27 January 2016
EMA/PDCO/835743/2015
Procedure Management and Committees Support Division

Paediatric Committee (PDCO)

Minutes for the meeting on 09-11 December 2015

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

9 December 2015, 08:30- 19:00, room 3A

10 December 2015, 08:30- 19:00, room 3A

11 December 2015, 08:30- 13:00, room 3A

Disclaimers

Some of the information contained in this set of minutes 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. Additional details on some of 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 set of minutes is a working document primarily designed for PDCO members and the work the Committee undertakes.

Further information with relevant explanatory notes can be found at the end of this document.

Note on access to documents

Some documents mentioned in the minutes 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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1. Introductions

1.1. Welcome and declarations of interest of members, alternates and experts

In accordance with the Agency's policy on handling of declarations of interests of scientific committees' members 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 some meeting participants in upcoming discussions as included in the pre-meeting list of participants and restrictions.

Participants in this meeting were asked to declare any changes, omissions or errors to their declared interests and/or additional restrictions concerning the matters for discussion. No new or additional interests or restrictions were declared.

Discussions, deliberations and voting took place in full respect of the restricted involvement of Committee members and experts in line with the relevant provisions of the Rules of Procedure and as included in the list of participants. All decisions taken at this meeting were made in the presence of a quorum of members (i.e. 23 or more members were present in the room). All decisions, recommendations and advice were agreed by consensus, unless otherwise specified.

1.2. Adoption of agenda

The agenda was adopted with amendments.

1.3. Adoption of the minutes

The minutes were adopted and will be published on the EMA website.

2. Opinions

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

2.1. Opinions on Products

2.2. 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

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.4. Opinions on Re-examinations

No items.

2.5. Finalisation and adoption of opinions

3. Discussion of applications

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

3.1. Discussions on Products D90-D60-D30

3.2. Discussions 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

3.3. Discussions on Modification of an Agreed Paediatric Investigation Plan

4. Nominations

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

4.1. List of letters of intent received for submission of applications with start of procedure March 2016 for Nomination of Rapporteur and Peer reviewer

Summary of committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

4.2. Nomination of Rapporteur for requests of confirmation on the applicability of the EMA decision on class waiver.

Summary of committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers.

4.3. Nominations for other activities

Summary of committee discussion:

The PDCO approved the lists of Rapporteurs and Peer Reviewers

5. Scientific Advice Working Party (SAWP) and Paediatric Committee (PDCO) Interaction

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

6. Discussion on the applicability of class waivers

Disclosure of information related to this section cannot be released at the present time as it is deemed to contain commercially confidential information.

6.1. Discussions on the applicability of class waiver for products

6.1.1. Streptozocin - EMEA-46-2015

KEOCYT; Treatment of gastroenteropancreatic neuroendocrine tumours (excluding neuroblastoma, neuroganglioblastoma, phaeochromocytoma)/ 1) Systemic treatment of inoperable, advanced or metastatic, progressive, well-differentiated, G1 or G2 neuroendocrine tumors of pancreatic origin, 2) treatment of progressive liver metastases of digestive neuroendocrine tumors and/or uncontrolled hormone related symptoms in transarterial chemoembolization (TACE) procedures

Rapporteur: Koenraad Norga

Summary of committee discussion:

The applicability of the class waiver as referred to in the Agency's Decision CW/1/2011 to the planned therapeutic indication was confirmed.

Other potential paediatric interest of this medicine suggested by PDCO: none currently identified.

Note: in case of removal from the list of class waivers listed in the Agency's Decision CW/1/2011, the requirements set out in Article 7 and 8 of Regulation (EC) No 1901/2006 of the Agency's Decision CW/0001/2015 shall apply after 36 months from the date of the removal from the list of class waivers.

6.1.2. MABp1 monoclonal antibody - EMEA-47-2015

XBiotech Germany GmbH; Treatment of adenocarcinoma of the colon and rectum / Treatment of metastatic colorectal cancer in patients who have failed oxaliplatin- and irinotecan-based chemotherapy

Rapporteur: Koenraad Norga

Summary of committee discussion:

The applicability of the class waiver as referred to in the Agency's Decision CW/1/2011 to the planned therapeutic indication was confirmed.

Other potential paediatric interest of this medicine suggested by PDCO: treatment of solid tumours, treatment of peripheral vascular disease, treatment of type 2 diabetes and dermatologic diseases.

Note: in case of removal from the list of class waivers listed in the Agency's Decision CW/1/2011, the requirements set out in Article 7 and 8 of Regulation (EC) No 1901/2006 of the Agency's Decision CW/0001/2015 shall apply after 36 months from the date of the removal from the list of class waivers.

6.1.3. Brigatinib - EMEA-48-2015

ARIAD Pharma Ltd; Treatment of lung carcinoma (small cell and non-small cell carcinoma)/ Treatment of adult patients with locally advanced or metastatic anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) who have previously been treated with crizotinib.

Rapporteur: Herbert Lenicker

Summary of committee discussion:

The applicability of the class waiver as referred to in the Agency's Decision CW/1/2011 to the planned therapeutic indication was confirmed.

Other potential paediatric interest of this medicine suggested by PDCO: treatment of neuroblastoma, treatment of rhabdomyosarcoma, treatment of juvenile fibromatosis.

Note: in case of removal from the list of class waivers listed in the Agency's Decision CW/1/2011, the requirements set out in Article 7 and 8 of Regulation (EC) No 1901/2006 of the Agency's Decision CW/0001/2015 shall apply after 36 months from the date of the removal from the list of class waivers.

6.1.4. Beclometasone dipropionate/Formoterol fumarate dihydrate/Glycopyrronium bromide (fixed combination) - EMEA-49-2015

Chiesi Farmaceutici S.p.A.; Treatment of chronic obstructive pulmonary disease (COPD) (excluding chronic lung diseases associated with long-term airflow limitation, such as asthma, bronchopulmonary dysplasia, primary cilia dyskinesia, obstructive lung disease related to graft-versus-host disease after [bone-marrow] transplantation)/ Maintenance treatment of adult patients with chronic obstructive pulmonary disease (COPD) with symptoms, airflow limitation and history of exacerbations, where triple therapy (ICS+LABA+LAMA) is appropriate.

Rapporteur: Herbert Lenicker

Summary of committee discussion:

The applicability of the class waiver as referred to in the Agency's Decision CW/0001/2015 to the planned therapeutic indication was confirmed.

Other potential paediatric interest of this medicine suggested by PDCO: treatment of asthma.

6.1.5. Crizotinib - EMEA-50-2015

Pfizer Limited; Treatment of lung carcinoma (small cell and non-small cell carcinoma)/ Treatment of adults with ROS1-positive advanced non-small cell lung cancer

Rapporteur: Riccardo Riccardi

Summary of committee discussion:

The applicability of the class waiver as referred to in the Agency's Decision CW/1/2011 to the planned therapeutic indication was confirmed.

Other potential paediatric interest of this medicine suggested by PDCO: treatment of ALK-positive neuroblastoma and treatment of anaplastic large cell lymphoma.

Note: in case of removal from the list of class waivers listed in the Agency's Decision CW/1/2011, the requirements set out in Article 7 and 8 of Regulation (EC) No 1901/2006 of the Agency's Decision CW/0001/2015 shall apply after 36 months from the date of the removal from the list of class waivers.

6.1.6. Ingenol 3-(3,5-diethylisoxazole-4-carboxylate) - EMEA-51-2015

LEO Pharma A/S; Treatment of actinic keratosis/ Field treatment of actinic keratosis of the face, balding scalp and of the chest

Rapporteur: Martina Riegl

Summary of committee discussion:

The applicability of the class waiver as referred to in the Agency's Decision CW/1/2011 to the planned therapeutic indication was confirmed.

Other potential paediatric interest of this medicine suggested by PDCO: treatment of acne.

Note: in case of removal from the list of class waivers listed in the Agency's Decision CW/1/2011, the requirements set out in Article 7 and 8 of Regulation (EC) No 1901/2006 of the Agency's Decision CW/0001/2015 shall apply after 36 months from the date of the removal from the list of class waivers.

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

7.1. Discussion on the possibility to include an indication within a condition in an agreed PIP/waiver

None.

8. Annual reports on deferrals

8.1.1. alemtuzumab - EMEA-001072-PIP01-10

Genzyme Europe B.V.

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.2. azacitidine - Orphan - EMEA-001272-PIP02-13-M01

Celgene Europe Ltd

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.3. Azilsartan medoxomil - EMEA-000237-PIP01-08-M06

Takeda Global Research and Development Centre (Europe) Ltd

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.4. Dasatinib - Orphan - EMEA-000567-PIP01-09-M04

Bristol-Myers Squibb Pharma EEIG

Difficulties progressing the PIP? No

Summary of committee discussion:

The report was noted.

8.1.5. Elvitegravir - EMEA-000968-PIP02-11-M04

Gilead Sciences International Limited

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.6. Human Cell Line recombinant human Factor VIII (human-cl rhFVIII) / Human Coagulation Factor VIII (rDNA) - EMEA-001024-PIP01-10-M01

Octapharma Pharmazeutika Produktionsges.m.b.H

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.7. Linaclotide - EMEA-000927-PIP01-10-M01

Almirall S.A.

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.8. Methyl [(2S)-1-{(6S)-6-[5-(9,9-difluoro-7-{2-[(1R,3S,4S)-2-{(2S)-2-[(methoxycarbonyl)amino]-3-methylbutanoyl}-2-azabicyclo[2.2.1]hept-3-yl]-1H-benzimidazol-6-yl}-9H-fluoren-2-yl)-1H-imidazol-2-yl]-5-azaspiro[2.4]hept-5-yl}-3-methyl-1-oxobutan-2-yl]carbamate (GS-5885) / (S)-Isopropyl 2-((S)-(((2R,3R,4R,5R)-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl)-4-fluoro-3-hydroxy-4-methyltetrahydrofuran-2-yl)methoxy)(phenoxy)phosphorylamino)propanoate (GS-7977) - EMEA-001411-12-M02

Gilead Sciences International Ltd.

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.9. Recombinant Factor VIII - EMEA-000428-PIP01-08-M02

Novo Nordisk A/S

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.10. triphenylacetic acid - 4-{(1R)-2-[(6-{2-[(2,6-dichlorobenzyl)oxy]ethoxy}hexyl)amino]-1-hydroxyethyl}-2-(hydroxymethyl)phenol (1:1) / fluticasone furoate - EMEA-000431-PIP01-08-M08

Glaxo Group Limited

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.11. Brentuximab vedotin / Monoclonal antibody against human CD30 covalently linked to the cytotoxin monomethylauristatin E - Orphan - EMEA-000980-PIP01-10-M02

Takeda Global Research and Development Centre (Europe), Ltd

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The report was noted.

8.1.12. Ceftobiprole medocaril sodium - EMEA-000205-PIP02-11-M01

Basilea Pharmaceutica International Ltd.

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.13. cobicistat / darunavir - EMEA-001280-PIP01-12

Janssen-Cilag International NV

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.14. Dapagliflozin - EMEA-000694-PIP01-09-M05

Bristol Myers Squibb /AstraZeneca EEIG

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.15. Etravirine - EMEA-000222-PIP01-08-M08

Janssen-Cilag International NV

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.16. exenatide - EMEA-000689-PIP01-09

Bristol-Myers Squibb/AstraZeneca EEIG

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.17. GLP-1 analogue linked to human IgG4 Fc-fragment (LY2189265) - EMEA-000783-PIP01-09-M02

Eli Lilly & Company

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.18. Human recombinant C1 inhibitor - Orphan – EMEA-000367-PIP01-08-M02

Pharming Group N.V.

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.19. Nilotinib - Orphan - EMEA-000290-PIP01-08

Novartis Europharm Limited

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the recent modifications of the agreed PIP.

8.1.20. posaconazole - EMEA-000468-PIP02-12-M02

Merck Sharp & Dohme (Europe), Inc.

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.21. Purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/2004 (H5N1) - EMEA-000160-PIP01-07-M04

GlaxoSmithKline Biologicals S.A.

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.22. Rilpivirine - EMEA-000317-PIP01-08-M07

Janssen-Cilag International N.V.

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. PDCO Workload and Duration of Plenary Meeting

PDCO Chair: Dirk Mentzer

Summary of committee discussion:

Postponed to PDCO members' training to be held on 26 January 2016.

9.2. Coordination with EMA Scientific Committees or CMDh-v

9.2.1. Committee for Medicinal Products for Human Use (CHMP)

Summary of committee discussion:

The PDCO members were informed about 3 products, Briviact, Oncaspar and Spectrila, for which the CHMP adopted positive opinions recommending paediatric indications during their meeting in November 2015. A new pharmaceutical form (granules for oral suspension) for Pyramax was approved to enable administration in younger children.

9.2.2. Oxybutynin – KENTERA (CAP)

Applicant: Nicobrand Limited
PRAC Rapporteur: Veerle Verlinden

Scope: Signal of psychiatric disorders

Summary of committee discussion:

Upon PRAC request the PDCO discussed a signal on psychiatric disorders with oxybutynin (KENTERA transdermal patch/gel) and related question asked by the PRAC.

The PDCO noted the assessment report provided by the PRAC on the signal and its outcome leading to the decision in including a wording under section 4.8 of the SmPC regarding the paediatric population.

The PDCO was aware that an assessment under Article 45 Regulation (EC) No 1901/2006 had been completed for the same active substance in oral formulations (Oxybutynin Hydrochloride UK/W/017/pdWS/001) and currently a warning for the paediatric population is included in the SmPC of such products under section 4.4 (… In children over 5 years of age, Oxybutynin hydrochloride should be used with caution as they may be more sensitive to the effects of the product, particularly the CNS and psychiatric adverse reactions.).

It was noted that the oral products are authorised for a paediatric patients above 5 years of age.

The PDCO concurred that the addition of a paediatric safety warning in Kentera might potentially have an unintended consequence of off-label prescribing of the product in children. However this risk will be appropriately mitigated by a SmPC wording clarifying that Kentera has not been studied in children and is not licensed for the paediatric population (in accordance to the SmPC guideline). Furthermore the PDCO considered such risk in the context of an active substance that, in other formulations, is authorised for use in paediatric patients and it is counterbalanced by the advantages of having fully informed prescribers on potential adverse reactions associated with oxybuthynin use, regardless of the formulation used.

Therefore the PDCO supported the introduction of a safety warning concerning the paediatric population as proposed.

9.2.3. Draft Concept paper on an addendum to the guideline on the evaluation of medicinal products indicated for treatment of bacterial infections (CPMP/EWP/558/95 rev 2) to address paediatric-specific clinical data requirements

PDCO member: Maria Fernandez Cortizo

Summary of committee discussion:

The Committee was informed of the draft concept paper under development and its timelines: Draft release for public consultation 1Q2016, first draft of Addendum to be released for consultation 1Q2017. Maria Fernandez Cortizo presented a comprehensive overview of the PDCO experience gained with PIPs of antibacterial agents and highlighted areas for comments.

The Committee supported her comments on the current draft of the concept paper and encouraged further update in due time before release for public consultation.

9.3. Coordination with EMA Working Parties / Working Groups / Drafting Groups

9.3.1. Non-clinical Working Group: D30 Products identified

PDCO member: Jacqueline Carleer

Summary of committee discussion:

The chair of the NcWG identified the products which will require NcWG evaluation and discussion.

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Summary of committee discussion:

Documents tabled for information.

9.3.3. Formulation Working Group

PDCO member: Brian Aylward

Delegation attending the PDCO

Summary of committee discussion:

The group discussed with the PDCO ways to improve communication, interaction and knowledge of quality issues between PDCO and FWG.

The Committee also nominated the FWG members.

9.4. Cooperation within the EU regulatory network

9.4.1. European Network of Paediatric Research (Enpr) - European Medicines Agency (EMA)

None.

9.4.2. Report on 'Analysis of Article 45 EU Work-sharing Procedure'

PDCO member: Birka Lehmann

Summary of committee discussion:

The Committee heard a presentation on the results of the Article 45 worksharing procedure.

9.4.3. Cooperation with International Regulators

None.

9.5. Contacts of the PDCO with external parties and interaction with the Interested Parties to the Committee

None.

9.6. PDCO work plan

9.6.1. Draft PDCO Work Plan 2016

Summary of committee discussion:

The PDCO discussed the draft work plan 2016 and supported the planned objectives and activities. PDCO members were invited to send additional comments in advance of the work plan adoption at the PDCO January 2016.

9.7. Planning and reporting

9.7.1. Report on the 'Data Gathering Initiative'

Summary of committee discussion:

The PDCO was informed of the objectives and outcome of the scientific advice pilot data gathering. Further to the informative results from the pilot phase, the Steering group recommended to start a next phase and continue per procedure, per delegation collection on key fee generating procedures (e.g. Initial MAAs, Type IIs) but also for non-fee generating activities in the area of Paediatric and orphan drugs procedures. The Steering group will develop a timetable and methodology plan for 2016 both for fee and non-fee generating activities.

Further details on the operational data collection structure will be provided at the PDCO January 2016 plenary meeting.

9.8. PDCO ORGAM

9.8.1. PDCO ORGAM Agenda for 2 December 2015

Summary of committee discussion:

Noted.

9.8.2. PDCO ORGAM Draft Minutes for 2 December 2015

Summary of committee discussion:

Noted.

10. Any other business

10.1. None

11. Breakout sessions

11.1.1. Paediatric oncology

Summary of committee discussion:

The working group co-ordinated participation in scientific meetings in the next months.

11.1.2. Neonatology

Summary of committee discussion:

The group met shortly in the margins of the plenary meeting.

11.1.3. Inventory

Summary of committee discussion:

The group met shortly in the margins of the plenary meeting.

11.1.4. Ethics drafting group

Summary of committee discussion:

The working group co-ordinated contributions to a possible revision of the ethical considerations (2008).

12. List of participants

List of participants including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the PDCO 9-11 December 2015 meeting.

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Dirk Mentzer	Chair	Germany	No interests declared	
Karl-Heinz Huemer	Member	Austria	No interests declared	
Christoph Male	Alternate	Austria	No participation in final deliberations and voting	EMEA-001229-PIP01-11-M02 EMEA-001139-PIP01-11-M02 EMEA-001296-PIP01-12-M03 EMEA-000661-PIP01-09-M07 EMEA-001886-PIP01-15 EMEA-001886-PIP02-15
Koenraad Norga	Member (Vice-Chair)	Belgium	To be replaced for discussions, final deliberations and voting on products when chairing the meeting	EMEA-C2-000429-PIP01-08-M04 EMEA-001175-PIP01-11-M03 EMEA-000116-PIP01-07-M08 EMEA-001792-PIP01-15 EMEA-001749-PIP01-15 EMEA-001765-PIP02-15 EMEA-000160-PIP01-07-M04 EMEA-000431-PIP01-08
Jacqueline Carleer	Alternate	Belgium	No restrictions applicable to this meeting	
Dimitar Roussinov	Member	Bulgaria	No restrictions applicable to this meeting	
Georgios Savva	Member	Cyprus	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Jaroslav Sterba	Member	Czech Republic	No interests declared	
Peter Szitanyi	Alternate	Czech Republic	No interests declared	
Marianne Orholm	Member	Denmark	No interests declared	
Irja Lutsar	Member	Estonia	No interests declared	
Jana Lass	Alternate	Estonia	No interests declared	
Ann Marie Kaukonen	Member	Finland	No interests declared	
Maija Pihlajamaki	Alternate	Finland	No interests declared	
Sylvie Benchetrit	Member	France	No interests declared	
Birka Lehmann	Member	Germany	No interests declared	
Immanuel Barth	Alternate	Germany	No interests declared	
Grigorios Melas	Member	Greece	No interests declared	
Ágnes Gyurasics	Member (CHMP member)	Hungary	No interests declared	
Brian Aylward	Member	Ireland	No interests declared	
Paolo Rossi	Member	Italy	No restrictions applicable to this meeting	
Francesca Rocchi	Alternate	Italy	No restrictions applicable to this meeting	
Dina Apele-Freimane	Member	Latvia	No interests declared	
Carola de Beaufort	Member (CHMP alternate)	Luxembourg	No restrictions applicable to this meeting	
Hendrik van den Berg	Member	Netherlands	No interests declared	
Siri Wang	Member	Norway	No interests declared	
Marek Migdal	Member	Poland	No restrictions applicable to this meeting	
Jolanta Witkowska-Ozogowska	Alternate	Poland	No interests declared	
Helena Fonseca	Member	Portugal	No interests declared	
Hugo Tavares	Alternate	Portugal	No interests declared	
Dana Gabriela Marin	Member (CHMP alternate)	Romania	No interests declared	
Stefan Grosek	Member	Slovenia	No interests declared	
Fernando de Andrés Trelles	Member	Spain	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Maria Jesús Fernández Cortizo	Alternate	Spain	No interests declared	
Ninna Gullberg	Member	Sweden	No restrictions applicable to this meeting	
Angeliki Siapkara	Member	United Kingdom	No interests declared	
Martina Riegl	Alternate	United Kingdom	No interests declared	
Riccardo Riccardi	Member	Healthcare Professionals' Representative	No participation in discussions, final deliberations and voting	EMEA-001072-PIP01-10
Johannes Taminiau	Member	Healthcare Professionals' Representative	No interests declared	
Günther Auerswald	Member	Patients' Organisation Representative	No participation in discussions, final deliberations and voting	EMEA-001886-PIP01-15 EMEA-001886-PIP02-15 EMEA-001229-PIP01-11-M02 EMEA-001139-PIP01-11-M02 EMEA-001296-PIP01-12-M03 EMEA-000661-PIP01-09-M07
Paola Baiardi	Alternate	Patients' Organisation Representative	No interests declared	
Tsvetana Schyns-Liharska	Member	Patients' Organisation Representative	No restrictions applicable to this meeting	
Juliana Min	Expert - in person*	United Kingdom	No restrictions applicable to this meeting	
Dominik Karres	Expert - in person*	United Kingdom	No restrictions applicable to this meeting	
Christopher Copland	Observer - in person*	n/a	No restrictions applicable to this meeting	
Jan Müller-Berghaus	Expert - via telephone*	Germany	No interests declared	
Isabelle Delneuville	Member	Formulation Working Group	No interests declared	
Anne Paavola	Member	Formulation	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
		Working Group		
Andreas Wilhelm Grummel	Member	Formulation Working Group	No interests declared	
Beata Szabady	Member	Formulation Working Group	No interests declared	
Diana van Riet-Nales	Member	Formulation Working Group	No interests declared	
Nela Vilceanu	Member	Formulation Working Group	No interests declared	
Adela Nunez Velazquez	Member	Formulation Working Group	No interests declared	
Anthony Nunn	Member	Formulation Working Group	No interests declared	
Gary Inwards	Member	Formulation Working Group	No interests declared	
Sara Arenas-Lopez	Member	Formulation Working Group	No interests declared	
Fokaline Vroom	Member	Formulation Working Group	No interests declared	
Delphine Ammar	Member	Formulation Working Group	No interests declared	
Meeting run with support from relevant EMA staff				

* Experts were only evaluated against the agenda topics or activities they participated in.

13. Explanatory notes

The Notes give a brief explanation of relevant agenda items and should be read in conjunction with the agenda.

Paediatric investigation plan (PIP) (section 2.1 Opinion on PIPs and section 3.1 Discussions on PIPs)
A paediatric investigation plan (PIP) is a development plan aimed at ensuring that the necessary data are obtained through studies in children, when it is safe to do so, to support the authorisation of a medicine for children. Pharmaceutical companies submit proposals for PIPs to the European Medicines Agency's Paediatric Committee (PDCO). This Committee is responsible for agreeing or refusing the plan.

Compliance checks (section 2.2 Opinions on Compliance check, section 3.2 Discussions on Compliance check)
A compliance check may be necessary before any application for marketing authorisation (even for an adult indication) can be considered valid, if there was no deferral for at least one of the studies agreed in the PIP, or after the due date of initiation or completion of a study/measure. The same applies to some regulatory applications for authorised products, as described above.

Modification of an Agreed Paediatric Investigation Plan (section 2.3 Opinions on Modification of an agreed PIP, section 3.3 Discussions on Modification of an agreed PIP)
The development plan for a medicine can be modified at a later stage as knowledge increases.
Modifications can also be made if the applicant encounters such difficulties with the implementation of a PIP, which render it unworkable or no longer appropriate.
In some cases, studies can be deferred until after the studies in adults have been conducted. This ensures that research in children is done only when it is safe and ethical to do so. Even when studies are deferred, the PIP will include details of the paediatric studies and their timelines.

Class waiver (section 6 Discussion on the applicability of class waiver)
As some diseases do not affect children (for example Parkinson's disease), the development of medicines for these diseases should not be performed in children. In these cases, a PIP is not required and it will be waived**.** For more information on the classes of diseases subject to waivers,
see class waivers.

Annual reports on deferrals (section 8)
If the medicinal product is approved in the EU, annual reports on the deferred measures in the PIP must be submitted to the Agency.

More detailed information on the above terms can be found on the EMA website: www.ema.europa.eu/