



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

17 October 2014  
EMA/PDCO/615064/2014 Rev. 1  
Procedure Management and Business Support Division

## Paediatric Committee (PDCO)

### Public agenda of the 08 - 10 October 2014 meeting

Chair: Dirk Mentzer - Vice-chair: Koenraad Norga

08 October 2014, 08:30 – 19:00, room 2A

09 October 2014, 08:30 – 19:00, room 2A

10 October 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 work the Committee undertakes.



**Oral explanation meetings:**

Wednesday 08 October 2014, 14:00 - 15:00, room 2A

Thursday, 09 October 2014, 11:00 - 12:00, room 2A

**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 08 - 10 October 2014.

See October 2014 PDCO Minutes (*to be published post November 2014 PDCO meeting*)

***1.4 External attendance***

Sabine Scherer, Bundesinstitut für Arzneimittel und Medizinprodukte, Germany

Nasir Hussain, Medicines and Healthcare Products Regulatory Agency, U.K.

Juliana Min, Medicines and Healthcare Products Regulatory Agency, U.K.

Dominik Karres, Medicines and Healthcare Products Regulatory Agency, U.K.

***1.5 Leaving/New Members and Alternates***

## **III Discussion of applications**

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

#### **Infectious Diseases**

Day 30 discussion

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

Day 30 discussion

#### **Oncology**

Day 30 discussion

#### **Haematology-Hemostaseology**

Day 30 discussion

#### **Pneumology - Allergology**

Day 90 discussion

#### **Gastroenterology-Hepatology**

Day 30 discussion

## **II Opinions**

### ***II.1 Silent adoption of opinions on Products***

#### **Vaccines**

Day 60 opinion

#### **Neurology**

Day 120 opinion

#### **Cardiovascular Diseases**

Day 60 opinion

#### **Pain**

Day 60 opinion

#### **Gastroenterology-Hepatology**

Day 60 opinion

## **II.2 Silent adoption of compliance checks♦**

♦ 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 60 opinion

## **II.3 Silent adoption of opinions on Modification of an Agreed Paediatric Investigation Plan**

### **Pneumology - Allergology**

Day 60 opinion

### **Haematology-Hemostaseology**

Day 60 opinion

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

Day 60 opinion

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

Day 60 opinion

## **Coffee break**

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

### **Immunology-Rheumatology-Transplantation / Dermatology**

Day 120 opinion

### **Vaccines**

Day 120 opinion

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

Day 120 opinion

### **Other**

Day 120 opinion

### **Pain / Gastroenterology-Hepatology**

Day 120 opinion

### **Gastroenterology-Hepatology**

Day 60 opinion

**Vaccines**

Day 60 opinion

**Infectious Diseases**

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

**Endocrinology-Gynaecology-Fertility-Metabolism**

Day 30 opinion

**Pneumology-Allergology**

Day 30 opinion

**Endocrinology-Gynaecology-Fertility-Metabolism**

Day 60 opinion

**Oncology**

Day 60 opinion

**Lunch break**

**II Opinions**

**Oto-rhino-laryngology / Neurology**

Day 120 opinion

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

**Pneumology - Allergology**

Day 30 opinion

**Oncology**

Day 60 opinion

**Endocrinology-Gynaecology-Fertility-Metabolism**

Day 60 opinion

**Cardiovascular Diseases**

Day 60 opinion

**Neurology**

Day 60 opinion

**Other**

Day 60 opinion

**Coffee break****IX Other topics**

Guidelines	
Revision of the asthma guideline Marek Migdal	For adoption
Workshop on the "Guideline on pharmaceutical development of medicines for paediatric use"	For information
Working groups	
Formulation	Documents tabled for information
Non-Clinical	Documents tabled for information
Oncology Working Group	Wednesday after plenary, room tbc
Election of the FWG Chair	For information
D30 Products identified for the Non-Clinical Working Group Jacqueline Carleer	For information
Product-related topics	
Art.31 referral to PRAC investigating the potential risk of immediate and delayed hypersensitivity reactions with Ambroxol and bromhexine-containing products: PDCO responses to PRAC list of questions Marek Migdal	For discussion Wednesday after afternoon coffee break
Signal on cardiovascular events with the sodium containing medicines	For information
CMDh request for PDCO advice on contraindication of medicines used for the treatment of cough and cold in children below 6 years of age Angeliki Siapkara	For discussion Wednesday after afternoon coffee break

Excipient draft for consultation Cyclodextrins and Propylene glycol	For information
CHMP update on paediatric topics	For information

Other topics	
Development of PDCO work plan	For discussion
Workshop on dose finding at the EMA Ine Skottheim Rusten	For discussion
The juvenile oncology project Jacqueline Carleer	For information
Flow of procedures and timely finalisation of Opinions	For discussion
Update on Enpr-EMA activities	For information
Training on use of PedRA and BI	For information 19:00 - 19:30

### **Any other business**



### **III Discussion of applications**

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

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

Day 30 discussion

##### **Gastroenterology-Hepatology**

Day 30 discussion

##### **Haematology-Hemostaseology**

Day 30 discussion

##### **Other**

Day 30 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.

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

Day 30 discussion

##### **Haematology-Hemostaseology**

Day 30 discussion

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

##### **Pneumology - Allergology**

Day 60 discussion

Day 90 discussion

#### ***III.3 Opinions on Modification of an Agreed Paediatric Investigation Plan***

##### **Gastroenterology-Hepatology**

Day 60 opinion

##### **Psychiatry**

Day 60 opinion

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

##### **Gastroenterology-Hepatology**

Day 60 discussion

### **Coffee break**

**II.3 Opinions on Modification of an Agreed Paediatric Investigation Plan**

**Other**

Day 60 opinion

**III Discussion of applications**

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

**Uro-nephrology**

Day 30 discussion

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

**Haematology-Hemostaseology**

Day 60 discussion

**Lunch break**

**Infectious Diseases**

Day 30 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**

Day 30 discussion

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

**Oncology**

Day 30 discussion

Day 60 discussion

**Endocrinology-Gynaecology-Fertility-Metabolism**

Day 30 discussion

**Gastroenterology-Hepatology**

Day 60 discussion

**Infectious Diseases**

Day 90 discussion

**Uro-nephrology**

Day 60 discussion

**Cardiovascular Diseases**

Day 30 discussion

**Oncology / Gastroenterology-Hepatology**

Day 90 discussion

**Psychiatry**

Day 30 discussion

**Coffee break**

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

**Endocrinology-Gynaecology-Fertility-Metabolism**

Day 30 discussion

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

**Other**

Day 30 discussion

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

**Endocrinology-Gynaecology-Fertility-Metabolism**

Day 30 discussion

**Oncology**

Day 30 discussion

**Pneumology - Allergology**

Day 30 discussion

**IX Other topics**

Working groups	
Neonatology group	Breakout session, 18:00 - 19:00, room 2H
White Paper Drafting Group	Breakout session, 18:00 - 19:00, room 2J

## V Finalisation and adoption of opinions

### 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.

#### Other

Day 30 discussion

#### Immunology-Rheumatology-Transplantation

Day 30 discussion

#### Vaccines

Day 30 discussion

#### Cardiovascular Diseases

Day 30 discussion

#### Haematology-Hemostaseology

Day 30 discussion

#### Oncology

Day 30 discussion

#### Endocrinology-Gynaecology-Fertility-Metabolism

Day 30 discussion

#### Cardiovascular Diseases

Day 30 discussion

## IX Other topics

Other topics	
Outcome of Scientific Advice / Protocol Assistance with Start of Procedure with paediatric questions	For information

### Coffee break

## IX Other topics

Other topics	
10-year Report to the European Commission	For information 10:45 – 11:15

New guideline on format and content	For information 11:15 – 11:45
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### III.3 Modification of an Agreed PIP – List of Products by Therapeutic Area

#### Haematology-Hemostaseology

Day 30 discussion

#### Cardiovascular Diseases

Day 30 discussion

#### Infectious Diseases

Day 30 discussion

#### Neurology

Day 30 discussion

## VI Discussion on the applicability of class waiver

Class waiver number	Active substance	Proposed indication	Condition
EMA-36-2014	4-[7-(6-Cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo 5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide	Treatment of prostate cancer in adults	Treatment of prostate carcinoma (excluding rhabdomyosarcoma)
EMA-37-2014	ABT-981	Treatment of osteoarthritis (OA) providing disease-modifying effects (including both structure and symptom modification)	Treatment of primary and secondary osteoarthritis
EMA-38-2014	Ipatasertib (GDC-0068)	<ul style="list-style-type: none"> <li>• Treatment of metastatic breast cancer;</li> <li>• Treatment of early stage breast cancer;</li> <li>• Treatment of castration-resistant prostate cancer (CRPC);</li> <li>• Treatment of inoperable locally-advanced or metastatic gastric including gastroesophageal junction adenocarcinoma.</li> </ul>	<ul style="list-style-type: none"> <li>• Treatment of breast carcinoma;</li> <li>• Treatment of prostate carcinoma (excluding rhabdomyosarcoma);</li> <li>• Treatment of gastric adenocarcinoma.</li> </ul>

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

No requests were received for the month of October.

## VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMA-000366-PIP02-09	Adalimumab	Humira	No	Yes
EMA-000366-PIP04-12	Adalimumab	Humira	No	No
EMA-000597-PIP02-10	mirabegron	Betmiga	No	Yes
EMA-000969-PIP01-10	Cobicistat	Tybost <sup>1</sup>	No	No
EMA-000060-PIP01-07	Recombinant human monoclonal antibody to human IL-1beta of the IgG1/K class (ACZ...	Ilaris	Yes	No
EMA-000060-PIP02-08	Canakinumab	Ilaris	Yes	No
EMA-000830-PIP02-10	Human normal immunoglobulin	Gammaplex	No	No
EMA-000196-PIP01-08	Telaprevir	Incivo	No	Yes
EMA-001071-PIP02-12	Certolizumab Pegol	Cimzia	No	No
EMA-000200-PIP01-08	Saxagliptin	Onglyza	No	Yes
EMA-000265-PIP01-08	golimumab	Simponi	No	No
EMA-000265-PIP02-11	golimumab	Simponi	No	No
EMA-000671-PIP01-09	Sildenafil citrate	Revatio	Yes	Yes

## 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 December 2014 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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<sup>1</sup> Revised product name