



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 October 2014
EMA/PDCO/633895/2014
Procedure Management and Business Support Division

Paediatric Committee (PDCO)

Public agenda of the 12-14 November 2014 meeting

Chair: Dirk Mentzer - Vice-chair: Koenraad Norga

12 November 2014, 08:30 – 19:00, room 2A

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

14 November 2014, 08:30 – 13:00, room 2A

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 regard to intended therapeutic indications or procedure scopes 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 ongoing 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.

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 ongoing 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 12 November 2014, 14:00 – 15:00, room 2A

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 12 - 14 November 2014.

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

I.4 External attendance

To be confirmed.

I.5 Leaving/New Members and Alternates

The PDCO would like to thank Kevin Connolly for his work as he has resigned from the Committee.

The PDCO welcomes Brian Aylward in his new role as member, nominated to represent Ireland.

The PDCO would like to thank Marina Fertek for her work at the end of her mandate as alternate.

The PDCO welcomes Jaroslav Sterba in his new role as member and Peter Szitanyi in his new role as alternate, nominated to represent the Czech Republic.

III Discussion of applications

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

Infectious Diseases / Dermatology

Day 30 discussion

Neonatology - Paediatric Intensive Care / Ophthalmology

Day 30 discussion

Oncology / Uro-nephrology

Day 30 discussion

Uro-nephrology

Day 90 discussion

Infectious diseases

Day 90 discussion

Haematology-Hemostaseology

Day 60 discussion

Other

Day 60 discussion

Oncology

II Opinions

II.1 Adoption of opinions on Products (without discussion)

Pneumology - Allergology

Day 120 opinion

Infectious Diseases

Day 120 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 60 opinion

Other

Day 60 opinion

Cardiovascular Diseases

Day 60 opinion

II.2 Adoption of compliance checks (without discussion)♦

♦ 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.

Haematology-Hemostaseology

Day 30 opinion

Immunology-Rheumatology-Transplantation

Day 60 opinion

II.3 Adoption of opinions on Modification of an Agreed Paediatric Investigation Plan (without discussion)

Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology

Day 60 opinion

Haematology-Hemostaseology

Day 60 opinion

Coffee break

II.1 Opinions on Products

Endocrinology-Gynaecology-Fertility-Metabolism

Day 60 opinion

Oncology

Day 60 opinion

Oncology

Day 60 opinion

Neurology

Day 60 opinion

II.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 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 60 opinion

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

Other

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 60 opinion

Haematology-Hemostaseology

Day 60 opinion

Lunch break

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

Pneumology - Allergology

Day 60 opinion

IX Other topics

Other topics	
Funding of paediatric trials (specifically for off-patent medicines) in children	For discussion Wednesday 12 November 2014, 15:00 – 17:00

Coffee break

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

Endocrinology-Gynaecology-Fertility-Metabolism

Day 60 discussion

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

Other

Day 30 discussion

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

Infectious Diseases

Day 60 opinion

Gastroenterology-Hepatology

Day 60 opinion

IX Other topics

Product-related topics	
Signal of cardiovascular events with sodium containing effervescent, dispersible and soluble medicines: Responses to the PRAC Questions Angeliki Siapkara,	For discussion
Art.31 referral on Codeine to PRAC: PRAC request for PDCO advice	For discussion
CHMP update on paediatric topics	For information
Other topics	
Involvement of children in PDCO and patients in committee evaluations	For discussion
Draft Work plan for the European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP) 2015	For adoption

Draft Work plan for the European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP)	For adoption
Update on Enpr-EMA activities	For information
Task Force on Registries	For information
The juvenile oncology project	For information
PDCO work plan 2015 – update	For discussion
Working groups	
Neonatology	Wednesday, 12 November 2014, 19:00 – 20:00, room 2B
Extrapolation	Breakout session - cancelled
Formulation	Documents tabled for information
Non-Clinical	Documents tabled for information
D30 Products identified for the Non-Clinical Working Group Jacqueline Carleer	Documents tabled for information

Any other business

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

Cardiovascular Diseases

Day 60 opinion

Uro-nephrology

Day 60 opinion

III Discussion of applications

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

Endocrinology-Gynaecology-Fertility-Metabolism / Neurology

Day 90 discussion

Psychiatry

Day 30 discussion

Day 60 discussion

Other / Oncology

Day 30 discussion

Day 90 discussion

Cardiovascular Diseases

Day 60 discussion

Dermatology

Day 30 discussion

Day 90 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 60 discussion

Pneumology - Allergology

Day 90 discussion

Coffee break

Oncology

Day 30 discussion

Day 60 discussion

Infectious Diseases

Day 30 discussion

Day 60 discussion

Cardiovascular Diseases

Day 30 discussion

Vaccines

Day 30 discussion

Lunch break

III Discussion of applications

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

Oncology

Day 60 discussion

Gastroenterology-Hepatology

Day 60 discussion

Day 90 discussion

Ophthalmology

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.

Uro-nephrology

Day 30 discussion

Cardiovascular Diseases

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 30 discussion

Neurology

Day 30 discussion

Other

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

Coffee break

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

Day 30 discussion

Immunology-Rheumatology-Transplantation

Day 30 discussion

Uro-nephrology

Day 30 discussion

Oncology

Day 30 discussion

Dermatology / Pneumology - Allergology / Oto-rhino-laryngology

Day 30 discussion

Pneumology - Allergology

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 January 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. 	<p>For adoption</p>
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IV.2 Nominations for other activities

<ul style="list-style-type: none"> Nomination of Rapporteur and Peer Reviewer for different types of activities. 	For adoption
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IX Other topics

Working groups	
Paediatric oncology	Thursday, 13 November 2014, 18:00 – 19:00, room 2B
Paediatric inventory	Thursday, 13 November 2014, 18:00 – 19:00, room 3L
PDCO Improvement exercise – second brainstorming session	Thursday, 13 November 2014, 18:00 – 19:00, room 2J

V Finalisation and adoption of opinions

III Discussion of applications

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

Endocrinology-Gynaecology-Fertility-Metabolism

Day 30 discussion

Infectious Diseases

Day 30 discussion

VI Discussion on the applicability of class waiver

Class waiver number	Active substance	Proposed indication	Condition	Rapporteur
EMA-39-2014	Veliparib	Treatment of brain metastases from Non-Small Lung Cancer (NSCLC) in combination with whole brain radiation therapy (WBRT).	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Herbert Lenicker
EMA-40-2014	Taselisib	Treatment of non-small cell lung cancer (NSCLC).	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Henk van den Berg

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

No requests were made for the month of November.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMA-000567-PIP01-09	Dasatinib	Sprycel	Yes	No
EMA-000431-PIP01-08	triphenylacetic acid - 4-{{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxy}hexyl)am...	Relvar Ellipta	No	No
EMA-000968-PIP02-11	elvitegravir	Vitekta	No	No
EMA-000599-PIP01-09	Influenza virus surface antigens (haemagglutinin and neuraminidase)* of H5N1 st...	Focetria and associated names, Aflunov and associated names	No	Yes

EMA-000689-PIP01-09	exenatide	Byetta	No	Yes
EMA-000430-PIP01-08-M04	rivaroxaban	Xarelto	No	No
EMA-000290-PIP01-08	nilotinib	Tasigna	Yes	No
EMA-000452-PIP02-10	Tadalafil	Cialis, Adcirca	No	No
EMA-000694-PIP01-09	dapagliflozin	Forxiga	No	No
EMA-000468-PIP02-12	posaconazole	Noxafil	No	Yes
EMA-000205-PIP01-08	ceftobiprole medocaril sodium	Zeftera	No	No
EMA-000205-PIP02-11	ceftobiprole medocaril sodium	Zevtera	No	No
EMA-000160-PIP01-07	purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/...	Pandemrix, Prepandemic influenza vaccine (H5N1) (split virion, inactivated, adjuvanted) (referring to Informed Consent for Prepandrix), Prepandrix	No	No
EMA-000317-PIP01-08	rilpivirine	Edurant	No	No
EMA-000980-PIP01-10	brentuximab vedotin / Monoclonal antibody against human CD30 covalently linked t...	Adcetris	Yes	Yes
EMA-001030-PIP01-10	canagliflozin	Invokana	No	Yes
EMA-001318-PIP01-12	zanamivir	Relenza	No	Yes
EMA-000035-PIP02-09	tiotropium bromide (monohydrate)	Spiriva Respimat 2.5 microgram, solution for inhalation, Spiriva 18 microgram, inhalation powder, hard capsule	No	Yes
EMA-000367-PIP01-08	human recombinant C1 inhibitor	Rhucin	Yes	Yes
EMA-001149-PIP01-11	human Fibrinogen / Human Thrombin	Evarrest, Evicel	No	Yes
EMA-000410-PIP01-08	regadenoson	Rapiscan	No	No

II.1 Opinions on Products**Oncology**

Day 120 opinion

IX Other topics

Product-related topics	
Outcome of Scientific Advice / Protocol Assistance with paediatric questions	For information, Friday 14 November 2014, 09:30 -11:30

Coffee break**IX Other topics**

Product-related topics	
Joint session with the Formulation Working Group	For discussion

II Opinions**II.1 Opinions on Products****Pneumology – Allergology**

Day 120 opinion

Oncology / Gastroenterology-Hepatology

Day 120 opinion