17 March 2015
EMA/PDCO/115468/2015
Procedure Management and Business Support Division

Paediatric Committee (PDCO)

Draft agenda of the 18-20 March 2015 meeting

18 March 2015, 08:30 – 19:00, room 3A

19 March 2015, 08:30 – 19:00, room 3A

20 March 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).

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Oral explanation meetings:

Wednesday 18 March 2015, 11:00 – 12:00

Wednesday 18 March 2015, 14:00 – 15:00

Wednesday 18 March 2015, 16:00 – 17:00

Thursday 19 March 2015, 12:00 – 13:00

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 18 - 20 March 2015.

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

I.4 External attendance

I.5 Leaving / New Members and Alternates

The PDCO welcomes Irene Pericleous in her new role as alternate, nominated to represent Cyprus.

The PDCO would like to thank Andreas Teloudes for his work at the end of his mandate as alternate.

II Opinions

II.1 Opinions on Products

Neurology

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 60 opinion

Cardiovascular Diseases

Day 60 opinion

Immunology-Rheumatology-Transplantation

Day 60 opinion

Pain

Day 60 opinion

Oncology

Day 60 opinion

Other

Day 60 opinion

Infectious Diseases

Day 120 opinion

Oncology

Day 120 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 120 opinion

Gastroenterology-Hepatology

Day 120 opinion

Pneumology – Allergology

Day 120 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

Haematology-Hemostaseology

Day 60 opinion

Neurology

Day 60 opinion

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

Uro-nephrology

Day 60 opinion

Dermatology / Pneumology - Allergology / Oto-rhino-laryngology

Day 60 opinion

Cardiovascular Diseases

Day 60 opinion

Vaccines

Day 60 opinion

Immunology-Rheumatology-Transplantation

Day 60 opinion

Infectious Diseases

Day 60 opinion

Oncology

Day 60 opinion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 60 opinion

Other

Day 60 opinion

Day 60 opinion

II.4 Opinions on Re-examination

Endocrinology-Gynaecology-Fertility-Metabolism

III Discussion of applications

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

Gastroenterology-Hepatology

Day 30 discussion

Immunology-Rheumatology-Transplantation

Day 60 discussion

Dermatology

Day 60 discussion

Day 90 discussion

Infectious Diseases

Day 60 discussion

Day 90 discussion

Diagnostic / Oncology

Day 30 discussion

Vaccines

Day 90 discussion

Ophthalmology

Day 60 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 30 discussion

Day 60 discussion

Neurology

Day 30 discussion

Day 60 discussion

Pneumology - Allergology

Day 30 discussion

Day 60 discussion

Day 90 discussion

Other

Day 60 discussion

Day 90 discussion

Cardiovascular Diseases

Day 30 discussion

Day 90 discussion

Uro-nephrology

Day 30 discussion

Oncology

Day 90 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.

Oncology

Day 30 discussion

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

Immunology-Rheumatology-Transplantation / Haematology-Hemostaseology

Day 30 discussion

Uro-nephrology

Day 30 discussion

Other

Day 30 discussion

Dermatology

Day 30 discussion

Haematology-Hemostaseology

Day 30 discussion

Immunology-Rheumatology-Transplantation

Day 30 discussion

Cardiovascular Diseases

Day 30 discussion

Neurology

Day 30 discussion

Endocrinology-Gynaecology-Fertility-Metabolism

Day 30 discussion

Infectious Diseases

Day 30 discussion

IV Nominations of Rapporteurs and Peer reviewers

IV.1 Nominations for paediatric procedures

• List of letters of intent received for submission of applications with start of procedure May 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

IV.2 Nominations for other activities

Early paediatric interaction meeting	For information
Appointment of PDCO representative in Cross-Committee Task Force on Registries	For adoption

V Finalisation and adoption of opinions

VI Discussion on the applicability of class waiver

Class waiver number	Active substance	Applicant	Proposed indication	Condition	Rapporteur
EMEA-4-2015	MPDL3280A	Roche Registration Limited	Treatment of Previously Untreated Metastatic Triple Negative Breast Cancer	Treatment of breast carcinoma	Koenraad Norga
EMEA-5-2015 (EMEA-000480-PIP01-08-M07)	Ticagrelor (Brilique)	AstraZeneca AB	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 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, myocardial infarction,	Treatment of coronary athero-sclerosis	Marek Migdal

			and ischaemic stroke) in adult patients with acute ischaemic stroke or transient ischaemic attack.		
EMEA-6-2015 (EMEA-000480-PIP01-08-M07)	Ticagrelor (Brilique)	AstraZeneca AB	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: Prevention of atherothrombosis events in adult patients with Type 2 Diabetes at high risk forcardiovascular events	Treatment of coronary atherosclerosis	Marek Migdal
EMEA-7-2015	Polatuzumab vedotin (R05541077)	Roche Registration Limited	Treatment of patients with follicular lymphoma	Treatment of Follicular Lymphoma	Koenraad Norga
EMEA-8-2015	^{18}F-fluoroestradiol	LABORATOIRES CYCLOPHARMA	Assessment of the estrogen receptor content of tumours in metastatic breast cancer using positron	Treatment of breast carcinoma	Koenraad Norga

			emission tomography (PET).		
EMEA-11-2015	Margetuximab	MacroGenics, Inc.	Treatment of patients with metastatic or locally advanced HER2-positive breast cancer and who have previously been treated with anti-HER2-targeted therapy	Treatment of breast carcinoma	Koenraad Norga

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

PIP number	Active substance	Applicant	Proposed indication	Condition	Rapporteur
EMEA-000081-PIP01-07-M07	dabigatran etexilate (Pradaxa)	Boehringer Ingelheim International GmbH	Prevention of recurrent stroke in patients with Embolic Stroke of Undetermined Source (ESUS)	Prevention of thrombo-embolic events	Marek Migdal

VIII Annual reports on deferrals

Annual report based on PIP decision for	Active substance	Applicant	Product Name	Orphan drug	Difficulties progressing the PIP?
EMEA-000311-PIP04-13	ustekinumab	Janssen-Cilag International NV	Stelara	No	No
EMEA-001115-PIP01-10	Loxapine	Alexza UK, Limited	Adasuve	No	Yes
EMEA-000469-PIP01-08	anidulafungin	Pfizer Limited	Ecalta	No	Yes
EMEA-000081-PIP01-07	dabigatran etexilate given as mesilate	Boehringer Ingelheim International GmbH	Pradaxa	No	Yes
EMEA-000170-PIP02-10	Eltrombopag	GlaxoSmithKline Trading Services Limited	Revolade	Yes	No
EMEA-000637-PIP02-10	Lanthanum carbonate hydrate	Shire Pharmaceutical Contracts Ltd	"Fosrenol" in the RMS (Sweden) and associated name "Foznol"	No	Yes
EMEA-000597-PIP02-10	mirabegron	Astellas Pharma Europe B.V.	Betmiga	No	No
EMEA-001175-PIP01-11	albiglutide	GlaxoSmithKline LLC	Eperzan	No	No
EMEA-001143-PIP01-11	Cabozantinib	Exelixis, Inc.	Cometriq	Yes	No
EMEA-000087-PIP01-07	Fingolimod hydrochloride	Novartis Europharm Limited	Gilenya	No	Yes
EMEA-000718-PIP01-09	Riociguat	Bayer Schering Pharma AG	Adempas	Yes	No
EMEA-000912-	(1R,2S)-6-	Janssen Infectious	Sirturo	Yes	No

Annual report based on PIP decision for	Active substance	Applicant	Product Name	Orphan drug	Difficulties progressing the PIP?
PIP01-10	bromo-alpha-[2-(dimethylamino) ethyl]-2-methoxy-alpha-1-naphthalenyl-be	Diseases BVBA			
EMEA-000673-PIP01-09	Pneumo-coccal poly-saccharide serotype 23F conjugated to Protein D	GlaxoSmithKline Biologicals S.A.	Synflorix	No	Yes
EMEA-000178-PIP01-07	Purified antigen fractions of inactivated split virion Influenza A/Indonesia/5/0	GlaxoSmithKline Biologicals S.A.	Pumarix	No	No
EMEA-000817-PIP02-11	Purified antigen fractions of inactivated split virion Influenza manufactured in the Dresden plant: A/H1N1 A/H3N2 B/Victoria B/Yamagata	GlaxoSmithKline Biologicals S.A.	Influsplit Tetra and associated names	No	No
EMEA-000696-PIP02-10	Eslicarbazepine acetate	BIAL - Portela & Ca, SA	Exalief, Zebinix	No	Yes

IX Other topics

Guidelines	
Guideline on clinical investigation of medicinal products for the treatment of Multiple Sclerosis rev. 2	For agreement
Working groups	
Formulation	Documents tabled for information
Non-Clinical	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
Other topics	
Neuromyelitis Optica (NMO)workshop – conclusion on paediatrics	For information
Feedback from the HCV Expert Meeting and next steps	For information

International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) E11 Clinical Investigation of Medicinal Products in the Paediatric Population Revision – status update Dirk Mentzer	For information
Outcome of Scientific Advice / Protocol Assistance with paediatric questions	For discussion
Breakout sessions	
Neonatology	Thursday, meeting room 2E
Paediatric oncology	Thursday, meeting room 2D
Inventory	Thursday, meeting room 2C

Any other business