16 July 2014
EMA/PDCO/364111/2014
Procedure Management and Business Support Division

Paediatric Committee (PDCO)

Minutes of the 18-20 June 2014 meeting

Chair: Dirk Mentzer - Vice-chair: Koenraad Norga

Note on access to documents

Some documents mentioned in the agenda/minutes cannot be released at present following a request for access to documents under 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).

Disclaimers

Some of the information contained in the PDCO discussions is considered commercially confidential or sensitive and therefore not disclosed in the present minutes. 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 disclosed 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). Documents mentioned in these minutes cannot be released at present as they are currently in draft format or are classified as confidential. They will become public when adopted in their final form or considered public according to the principles stated in the Agency policy on access to documents (EMA/127362/2006). Of note, this set of minutes is a working document primarily designed for PDCO members and the work the Committee undertakes.

I Introduction

I.1 Adoption of the minutes from previous meeting

The Minutes of the PDCO plenary session held 22-23 May 2014 were adopted.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7523 7040
E-mail info@ema.europa.eu **Website** www.ema.europa.eu
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I.2 Adoption of the Agenda

The agenda was adopted with amendments.
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

All decisions taken at this meeting were made in presence of a quorum of members – i.e. 23 or more members were present in the room.

I.3 Declaration of Conflict of Interest

See Annex I

I.4 External attendance

Please refer to the June 2014 PDCO monthly report published on the EMA Website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

I.5 Leaving/New Members and Alternates

Please refer to the June 2014 PDCO monthly report published on the EMA Website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

II Opinions

II.1 Opinions on Products

II.2 Opinions on Compliance Check

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

Please refer to the June 2014 PDCO monthly report published on the EMA Website:

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab

III Discussion of applications

The PDCO discussed 100 procedures in total[1], of which:

- 38 paediatric investigation plan applications;
- 9 product-specific waiver applications;
- 14 compliance check procedures (interim and final);
- 39 requests for modifications of an agreed paediatric investigation plan.

[1] The procedures discussed by the PDCO are on-going and therefore are considered confidential. Additional details on these procedures will be disclosed 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).

IV Nomination

IV.1 Nomination of Rapporteurs and Peer reviewers

• List of letters of intent received for submission of applications with start of procedure August 2014[1] for Nomination of Rapporteur and Peer reviewer • Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver	The PDCO approved the lists of Rapporteurs and Peer Reviewers.

IV.2 Nomination for other activities

Translator list for EC guideline	The collaboration of PDCO members was requested, to assist the translation service of the EC for the language versions of the revised guideline on the format and content of PIP/waiver applications.

V Update and finalisation of opinions and requests for modification

The opinions adopted during the Paediatric Committee meeting of June 2014 are published on the same month's meeting report published in the EMA website: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/document_listing/document_listing_000192.jsp&mid=WC0b01ac0580028eab.

VI Discussion on the applicability of class waiver

Active substance	Proposed indication	Condition	Outcome	Potential paediatric interest of this medicine suggested by PDCO
Emixustat Hydrochloride	Treatment of geographic atrophy associated with age-related macular degeneration	Treatment of age-related macular degeneration	Confirmed	N/A
Rituximab	In combination with chemotherapy for the treatment of adult patients with previously untreated and relapsed/refractory chronic lymphocytic leukaemia	Treatment of chronic lymphocytic leukaemia	Confirmed	N/A

Active substance	Proposed indication	Condition	Outcome	Potential paediatric interest of this medicine suggested by PDCO
DNIB0600A (company code)	Treatment of patients with non-small cell lung cancer	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Confirmed	There is a scientific rationale for further studies in various paediatric malignancies to identify tumor types that may respond to this product.
DNIB0600A (company code)	Treatment of patients with ovarian cancer	Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)	Confirmed	There is a scientific rationale for further studies in various paediatric malignancies to identify tumor types that may respond to this product.
Topsalysin, PRX302	Treatment and control of benign prostatic hyperplasia (BPH) in patients with enlarged prostate	Treatment of Benign Prostatic Hyperplasia	Confirmed	N/A

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

No requests were received for the month of June.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan	Difficulties progressing the PIP?	Outcome
EMEA-000583-PIP01-09	boceprevir	Victrelis	No	Yes	The PDCO noted the report. A PIP

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan	Difficulties progressing the PIP?	Outcome
					modification requesting a full waiver has been submitted.
EMEA-000342-PIP01-08	Sunitinib malate	Sutent	No	Yes	The PDCO noted the report as well as previous and ongoing procedures.
EMEA-001095-PIP02-12	Natalizumab	Tysabri	No	No	The PDCO noted the report.
EMEA-001332-PIP01-12	Estetrol & Drospirenone	Estelle	No	Yes	The PDCO noted the report and will await the applicants' next steps as announced in the report.
EMEA-000235-PIP02-10	Aripiprazole	Abilify	No	No	The PDCO noted the report.
EMEA-000308-PIP02-11	Rituximab	MabThera	No	No	The PDCO noted the report.
EMEA-000373-PIP02-09	Ferumoxytol	Rienso	No	Yes	The PDCO noted the report. A PIP modification is planned by the applicant.

IX Other topics

Guidelines	
Presentation of the Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections	The chair of the CHMP Infectious Disease Working Party (IDWP) presented to the PDCO the "Addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections", outlining the new regulatory pathway for anti-infectives addressing a specific unmet need: limited evidence of clinical safety and efficacy could be accepted to support an initial approval for the treatment of infections caused by multidrug-resistant (MDR) organisms for which there are few therapeutic options.
Guideline on asthma	Discussion postponed to PDCO July 2014 meeting.
Guideline on Influenza vaccines	The revision of the guidelines on influenza vaccines has been planned with the aim of developing one single influenza guideline that covers the regulatory, quality, non-clinical and clinical aspects. The draft guideline was agreed by VWP. PDCO to provide comments by the 26 June 2014.
Working groups	
Paediatric inventory	The group discussed the inventory for the therapeutic area of oncology.
Paediatric oncology	The group prepared product-related discussions.
Extrapolation	Meeting cancelled.
Formulation	No non-product related issues were reported to the Committee.
Non-Clinical	No non-product related issues were reported to the Committee.
Other topics	
CHMP update on paediatric topics	Document tabled for information.
PIP on DTaP-containing combination vaccine: feedback from VWP	The Committee was informed that the VWP is finalising its answer to the PDCO's letter on this issue. Their answer will be circulated to PDCO members via the June 2014 post-meeting mail.
CoI policy	Postponed to PDCO July 2014 meeting.
Update on Enpr-EMA activities	The agenda of the forthcoming annual Enpr-EMA workshop was presented to the Committee.

Initial consultation on paediatric development	The Committee discussed the proposed new procedure "Initial consultation on paediatric development" and its role in the global "one-stop shop" initiative of the Agency. Several concerns were raised regarding in particular the risk of introducing additional workload, without a corresponding fee to cover the additional effort. A presentation on the concept and practical implementation was shown by the EMA Secretariat. The PDCO formed a subgroup to contribute and refine the proposal, which is scheduled to be discussed via teleconference.
PDCO Meeting Dates 2016, 2017, 2018	The PDCO adopted the meeting dates for 2016, 2017, and 2018.
Chlorhexidine cutaneous solutions and chemical skin burns in neonates Angeliki Siapkara	The PDCO was informed about the ongoing PRAC procedure and discussed the list of questions to the PDCO. These will be also distributed in the June 2014 post-meeting mail so further input can be provided by the PDCO members for the final discussion at the next PDCO meeting.
Funds - Horizon 2020	The PDCO was updated on the status of paediatric funding and discussed the way forward including the planned interaction with the EC and stakeholders.
Draft Agenda for Informal PDCO/SAWP, 16-17 October 2014, Rome Paolo Rossi	The Committee agreed with the topics currently identified in the draft agenda of the joint informal PDCO/SAWP meeting to be held in Rome in October 2014 under the auspices of the Italian Presidency of the Council of the European Union.
Paediatric inventory	Cancelled

Any other business

Annex I to the Minutes of the PDCO of June 2014

Documentation on Declaration of interest of members, alternates and experts

Based on the Declarations of interest submitted by the Committee members, alternates and experts and based on the topics in the agenda of the current meeting, the Committee Secretariat announced the restricted involvement of Committee members for the upcoming discussions.

In accordance with the Agency's revised Policy and Procedure on the handling of conflicts of interests, participants in this meeting were asked to declare any conflict of interests on the matters for discussion (in particular any changes, omissions or errors to the already declared interests).

No new or additional conflicts were declared.

Member, alternate, expert name	Outcome restriction following evaluation of electronic evaluation form	Topics on the current Committee Agenda for which this restriction applies
Adriana Ceci	Restriction level XR	EMEA-000527-PIP04-13
Adriana Ceci	Restriction level DP	EMEA-001619-PIP01-14
Adriana Ceci	Restriction level DP	EMEA-001530-PIP01-13
Adriana Ceci	Restriction level DP	EMEA-000265-PIP01-08-M04
Adriana Ceci	Restriction level DP	EMEA-21-2014
Alexandra Compagnucci	Restriction level XC	EMEA-000527-PIP04-13
Alexandra Compagnucci	Restriction level XC	EMEA-001485-PIP01-13
Alexandra Compagnucci	Restriction level XC	EMEA-001527-PIP01-13
Alexandra Compagnucci	Restriction level XC	EMEA-001452-PIP01-13
Alexandra Compagnucci	Restriction level XC	EMEA-001501-PIP02-13
Alexandra Compagnucci	Restriction level XC	EMEA-000689-PIP01-09-M05
Alexandra Compagnucci	Restriction level XC	EMEA-000455-PIP02-10-M02
Alexandra Compagnucci	Restriction level XR	EMEA-001191-PIP01-11-M01
Alexandra Compagnucci	Restriction level XC	EMEA-000184-PIP01-08-M02
Alexandra Compagnucci	Restriction level XC	EMEA-001618-PIP01-14
Alexandra Compagnucci	Restriction level XC	EMEA-001613-PIP01-14
Alexandra Compagnucci	Restriction level XC	EMEA-001497-PIP01-13
Alexandra Compagnucci	Restriction level XC	EMEA-000599-PIP01-09-M04
Alexandra Compagnucci	Restriction level XC	EMEA-19-2014
Carine de Beaufort	Restriction level XR	SA procedure

Member, alternate, expert name	Outcome restriction following evaluation of electronic evaluation form	Topics on the current Committee Agenda for which this restriction applies
Christoph Male	Restriction level XP/DP/XR	EMEA-000527-PIP04-13
Christoph Male	Restriction level XP/DP/XR	EMEA-001456-PIP01-13
Christoph Male	Restriction level XP/DP/XR	EMEA-001215-PIP01-11-M01
Christoph Male	Restriction level XP/DP/XR	EMEA-000480-PIP01-08-M06
Christoph Male	Restriction level XP/DP/XR	SA procedure
Marek Migdal	Restriction level DP	SA procedure
Marek Migdal	Restriction level DP	SA procedure
Marina Dimov Di Gusti	Restriction level DC	EMEA-001501-PIP02-13
Paolo Rossi	Restriction level XR	EMEA-000576-PIP03-12
Paolo Rossi	Restriction level DP/XR	EMEA-001493-PIP01-13
Paolo Rossi	Restriction level DP/XR	EMEA-001533-PIP01-13
Paolo Rossi	Restriction level DP/XR	SA procedure
Paolo Rossi	Restriction level XR	EMEA-000120-PIP01-07-M04
Violeta Iotova	Restriction level XP	EMEA-001527-PIP01-13
Violeta Iotova	Restriction level XP	EMEA-001533-PIP01-13

Discussions, deliberations and voting took place in full respect of the restricted involvement of Scientific Committee members and, where relevant, experts attending the plenary meeting, as announced by the Scientific Committee Secretariat at the start of meeting.

Restriction levels:

Evaluation of the conflict of interest	
Outcome	Impact
R-P	To be replaced for the discussions, final deliberations and voting as appropriate in relation to the relevant product or a competitor product.
XP	Where Individual product involvement is declared - PRODUCT INDICATION: - No involvement with respect to procedures involving the relevant product or a competitor product in the relevant indication i.e. no part in discussions, final deliberations and voting as appropriate as regards these medicinal products. - Cannot act as Rapporteur for these products - [Cannot act as Rapporteur for development of guidelines in concerned therapeutic area].
XC	Where cross product / general involvement is declared - COMPANY: - No involvement (as outlined above) with respect to products from the specified company. - Cannot act as Rapporteur for products from the relevant company(ies).

DP	Where Individual product involvement is declared - PRODUCT INDICATION: - Involvement in discussions only with respect to procedures involving the relevant product or a competitor product i.e. no part in final deliberations and voting as appropriate as regards these medicinal products. - Cannot act as Rapporteur for these products.
DC	Where cross product / general involvement is declared - COMPANY: - Involvement in discussions only with respect to products from the specified company. - Cannot act as Rapporteur on products from the relevant company(ies).
XR	Committee member cannot act as Rapporteur or Peer reviewer in relation to any medicinal product from the relevant company.
R-C	To be replaced for the discussions, final deliberations and voting as appropriate in relation to any medicinal product from the relevant company

Annex II to the Minutes of the PDCO of June 2014

List of Participants

Chair

Dirk MENTZER

Members appointed by Member States or CHMP

Koenraad NORGA	Belgium
Violeta IOTOVA	Bulgaria
Marina DIMOV DI GUSTI	Croatia
George SAVVA	Cyprus
Pirjo LAITINEN-PARKONNEN	Finland
Sylvie BENCHETRIT	France
Birka LEHMANN	Germany
Grigorios MELAS	Greece
Agnes GYURASICS	Hungary
Gylfi OLKARSSON	Iceland
Kevin CONNOLLY	Ireland
Paolo ROSSI	Italy
Dina APELE-FREMIANE	Latvia
Carine de BEAUFORT	Luxembourg
Hendrik van den BERG	The Netherlands
Siri WANG	Norway
Marek MIGDAL	Poland
Helena FONSECA	Portugal
Dana Gabriela MARIN	Romania
Stefan GROSEK	Slovenia
Fernando DE ANDRÉS TRELLES	Spain
Angeliki SIAPKARA	United Kingdom

Alternates appointed by Member States or CHMP

Christoph MALE	Austria
Jacqueline CARLEER	Belgium
Marta GRANSTRÖM	Denmark
Immanuel BARTH	Germany
Stefanos MANTAGOS	Greece
Brian AYLWARD	Ireland
Francesca ROCCHI	Italy
Herbert LENICKER	Malta
Jolanta WITKOWSKA-OZOGOWSKA	Poland
Hugo TAVARES	Portugal
Maria Jesus FERNANDEZ CORTIZO	Spain
Ninna GULLBERG	Sweden
Martina RIEGL	United Kingdom

Members representing patients' organisations

Tsveta SCHYNS-LIHARSKA, European Network for Research on Alternating Hemiplegia, Belgium

Alternates representing patients' organisations

Gerlind BODE, Deutsche Leukämieforschungshilfe and Deutsche Kinderkrebsstiftung, Germany

Members representing health care professionals

Anthony James NUNN, Alder Hey Children's Hospital, UK

Alternates representing health care professionals

Paolo PAOLUCCI, Polyclinic of Modena, Italy

European Medicines Agency support

Meeting run with relevant support from the EMA staff