



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

8 December 2014  
EMA/PDCO/713847/2014  
Procedure Management and Business Support Division

## Paediatric Committee (PDCO)

### Public Agenda of the 10-12 December 2014 meeting

Chair: Dirk Mentzer - Vice-chair: Koenraad Norga

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

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

12 December 2014, 08:30 – 13:00, room 2A

#### **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.



## **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 December 2014.

See December 2014 Minutes (to be published post January 2015 PDCO meeting)

### ***I.4 External attendance***

### ***I.5 Leaving/New Members and Alternates***

The PDCO welcomes Ninna Gullberg in her new role as member and Anna-Karin Hamberg in her new role as alternate, nominated to represent Sweden.

The PDCO would like to thank Viveca Odland for her work as she has resigned from the Committee.

The PDCO welcomes Ann Marie Kaukonen in her new role as member and Maija Pihlajamäki in her new role as alternate, nominated to represent Finland.

The PDCO would like to thank Pirjo Laitinen-Parkkonen for her work at the end of her mandate as member.

## **II Opinions**

### ***II.1 Opinions on Products***

#### **Uro-nephrology**

Day 120 opinion

#### **Infectious Diseases**

Day 120 opinion

#### **Haematology-Hemostaseology**

Day 120 opinion

#### **Gastroenterology-Hepatology**

Day 120 opinion

#### **Endocrinology-Gynaecology-Fertility-Metabolism / Neurology**

Day 120 opinion

#### **Pneumology – Allergology**

Day 120 opinion

**Dermatology**

Day 120 opinion

**Cardiovascular Diseases**

Day 60 opinion

**Oncology**

Day 60 opinion

**Other / Oncology**

Day 60 opinion

**Vaccines**

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

**Endocrinology-Gynaecology-Fertility-Metabolism**

Day 60 opinion

**Immunology-Rheumatology-Transplantation**

Day 60 opinion

**Oncology**

Day 30 opinion

**Other**

Day 30 opinion

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

Day 60 opinion

**Endocrinology-Gynaecology-Fertility-Metabolism**

Day 60 opinion

**Uro-nephrology**

Day 60 opinion

## **Neurology**

Day 60 opinion

## **Other**

Day 60 opinion

## **Pneumology - Allergology**

Day 60 opinion

## **Immunology-Rheumatology-Transplantation**

Day 60 opinion

## **Immunology-Rheumatology-Transplantation / Endocrinology-Gynaecology-Fertility-Metabolism / Oncology**

Day 60 opinion

## **Oncology**

Day 60 opinion

### ***II.4 Opinions on Re-examination***

## **III Discussion of applications**

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

#### **Infectious Diseases**

Day 30 discussion

Day 60 discussion

Day 90 discussion

#### **Diagnostic / Oncology**

Day 30 discussion

#### **Immunology-Rheumatology-Transplantation**

Day 30 discussion

Day 90 discussion

#### **Neurology**

Day 90 discussion

#### **Psychiatry**

Day 30 discussion

Day 60 discussion

**Pain / Neonatology - Paediatric Intensive Care / Anaesthesiology**

Day 30 discussion

**Cardiovascular Diseases**

Day 30 discussion

**Oncology**

Day 60 discussion

Day 90 discussion

**Infectious Diseases / Dermatology**

Day 60 discussion

Day 90 discussion

**Pneumology - Allergology**

Day 30 discussion

**Other / Pain / Gastroenterology-Hepatology**

Day 30 discussion

**Neonatology - Paediatric Intensive Care / Ophthalmology**

Day 60 discussion

**Oncology / Uro-nephrology**

Day 60 discussion

**Dermatology**

Day 60 discussion

**Haematology-Hemostaseology**

Day 90 discussion

**Endocrinology-Gynaecology-Fertility-Metabolism**

Day 30 discussion

**Other**

Day 30 discussion

**Ophthalmology**

Day 60 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.

#### **Infectious diseases/Pneumology – Alergology**

Day 30 discussion

#### **Immunology/Rheumatology/Transplantation**

Day 30 discussion

#### **Endocrinology/Gynaecology/Fertility/Metabolism**

Day 30 discussion

#### **Cardiovascular disease**

Day 30 discussion

#### **Vaccines**

Day 30 discussion

#### **Oncology**

Day 30 discussion

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

#### **Infectious Diseases / Oncology / Gastroenterology-Hepatology / Haematology-Hemostaseology**

Day 30 discussion

#### **Pneumology - Allergology**

Day 30 discussion

#### **Other / Haematology-Hemostaseology**

Day 30 discussion

#### **Endocrinology-Gynaecology-Fertility-Metabolism**

Day 30 discussion

#### **Cardiovascular Diseases**

Day 30 discussion

#### **Other**

Day 30 discussion

## Neurology

Day 30 discussion

## Vaccines

Day 30 discussion

## Haematology-Hemostaseology

Day 30 discussion

## Dermatology

Day 30 discussion

## IV Nominations of Rapporteurs and Peer reviewers

### IV.1 Nominations for paediatric procedures

<ul style="list-style-type: none"><li>List of letters of intent received for submission of applications with start of procedure February 2015 for Nomination of Rapporteur and Peer reviewer</li><li>Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver.</li></ul>	For adoption
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### IV.2 Nominations for other activities

<ul style="list-style-type: none"><li>Nomination of Rapporteur and Peer Reviewer for different types of activities.</li></ul>	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-41-2014	Palbociclib	Treatment of advanced breast cancer in combination with endocrine therapy	Treatment of breast cancer	Henk van den Berg

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

No requests were received for the month of December.

## VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMA-000480-PIP01-08	Ticagrelor	Brilique, Possia	No	No
EMA-000636-PIP01-09	3-[[[6-Deoxy-4-O-(3,5-dichloro-2-ethyl-4,6-dihydroxybenzoyl)-2-O-methyl-β-D-man...	Dificid	No	No
EMA-000056-PIP01-07	Bevacizumab	Avastin	No	No
EMA-000056-PIP03-10	Bevacizumab	Avastin	No	Yes
EMA-000279-PIP01-08	raltegravir	Isentress	No	No
EMA-000455-PIP02-10	Lu AA21004	Brintellix	No	No
EMA-001272-PIP02-13	azacitidine	Vidaza	Yes	No
EMA-000282-PIP01-08	clevidipine butyrate	Cleviprex <sup>TM</sup> (clevidipine butyrate injectable emulsion)	No	Yes
EMA-000927-PIP01-10	Linacotide	Constella	No	Yes
EMA-000237-PIP01-08	Azilsartan medoxomil	Ipreziv	No	No

## IX Other topics

Guidelines	
Note for guidance on clinical investigation of medicinal products for treatment of asthma Marek Migdal	For adoption
Working groups	
Formulation Future workings of the group	For information
Paediatric inventory	For discussion
Neonatology	For discussion
Paediatric oncology	For discussion
PDCO Optimisation exercise	For discussion
Non-Clinical	Documents tabled for information

D30 Products identified for the Non-Clinical Working Group Jacqueline Carleer	For information
Product-related topics	
Art.31 Referral of Codeine to PRAC: presentation and request for PDCO advice Angeliki Siapkara	For discussion
Signal of sodium-containing medicines and cardiovascular risk: PDCO responses to PRAC questions Angeliki Siapkara	For adoption
CHMP update on paediatric topics	For information
Other topics	
Debriefing on the White Paper Drafting Group Koenraad Norga	For information
Debriefing on PDCO work plan	For information
Involvement of children and members' representing patients' organisation in the PDCO activities: outcomes of the questionnaire to PDCO	For discussion
Agenda - EMA Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) meeting with all eligible organisations – 26 November (EMA/632557/2014)	Document tabled for information
Agenda - Training session for patients and consumers involved in EMA activities – 25 November (EMA/632556/2014)	Document tabled for information
Minutes of the EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP) joint meeting – 16 September (EMA/563152/2014)	Document tabled for information
Benefit-risk communication to medicines users - How can regulators best meet the information needs of patients and healthcare professionals? - Workshop report (EMA/581546/2014)	Document tabled for information
Annual reports on deferred measures: to be sent routinely to PDCO Rapporteur	For discussion
Art. 46 studies submitted to EMA: to be evaluated by PDCO or CHMP	For discussion

Strategy of investigating paediatric patients in Ebola development programs	For adoption
EMA's activities as part of the global response against the Ebola outbreak	For discussion
Adaptive licence – update on pilot phase	For discussion
PDCO class waiver review Henk van den Berg, Koen Norga	For discussion
Accessibility of full paediatric applications to PDCO members	For discussion
Outcome of Scientific Advice / Protocol Assistance with Start of Procedure November 2014 with paediatric questions	For discussion

### **Any other business**