21 May 2014
EMA/PDCO/212992/2014
Procedure Management and Business Support Division

Paediatric Committee (PDCO)

Minutes of the 23-25 April 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

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

I.2 Adoption of the Agenda

Adopted with modifications.

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

I.3 Declaration of Conflict of Interest

See Annex I

I.4 External attendance

Please refer to the April 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 April 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 April 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 72 procedures in total, of which:

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

IV Nomination of Rapporteurs and Peer reviewers

• List of letters of intent received for submission of applications with start of procedure June 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	The PDCO approved the lists of Rapporteurs and Peer Reviewers.

V Update and finalisation of opinions and requests for modification

All opinions taken at this meeting (relating to adoption of opinions, recommendations, requests for modifications and applicability of class waivers) were made in the presence of the required quorum of members.

The opinions adopted during the Paediatric Committee meeting of April 2014 are published in the same month's meeting 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.

VI Discussion on the applicability of class waiver

Active substance	Proposed indication	Condition	Outcome	Potential paediatric interest of this medicine suggested by PDCO
(18F)-Fluoromethylcholine	Initial staging of prostate cancer: regional nodal disease and distant metastases	Treatment of prostate carcinoma (excluding rhabdomyosarcoma)	Not confirmed. The medicinal product development plans to address the diagnosis of prostate cancer, which cannot be considered covered by the class waiver condition for treatment of prostate cancer.	N/A
Cediranib (AZD2171)	Cediranib, in combination with platinum-based chemotherapy, followed by monotherapy maintenance, is indicated for the treatment of adult patients with	Treatment of ovarian carcinoma (excluding rhabdomyosarcoma and germ cell tumours)	Confirmed. 3 class waiver conditions are concerned: • Treatment of ovarian carcinoma (excluding	A PIP for treatment of high-grade glioma has already been agreed.

Active substance	Proposed indication	Condition	Outcome	Potential paediatric interest of this medicine suggested by PDCO
	platinum sensitive relapsed (PSR) ovarian cancer (including fallopian tube or primary peritoneal)		rhabdomyosarcoma and germ cell tumours) • Treatment of Fallopian tube carcinoma (excluding rhabdomyosarcoma and germ cell tumours) • Treatment of peritoneal carcinoma (excluding blastomas and sarcomas)	
S 47445	Symptomatic treatment of mild to moderate Alzheimer's disease in patients with depressive symptoms	Treatment of Alzheimer's disease	Confirmed.	• Autism • Schizophrenia as add-on therapy • Depressive and anxiety disorder • Attention Deficit/ Hyperactivity disorder
Pimavanserin tartrate	Treatment of Alzheimer's disease psychosis (ADP) Treatment of Parkinson's disease psychosis (PDP)	Treatment of Alzheimer's disease Treatment of Parkinson's disease (non-juvenile)	Not confirmed. The treatment of psychosis complications of Alzheimer's disease was considered to be a distinct condition from the treatment of Alzheimer's disease.	N/A

Active substance	Proposed indication	Condition	Outcome	Potential paediatric interest of this medicine suggested by PDCO
Bavituximab	Treatment of previously treated non-squamous non-small cell lung cancer	Treatment of lung carcinoma (small cell and non-small cell carcinoma)	Confirmed.	After efficacy and safety are demonstrated in adults, this medicinal product could have a potential in the treatment of various solid tumours and chronic viral infections (e.g. HCV and HIV) in children. There is a potential need for developing bavituximab for use in children with hepatoblastoma, neuroblastoma and other solid tumours refractory to treatment and also for children with chronic viral infections.
Doxorubicin hydrochloride	Treatment of unresectable hepatocellular carcinoma (HCC) after sorafenib	Treatment of liver and intrahepatic bile duct carcinoma (excluding hepatoblastoma)	Confirmed.	Doxorubicin-resistant paediatric malignancies.
E2609	Treatment of Alzheimer's disease	Treatment of Alzheimer's disease	Confirmed.	• Fragile X syndrome • Down syndrome • Epilepsy

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

PIP number	Active substance	Proposed indication	Condition	Outcome
EMEA-000019-PIP03-08	Everolimus	Treatment of adult patients with progressive neuroendocrine tumours of gastrointestinal or lung origin	Treatment of carcinoid tumours	The PDCO did not confirm the inclusion of the proposed indication ("Treatment of adult patients with progressive neuroendocrine tumours of gastrointestinal or lung origin") within the agreed PIP condition ("Treatment of carcinoid tumours"). The proposed indication was considered wider than the agreed condition. Neuroendocrine tumours also encompass tumours with no carcinoid syndrome. Therefore a separate PIP or Waiver application should be submitted by the applicant.
EMEA-000329-PIP02-09	Darbepoetin alfa (Aranesp)	Treatment of anaemia due to myelodysplastic syndromes (MDS)	Treatment of anaemia due to chronic disorders	The PDCO was of the view that the proposed indication "Treatment of anaemia due to myelodysplastic syndromes (MDS)", is not covered by the condition "Treatment of anaemia due to chronic disorders" listed in the

PIP number	Active substance	Proposed indication	Condition	Outcome
				Agency's Decision. The indication "Treatment of anaemia due to myelodysplastic syndromes (MDS)" was not discussed by the PDCO in the context of anaemias due to chronic disorders. Moreover, it is considered that marrow depression and hypoplastic anaemias are different conditions.

VIII Annual reports on deferrals

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan	Difficulties progressing the PIP?	Outcome
EMEA-000153-PIP01-07	Piperaquine phosphate anhydride / Dihydroartemisinin	Eurartesim	Yes	Yes	Delays were reported due to trial authorisation and recruitment issues. The applicant plans to submit a request for modification in the near future.
EMEA-000347-PIP01-08	Bilastine	Bilaxten	No	No	The PDCO noted the report.
EMEA-000713-PIP02-10	pixantrone dimaleate	Pixuvri	Yes	No	The PDCO noted the report and was made aware of the issues addressed in

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan	Difficulties progressing the PIP?	Outcome
					the recent PIP modification.
EMEA-000777-PIP01-09	Artemether (20mg) and lumefantrine (120mg)	RIAMET	No	Yes	PIP modification on going.
EMEA-000178-PIP01-07-M03	Purified antigen fractions of inactivated split virion Influenza A/Indonesia/05/2005 (H5N1) like strain used	Pumarix	No	No	The PDCO was informed that there are no issues as regards the progression of the PIP studies.
EMEA-000128-PIP02-09	Liraglutide	Victoza	No	No	The PDCO was informed that there are no issues as regards the progression of the PIP studies.
EMEA-000309-PIP01-08	Tocilizumab	Tocilizumab Roche	No	No	The PDCO was informed that there are no issues as regards the progression of the PIP studies.
EMEA-000673-PIP01-09	Pneumococcal polysaccharide serotype 23F conjugated to Protein D	Synflorix	No	Yes	The PDCO was informed that there are no issues as regards the progression of the PIP studies.
EMEA-000054-PIP01-07, EMEA-000300-PIP01-08, EMEA-000301-PIP01-08	Pitavastatin calcium		No	No	The PDCO was informed that there are no issues as regards the progression of the PIP studies.

Annual report based on PIP decision for	Substances (abbrev.)	Product Name	Orphan	Difficulties progressing the PIP?	Outcome
EMEA-000065-PIP01-07	telbivudine	Sebivo	No	No	The PDCO was informed that there are no issues as regards the progression of the PIP studies.
EMEA-000436-PIP01-08	Mannitol	Bronchitol	Yes	No	The PDCO noted the report.
EMEA-001201-PIP01-11	Haemophilus influenzae type b polysaccharide conjugated to tetanus protein	Hexaxim	No	No	The PDCO was informed that there are no issues as regards the progression of the PIP studies.
EMEA-001261-PIP01-11	Eribulin	Halaven	No	Yes	The PDCO was informed of the issues regarding the progression of the PIP studies and that, as far as completion is concerned, studies are progressing as expected.

IX Other topics

Guidelines	
Concept paper on the revision of the guideline on conduct of pharmacovigilance for medicines used by the paediatric population	The PDCO adopted the concept paper on the revision of the guideline on conduct of pharmacovigilance for medicines used by the paediatric population.. The PRAC adopted that same concept paper at the PRAC ORGAM April 2014 meeting. The revised guideline will be drafted and presented to both PRAC and PDCO in due course.

Guideline on the clinical development of medicinal products intended for the treatment of chronic primary immune thrombocytopenia (Adopted by CHMP)	The guideline, adopted by the CHMP in February 2014 and published on EMA external website, will come into effect in September 2014.
Guideline on the clinical investigation of human normal immunoglobulin for subcutaneous and/or intramuscular administration (SCIg/IMIg) - Draft revised guideline and overview of comments	The Draft revised guideline and overview of comments were agreed by PDCO in view of CHMP adoption.
Guideline on clinical investigation of hepatitis B immunoglobulin (updated with comments after public consultation)	Postponed to next PDCO plenary meeting.
Working groups	
White paper drafting group: The paediatric regulation beyond 2017	The Paediatric Regulation is scheduled for revision in 2017. The PDCO created an ad-hoc working group to discuss the topic, with a view to providing input to the European Commission for the revision process. This first meeting was seen as a brain-storming session to establish the way forward.
Paediatric inventory	The PDCO working group discussed the therapeutic areas of oncology and ophthalmology. The inventory for ophthalmology was prepared for adoption by the PDCO for public consultation.
Paediatric oncology	The PDCO working group discussed the further collaboration and contribution to working groups of the BDA Paediatric Oncology platform and drafted a work plan for discussions of paediatric oncology matters in the Inter-committee Scientific advisory group-Oncology (IC SAG-O), with the members of the former Paediatric oncology task force.
Extrapolation	The PDCO working group meet informally, and the aspects of the extrapolation topics coordination with other groups such as biostatistics, modelling and simulation, scientific advice working parties were discussed. A need for structured interactions was identified. A system will be set to ensure that the right expertise at the right time is available.
Formulation	No non-product related issues where reported to the Committee.
Non-Clinical	No non-product related issues where reported to the Committee.

Other topics	
CHMP update on paediatric topics	The PDCO members were informed about the final CHMP opinions on medicinal products with paediatric relevance adopted in March 2014.
Update on Enpr-EMA activities	No updates were to be reported.
Draft inventory of paediatric therapeutic needs - Ophthalmology for public consultation	The inventory was adopted for public consultation. Comments were received from Spain, which will be taken into consideration in the consultation phase.
Draft standard PIP on DTP-containing vaccine: document for PDCO comments	The PDCO discussed the Draft standard Paediatric Investigation Plan for DTaP combination containing vaccine. This document drafted following 2 meetings with a panel of public health vaccinology experts, convened by the ECDC and EMA. During the second expert meeting, it was agreed to enlarge the scope of the document to any DTaP combination containing vaccine. It was proposed to conduct trials in 2 countries where immunization strategies differ, to account for the historical background of previous immunizations in life and risk of interference with maternal antibodies at 2 months of age. The proposed time window of +/- 2 weeks around the schedule for the clinical trials was revised. The design of the first study with priming schedule was simplified to evaluate only one concomitant pneumococcal vaccine. The need for seroprotective titres as part of the primary endpoint evaluating immunogenicity was discussed. It was discussed whether non-inferiority to comparator for each valence could be the primary endpoint. The Paediatric Committee endorsed the enlarged scope, the conduct of the trials in 2 different countries and the revised schedule proposed. The Committee was not in favour of evaluating the concomitant pneumococcal vaccine against placebo. Placebo is not usually part of a paediatric vaccine clinical development. It was considered enough to have a 2 arms study design, evaluating the new vaccine with concomitant pneumococcal vaccine against a known vaccine of same valences with concomitant pneumococcal vaccine. According to the CHMP Note for Guidance on the clinical evaluation of vaccines (CHMP/VWP/164653/2005), “for antigens for which a widely accepted immunological correlate of protection already exists (e.g. diphtheria

	and tetanus toxoids and hepatitis B surface antigen), evaluation of the immune response to these antigens in a candidate vaccine may be limited to the usual parameters used to assess immunogenicity (and, thus, predict protective efficacy). For well-known antigens for which no immunological correlate of protection exists (e.g. pertussis toxin), evaluation of the immune response should at least employ a comparison with results obtained with other vaccines containing the same or similar antigens." The PDCO recommendations were in compliance with the CHMP guideline. A revised version incorporating those comments will be circulated in PDCO post-mail. The PDCO will adopt the draft standard PIP during May PDCO plenary, before addressing the document to the VWP and CHMP for review.
Inclusion of young adults into paediatric type 2 diabetes studies in PIPs: FDA and EMA views	The PDCO was informed of a recent discussion between EMA and FDA. The FDA flagged their concerns over allowing young adults (i.e. below 25 years of age) into paediatric type 2 diabetes studies. Firstly, the FDA has scientific concerns over the lack of data which demonstrates that the PK (and PD) behaves similarly in young adults and adolescents. Secondly, it would appear that in the US (where most of the patients are found) it is difficult or not possible to conduct studies that involve both adults and children. The EMA clarified that the basis for allowing young adults into the paediatric T2D studies was an expert consensus from the meeting taking place at EMA in February 2013 on paediatric T2D. The European and US experts at the meeting agreed that young adults behave very similar compared to adolescents as regards clinical presentation and therapeutic needs and that most young adults with T2D had the disease onset during childhood. Furthermore, it was pointed out that in any case different regulatory requirements on age inclusion criteria would not prevent the possibility of a single paediatric development: it would be sufficient to comply with the stricter requirement to be also compliant with the other requirement.

Comments from NcWG/SWP on the ICH Juvenile Draft Concept Paper	The main comment from NcWG/SWP was that the guideline should cover a broader scope. In particular: 1. the guideline should cover the "nonclinical strategy to support the development of paediatric medicines" (e.g. including also pharmacology aspects) rather than to be restricted to the need of juvenile toxicity studies; 2. all therapeutic fields and types of products should be covered to ensure the safety of children (including risk monitoring or minimisation) in paediatric trials. A comprehensive review of nonclinical juvenile versus adult data was strongly endorsed. This could form a solid basis for recommendations on the use of studies in certain situations and on study designs. However, the question is who will do this review as it will be very resource intense as learned from the on-going EMA/NcWG/PDCO review of the nonclinical juvenile versus adult data in the area of oncology. During the ICH Steering Committee (SC) meeting (TC) mid April 2014, PhRMA did not have any objections to the EMA comments an updated concept paper is likely to be circulated. The next meeting of the SC will take place in Minneapolis (US) in June 2014.
Revision of class waivers	The PDCO resumed its discussion of the revision of the class waivers, and intends to revise the current list in the next meetings. The issue will also be discussed at the next EMA Scientific Coordination Board.
Definition of the condition(s) for the PIP/waiver opinions	The PDCO discussed how evolving scientific knowledge and experience is to be used to define the scope of the PIP. In conjunction with the revision of the class waivers, a draft action plan for paediatric oncology was agreed.
Experts nomination for the Paediatric Formulary Group	The PDCO nominated two PDCO representatives to the Paediatric Formulary Group of the European Pharmacopoeia: Professor Anthony Nunn and Doctor Siri Wang.

Advanced Therapy Medicinal Products (ATMPs) at the PDCO, collaboration CAT-PDCO	At last year's PDCO-CAT informal meeting, the collaboration between the two committees was presented. In all aspects of PIPs, the CAT has been providing help, from quality to endpoint design and follow-up requirements. Also, waiver requests in principle as well as significant therapeutic benefit have been subject to discussions.
Flexibility in the timeline for submission of PIP/waiver applications	The PDCO discussed a proposal to create a new procedure, the "Initial consultation on paediatric development", which will include a pre-assessment of the applicant's proposed global paediatric strategy by the Rapporteur, Peer Reviewer and Paediatric coordinator. The Committee agreed that this new procedure should include full discussion at the PDCO, result in an outcome letter to the applicant, and would constitute appropriate justification for a 'late' submission of a PIP/waiver application (provided the submission is in line with the guidance received). The Agency is working on the necessary procedural details, and a public announcement is being prepared. More details on the procedure will be discussed at the next PDCO meeting.
Project 2014 - Move to Churchill Place	A presentation was given on the characteristics of the new EMA offices in Churchill Place. The first PDCO meeting in Churchill Place will be the August meeting, but the Paediatric Medicines Office will be moving in early July.
ISO IDMP standards: These standards cover the identification of medicinal products, substances and related controlled vocabularies.	Session aimed to provide an update on the international activities and the plan for the implementation of the ISO Identification of Medicinal Products Standards Their implementation is expected to have a massive impact on the EU network. In order to facilitate the implementation process the EMA proposed to set up a task force to gather input from all EU business processes and regulatory framework. The Task Force will meet on 24 May 2014. EMA will draft a list of expertise required for the European Task Force. PDCO experts were requested to volunteer as soon as possible to take part in the task force. The EMA representative will circulate the list of all Committees and Working Parties that have been approached.

Any other business

- Update from MHRA on Buccolam related activities: Angeliki Siapkara updated the Committee on the recent MHRA inspection on Buccolam.
- Handling extrapolation/modelling and simulation at PDCO: it was agreed that there is the need to have explicit presentation and discussion in the PDCO plenary about the level of extrapolation and the use of modelling and simulation to optimise paediatric development. Guidance on how to address extrapolation in PIP application should be published short term.
- Update on status of EC selection procedure for new patients' organisations representatives and healthcare professionals at PDCO: the EC observer updated the PDCO on the nomination of the representatives of civil society (healthcare professionals, parents of patients) in the PDCO; the participation of the new nominees is foreseen for the August PDCO.
- Debrief on the European experience on paediatric PBPK: a brief overview was given and call for providing information was made.
- Information related to the PDCO Informal Meeting in Portugal: proposed dates 30 May – 1 June 2014
- PDCO was informed that public consultation period of the revised asthma guideline ended; PDCO will be approached to review the comments received.
- Procedural obligations introduced at Day 120: the PDCO was reminded that any 'procedural obligations' in PIP Opinions need to be checked with the Agency Regulatory and Legal staff, and therefore they should not be added to the Opinions shortly before adoption, unless they have been explicitly discussed previously.

Annex I to the Minutes of the PDCO of April 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).

Member, alternate, expert name	Outcome restriction following evaluation of electronic evaluation form	Topics on the current Committee Agenda for which this restriction applies
Jaroslav Sterba	Restriction level DP	EMEA-001372-PIP02-13
Marek Migdal	Restriction level DP	EMEA-000525-PIP01-08-M02
Paolo Rossi	Restriction level XR	EMEA-000120-PIP01-07-M04

No new or additional conflicts were declared.

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 April 2014

List of Participants

Chair

Dirk MENTZER

Members appointed by Member States or CHMP

Karl Heinz HUEMER	Austria
Koenraad NORGA	Belgium
Violeta IOTOVA	Bulgaria
Marina DIMOV DI GUSTI	Croatia
George SAVVA	Cyprus
Jaroslav STERBA	Czech Republic
Pirjo LAITINEN-PARKONNEN	Finland
Birka LEHMANN	Germany
Agnes GYURASICS	Hungary
Paolo ROSSI	Italy
Dina APELE-FREMIANE	Latvia
Carola de BEAUFORT	Luxembourg
John Joseph BORG	Malta
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
Viveca Lena ODLIND	Sweden
Angeliki SIAPKARA	United Kingdom

Alternates appointed by Member States or CHMP

Christoph MALE	Austria

Jacqueline CARLEER	Belgium
Bernard KAIC	Croatia
Peter SZITANYI	Czech Republic
Marta GRANSTRÖM	Denmark
Immanuel BARTH	Germany
Brian AYLWARD	Ireland
Francesca ROCCHI	Italy
Ine Skottheim RUSTEN	Norway
Jolanta WITKOWSKA-OZOGOWSKA	Poland
Hugo TAVARES	Portugal
Maria Jesus FERNANDEZ CORTIZO	Spain
Ninna GULLBERG	Sweden
Martina RIEGL	United Kingdom

Members representing health care professionals

Anthony James NUNN

Observers

Parastoo Karoon	Medicines and Healthcare Products Regulatory Agency, United Kingdom

Observer from the European Commission

DG SANCO representative.

European Medicines Agency support

Meeting run with relevant support from the EMA staff