



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

10 February 2015
EMA/PDCO/41469/2015
Procedure Management and Business Support Division

Paediatric Committee (PDCO)

Draft agenda of the 11-13 February 2015 meeting

11 February 2015, 09:00 – 19:00, room 3E

12 February 2015, 08:30 – 19:00, room 3E

13 February 2015, 08:30 – 13:00, room 3E

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 11 February 2015, 11:00 – 12:00

Wednesday, 11 February 2015, 14:00 – 15:00

Wednesday 11 February 2015, 15:30 – 16:30

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 11- 13 February 2015.

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

I.4 External attendance

I.5 Leaving/New Members and Alternates

II Opinions

II.1 Opinions on Products

Neurology

Day 120 opinion

Immunology-Rheumatology-Transplantation

Day 120 opinion

Infectious Diseases

Day 120 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 120 opinion

Oncology

Day 120 opinion

Psychiatry

Day 120 opinion

Pain

Day 60 opinion

Cardiovascular Diseases

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

Infectious Diseases

Day 0 opinion

Haematology-Hemostaseology

Day 30 opinion

11.3 Opinions on Modification of an Agreed Paediatric Investigation Plan

Day 60 opinion

Haematology-Hemostaseology

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 60 opinion

Psychiatry

Day 60 opinion

Ophthalmology / Dermatology / Neurology

Day 60 opinion

Infectious Diseases

Day 60 discussion

Pain

Day 60 opinion

Oncology

Day 60 opinion

Other / Endocrinology-Gynaecology-Fertility-Metabolism

Day 60 opinion

Immunology-Rheumatology-Transplantation

Day 60 opinion

Cardiovascular Diseases

Day 60 opinion

Gastroenterology-Hepatology

Day 60 opinion

III Discussion of applications

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

Neurology

Day 30 discussion

Pneumology - Allergology

Day 30 discussion

Day 90 discussion

Oncology

Day 30 discussion

Day 90 discussion

Gastroenterology-Hepatology

Day 60 discussion

Day 90 discussion

Infectious Diseases

Day 30 discussion

Day 90 discussion

Immunology-Rheumatology-Transplantation

Day 30 discussion

Neonatology - Paediatric Intensive Care / Pneumology - Allergology

Day 60 discussion

Dermatology

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 30 discussion

Day 90 discussion

Cardiovascular Diseases

Day 30 discussion

Day 60 discussion

Other

Day 30 discussion

Ophthalmology

Day 30 discussion

Pain

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.

Neurology

Day 30 discussion

Haematology-Hemostaseology

Day 30 discussion

Immunology-Rheumatology-Transplantation

Day 30 discussion

Pneumology – Allergology

Day 30 discussion

Infectious Diseases

Day 30 discussion

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

Uro-nephrology

Day 30 discussion

Infectious Diseases

Day 30 discussion

Vaccines

Day 30 discussion

Other

Day 30 discussion

Dermatology / Pneumology - Allergology / Oto-rhino-laryngology

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 30 discussion

Oncology

Day 30 discussion

Immunology-Rheumatology-Transplantation

Day 30 discussion

Cardiovascular Diseases

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 April 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">• Nomination of PDCO representative in Cross-	For adoption
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Committee Task Force on Registries (replacement of Viveca Odling)	
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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-3-2015	GDC-0810	Treatment of ER+ advanced and metastatic breast cancer	Treatment of breast carcinoma	Paolo Paolucci
EMA-4-2015	MPDL3280 A	Treatment of Previously Untreated Metastatic Triple Negative Breast Cancer	Treatment of breast carcinoma	Koenraad Norga
EMA-5-2015 (EMA-000480-PIP01-08-M07)	Ticagrelor (Brilique)	Authorised indication: Brilique, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with Acute Coronary Syndromes (unstable angina, non ST elevation Myocardial Infarction [NSTEMI] or ST elevation Myocardial Infarction [STEMI]); including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery by-pass grafting (CABG). Proposed indication: Ticagrelor is indicated for the prevention of atherothrombotic events (cardiovascular events death,	Treatment of coronary atherosclerosis	Marek Migdal

		myocardial infarction, and ischaemic stroke) in adult patients with acute ischaemic stroke or transient ischaemic attack.		
EMA-6-2015 (EMA-000480-PIP01-08-M07)	Ticagrelor (Brilique)	<p>Authorised indication: Brilique, co-administered with acetylsalicylic acid (ASA), is indicated for the prevention of atherothrombotic events in adult patients with Acute Coronary Syndromes (unstable angina, non ST elevation Myocardial Infarction [NSTEMI] or ST elevation Myocardial Infarction [STEMI]); including patients managed medically, and those who are managed with percutaneous coronary intervention (PCI) or coronary artery bypass grafting (CABG).</p> <p>Proposed indication: Prevention of atherothrombosis events in adult patients with Type 2 Diabetes at high risk for cardiovascular events</p>	Treatment of coronary atherosclerosis	Marek Migdal

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

PIP number	Active substance	Proposed indication	Condition	Rapporteur
EMA-001207-PIP01-11	Obinutuzumab	Treatment of diffuse large B-cell lymphoma, of indolent non-Hodgkin's lymphoma and of small lymphocytic lymphoma	Treatment of mature B cell lymphoma	Hendrik van den Berg

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan drug	Difficulties progressing the PIP?
EMA-000533-PIP01-08	Tenofovir	Viread	No	No
EMA-000978-PIP01-10	Vemurafenib	Zelboraf	No	Yes
EMA-000306-PIP01-08	corifollitropin alfa	Elonva	No	No
EMA-000816-PIP02-10	Potassium sulphate / Magnesium sulphate, heptahydrate / Sodium sulphate, anhydro	Izinova/ Eziclen	No	Yes
EMA-001115-PIP01-10	Loxapine	Adasuve	No	Yes
EMA-000878-PIP02-11	Colestilan	BindRen	No	Yes
EMA-000709-PIP01-09	rufinamide	Inovelon	Yes	No
EMA-001318-PIP01-12	zanamivir	Relenza	No	Yes
EMA-000553-PIP01-09	Lisdexamfetamine dimesylate	Venvanse	No	No
EMA-001066-PIP02-11	Aciclovir	Sitavir	No	No

IX Other topics

Working groups	
Mandate of the joint PDCO/PRAC Working Group Dirk Mentzer	For adoption
D30 Products identified for the Non-Clinical Working Group Jacqueline Carleer	For information
Product-related topics	
CHMP update on paediatric topics	For information
Other topics	
PDCO ORGAM dates 2015 and Minutes of the 1 st PDCO ORGAM held on 29 January 2015	For adoption
PDCO White Paper Koenraad Norga	For agreement

PDCO class waiver review Koenraad Norga	For information
PDCO - COMP and IMI-2 Activities Koenraad Norga	For discussion
Involvement of PDCO in Art. 46 procedures and MAA procedures - BI report	For information
Update on Enpr-EMA activities: <ul style="list-style-type: none"> • Nomination of PDCO member within Enpr-EMA coordination group; • European Strategy Forum on Research Infrastructure - call for projects 	For information
Outcome of Scientific Advice / Protocol Assistance with paediatric questions	For information
Modelling and Simulation Working Group report and workplan	For information
Standard allergen PIP	For adoption
Breakout sessions	
Inventory: Gastroenterology	Thursday, 18:00 - 19:00, 2J
Neonatology	Thursday, 18:00 - 19:00, 2B
Paediatric oncology	Thursday, 18:00 - 19:00, 2C

Any other business