



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

10 April 2015  
EMA/PDCO/200198/2015  
Procedure Management and Committees Support Division

## Paediatric Committee (PDCO)

### Draft agenda of the 15-17 April meeting

15 April 2015, 08:30 – 19:00, room 2A

16 April 2015, 08:30 – 19:00, room 2A

17 April 2015, 08:30 – 13:00, room 2A

Chair: Dirk Mentzer - Vice-chair: Koenraad Norga

#### Health and 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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#### Note on access to documents

Some documents mentioned in the agenda cannot be released at present following a request for access to documents within the framework of Regulation (EC) No 1049/2001 as 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).



**Oral explanation meetings:**

Wednesday 15 April 2015, 11:00- 12:00 (to be confirmed)

Wednesday 15 April 2015, 14:00 – 15:00

**I Introduction**

*1.1 Adoption of the minutes from previous meeting*

*1.2 Adoption of the Agenda*

*1.3 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 15 – 17 April 2015.

See April Minutes 2015 (to be published post May 2015 PDCO meeting)

*1.4 External attendance*

*1.5 Leaving/New Members and Alternates*

**II Opinions**

*II.1 Opinions on Products*

**Dermatology**

Day 120 opinion

**Vaccines**

Day 120 opinion

**Other**

Day 120 opinion

**Infectious Diseases**

Day 120 opinion

**Pneumology – Allergology**

Day 120 opinion

**Cardiovascular Diseases**

Day 120 opinion

**Oncology**

Day 120 opinion

## **Cardiovascular Diseases**

Day 60 opinion

## **Neurology**

Day 60 opinion

## **Uro-nephrology**

Day 60 opinion

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

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

## **Infectious Diseases**

Day 30 opinion

### ***11.3 Opinions on Modification of an Agreed Paediatric Investigation Plan***

## **Uro-nephrology**

Day 60 opinion

## **Cardiovascular Diseases**

Day 60 opinion

## **Infectious Diseases**

Day 60 opinion

## **Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology**

Day 60 opinion

## **Other**

Day 60 opinion

## **Haematology-Hemostaseology**

Day 60 opinion

## **Dermatology**

Day 60 opinion

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

Day 60 opinion

## **Immunology-Rheumatology-Transplantation**

Day 60 opinion

## **Neurology**

Day 60 opinion

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

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

Day 30 opinion

## **III Discussion of applications**

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

## **Neurology**

Day 90 discussion

## **Psychiatry**

Day 90 discussion

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

Day 30 discussion

Day 90 discussion

## **Immunology-Rheumatology-Transplantation**

Day 30 discussion

## **Pneumology - Allergology**

Day 60 discussion

## **Oncology**

Day 30 discussion

Day 90 discussion

## **Pain**

Day 30 discussion

## **Gastroenterology-Hepatology**

Day 60 discussion

Day 90 discussion

### **Endocrinology-Gynaecology-Fertility-Metabolism / Cardiovascular Diseases**

Day 30 discussion

### **Oncology / Haematology-Hemostaseology**

Day 30 discussion

### **Dermatology**

Day 30 discussion

### **Infectious Diseases**

Day 30 discussion

Day 90 discussion

### **Neonatology - Paediatric Intensive Care**

Day 30 discussion

### **Diagnostic / Oncology**

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.

### **Uro-nephrology**

Day 30 discussion

### **Haematology-Hemostaseology**

Day 30 discussion

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

Day 30 discussion

### **Infectious Diseases**

Day 30 discussion

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

Day 30 discussion

### **Gastroenterology-Hepatology**

Day 30 discussion

## **Immunology-Rheumatology-Transplantation**

Day 30 discussion

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

## **Neurology**

Day 30 discussion

## **Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology**

Day 30 discussion

## **Pneumology - Allergology**

Day 30 discussion

## **Psychiatry**

Day 30 discussion

## **Ophthalmology**

Day 30 discussion

## **Infectious Diseases**

Day 30 discussion

## **Gastroenterology-Hepatology**

Day 30 discussion

## **Immunology-Rheumatology-Transplantation / Gastroenterology-Hepatology**

Day 30 discussion

## **Immunology-Rheumatology-Transplantation**

Day 30 discussion

## **Pain**

Day 30 discussion

## **Neonatology - Paediatric Intensive Care / Infectious Diseases**

Day 30 discussion

### ***III.4 Discussion on Re-examination***

## **Oncology**

Day 1 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 June 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

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

No requests were received for the month of April.

## VIII Annual reports on deferrals

Annual report based on PIP decision for	Active substance	Applicant	Product Name	Orphan drug	Difficulties progressing the PIP?
EMA-000973-PIP01-10	recombinant human N-acetylgalactosamine-6-sulfatase	BioMarin Europe Limited	Vimizim	Yes	Yes
EMA-000116-PIP01-07	Retigabine	Valeant Pharmaceuticals Ltd.	Trobalt	No	Yes
EMA-001113-PIP01-10	Delamanid	Otsuka Frankfurt Research Institute GmbH	Deltyba	Yes	No
EMA-001261-PIP01-11	Eribulin	Eisai Europe Ltd	Halaven	No	No
EMA-000434-PIP01-08	ambrisentan	Glaxo Group Limited	Volibris	Yes	No

Annual report based on PIP decision for	Active substance	Applicant	Product Name	Orphan drug	Difficulties progressing the PIP?
EMA-000727-PIP01-09	Bosutinib (SKI-606)	Pfizer Limited	Bosulif	Planned	Yes

## IX Other topics

Working groups	
Public consultation of the Inventories for gastroenterology and for endocrinology Birka Lehmann	For adoption
Formulation Working Group	Documents tabled for information
D30 Products identified for the Non-Clinical Working Group Jacqueline Carleer	For information
Product-related topics	
CHMP update on paediatric topics	For information
Signal Reduced bone density in children with long term use of warfarin Christoph Male	For discussion PRAC Rapporteur Torbjörn Callréus to be connected via teleconference
Other topics	
Draft PDCO work plan 2015	For discussion
Presentation of Workshop on Haemophilia Registries	For discussion
Outcome of Scientific Advice / Protocol Assistance with paediatric questions	For discussion
Discussion of 1 <sup>st</sup> reports	
Breakout sessions	
Neonatology	Thursday, Meeting room 2E
Paediatric oncology	Thursday, Meeting room 2D

## Any other business