Day 30 discussion

Pain

Day 30 discussion

Gastroenterology-Hepatology

Day 30 discussion

Other / Endocrinology-Gynaecology-Fertility-Metabolism

Day 30 discussion

Ophthalmology / Dermatology / Neurology

Day 30 discussion

IV Nominations 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 March 2015 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
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IV.2 Nominations for other activities

<ul style="list-style-type: none">• PDCO representation within coordination group of Enpr-EMA: expiry of 3-year term. Need to renew or nominate other representatives.	For adoption
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V Finalisation and adoption of opinions

VI Discussion on the applicability of class waiver

Class waiver number	Active substance	Proposed indication	Condition	Rapporteur
EMA-1-2015	¹⁷⁷ Lu-DOTA ⁰ -Tyr ³ -Octreotate	Treatment of metastatic or unresectable, well differentiated, midgut neuroendocrine tumours, which overexpress somatostatin receptors	Treatment of gastroenteropancreatic neuroendocrine tumours (excluding neuroblastoma, neuroganglioblastoma, pheochromocytoma)	Hendrik van den Berg
EMA-2-2015	Ramucirumab	<ul style="list-style-type: none"> • Cyramza in combination with paclitaxel is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum and fluoropyrimidine chemotherapy; • Cyramza monotherapy is indicated for the treatment of adult patients with advanced gastric cancer or gastro-oesophageal junction adenocarcinoma with disease progression after prior platinum or fluoropyrimidine chemotherapy, for whom treatment in combination with paclitaxel is not appropriate. <p>Proposed indications:</p> <ul style="list-style-type: none"> • Treatment of non-small cell lung cancer (NSCLC); 	<ul style="list-style-type: none"> • Treatment of lung carcinoma (small and non-small cell carcinoma); • Treatment of liver and intrahepatic bile duct carcinoma (excluding hepatoblastoma); • Treatment of gastric adenocarcinoma; • Treatment of adenocarcinoma of the colon and rectum; • Treatment of ureter and bladder carcinoma. 	Koenraad Norga

Class waiver number	Active substance	Proposed indication	Condition	Rapporteur
		<ul style="list-style-type: none"> • Treatment of hepatocellular cancer; • Treatment of gastric cancer (other than second line); • Treatment of colorectal cancer; • Treatment of bladder cancer. 		

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

No requests were received for the month of January.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMA-000479-PIP01-08-M02	insulin aspart insulin degludec	Ryzodeg	No	No
EMA-000409-PIP01-08	Sodium (4R,9aS)-5-Hydroxy-4-methyl-6,10-dioxo-3,4,6,9,9a,10-hexahydro-2H-1-oxa-4	Tivicay	No	No
EMA-001032-PIP01-10	Macitentan	Macitentan	Planned	Yes
EMA-001181-PIP01-11	AGOMELATINE	Valdoxan, Thymanax	No	Yes
EMA-001276-PIP01-12	(S)-Isopropyl 2-((S)-(((2R,3R,4R,5R)-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl)...	Sovaldi	No	No
EMA-000139-PIP01-07	N.meningitidis 961c purified antigen / N.meningitidis 287-953 purified antigen	Bexsero	No	No
EMA-000311-PIP01-08	ustekinumab	Stelara	No	No
EMA-000311-PIP03-11	ustekinumab	Stelara	No	No
EMA-001308-PIP01-12	Paclitaxel	Abraxane	Yes	No

IX Other topics

Guidelines	
Guideline on the evaluation of medicinal products for the treatment of chronic constipation (including opioid induced constipation) and for bowel cleansing Johannes Taminiau	For adoption
Working groups	
Formulation Working Group work plan Brian Aylward	For discussion
Update on the work of the Paediatric Inventory Working Group Birka Lehmann	For information
Outcome of the PDCO Optimisation Working Group held in December 2014	For information
D30 Products identified for the Non-Clinical Working Group Jacqueline Carleer	For information
Product-related topics	
Art.31 Referral of Codeine: PDCO responses to the PRAC questions Angeliki Siapkara	For adoption
CHMP update on paediatric topics	For information
Other topics	
Adaptive pathway – update on pilot phase	For discussion
Debriefing on the outcome of the Review and Reconnect exercise for Paediatrics	For information
PDCO class waiver review list Koenraad Norga, Hendrik van den Berg	For discussion
Draft FDA Pediatric Clinical Pharmacology guidance	For information
Revision of the standard allergen PIP	For discussion
Paediatric considerations on Ebola	For discussion
Outcome of Scientific Advice / Protocol Assistance with Start of Procedure December 2014 with paediatric questions	For information

Improvement of SAWP-PDCO interactions Karl-Heinz Huemer	For discussion
Breakout sessions	
Inventory: Gastroenterology	For discussion
Inventory: Endocrinology	For discussion
Neonatology	For discussion
Paediatric oncology	For discussion
PDCO Optimisation Exercise	For discussion

Any other business