9 December 2015
EMA/PDCO/750371/2015
Procedure Management and Committees Support Division

Paediatric Committee (PDCO)

Minutes for the meeting on 11-13 November 2015

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

11 November 2015, 08:30- 19:00, room 3A

12 November 2015, 08:30- 19:00, room 3A

13 November 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.

2.5. Finalisation and adoption of opinions

3. Discussion of applications

Disclosure of some 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 February 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

4.3.1. Nomination of PDCO Chair to represent the committee at the workshop 'Successes and Challenges of Performing Long-Term Paediatric Safety Studies' organised by the Food and Drug Administration (FDA) on 13-14 April 2016

Summary of committee discussion:

The PDCO nominated its Chair, Dirk Mentzer, to represent the committee at the workshop 'Successes and Challenges of Performing Long-Term Paediatric Safety Studies' organised by the Food and Drug Administration (FDA) on 13-14 April 2016.

4.3.2. Ethical considerations for clinical trials on medicinal products conducted with the paediatric population: call for expression of interest from PDCO members

Summary of committee discussion:

Committee members volunteered to collect experience and expertise to prepare discussions about an update of this document.

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. Algenpantucel-L - EMEA-44-2015

NewLink Genetics Inc.; Adjuvant treatment of surgically resected pancreatic cancer in combination with chemotherapy /revised classes of medicinal products for the treatment of pancreatic malignant neoplasms

Rapporteur: Koenraad Norga

Summary of committee discussion:

The applicability of the class waiver to the planned therapeutic indication was not confirmed because algenpantucel-L does not belong to the classes of the revised class waivers for the treatment of pancreatic malignant neoplasms as referred to in the Agency's Decision CW/0001/2015. However, in case of removal from the list of class waivers, the requirements

set out in Article 7 and 8 of Regulation (EC) No 1901/2006 shall not apply for 36 months from the date of the removal from the list of class waivers.

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

6.1.2. Encorafenib - EMEA-45-2015

Array BioPharma, Inc.; Treatment of patients with BRAF-mutant, metastatic colorectal cancer after failure of a prior line of therapy in combination with cetuximab / treatment of intestinal malignant neoplasms

Rapporteur: Koenraad Norga

Summary of committee discussion:

The applicability of the class waiver to the planned therapeutic indication was not confirmed because encorafenib does not belong to the classes of the revised class waivers for the treatment of treatment of intestinal malignant neoplasms as referred to in the Agency's Decision CW/0001/2015. However, in case of removal from the list of class waivers, the requirements set out in Article 7 and 8 of Regulation (EC) No 1901/2006 shall not apply for 36 months from the date of the removal from the list of class waivers.

Other potential paediatric interest of this medicine suggested by PDCO: treatment of children with solid malignant tumours and hematologic malignancies.

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. Brentuximab vedotin / Monoclonal antibody against human CD30 covalently linked t...– Adcetris - EMEA-000980-PIP01-10-M03

Takeda Pharma A/S

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.2. Cannabidiol / Delta-9-tetrahydrocannabinol – Sativex - EMEA-000181-PIP01-08

GW Pharma Ltd

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.3. Golimumab – Simponi - EMEA-000265-PIP02-11-M01

Janssen Biologics B.V.

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.4. Regadenoson – Rapiscan - EMEA-000410-PIP01-08-M01

Rapidscan Pharma Solutions (RPS) EU Ltd

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.5. Saxagliptin – Onglyza- EMEA-000200-PIP01-08-M04

AstraZeneca AB

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.6. Certolizumab Pegol – Cimzia - EMEA-001071-PIP02-12-M01

UCB Pharma SA

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report. The paediatric development is progressing as planned.

8.1.7. Tiotropium bromide (monohydrate) – Spiriva Respimat, Spiriva - EMEA-000035-PIP02-09-M02

Boehringer Ingelheim International GmbH

Difficulties progressing the PIP? No

Summary of committee discussion:

The committee noted the report.

8.1.8. Tadalafil - Cialis, Adcirca - EMEA-000452-PIP02-10-M03

Eli Lilly and Company Ltd

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.9. Sildenafil citrate - Revatio- EMEA-000671-PIP01-09-M07

Pfizer Limited

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.10. Cobicistat- Tybost - EMEA-000969-PIP01-10-M03

Gilead Sciences International Limited

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.11. Idelalisib - Zydelig - EMEA-001350-PIP02-13-M01

Gilead Sciences International Limited

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.12. Telaprevir - Incivo - EMEA-000196-PIP01-08-M03

Janssen Infectious Diseases BVBA

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 members' training 26 January 2016

Summary of committee discussion:

The Committee was informed of the planned training for members in January 2016 and supported the proposed draft training programme. The final programme will be circulated in December 2015.

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, Cubicin, Edurant and Emend, for which the CHMP adopted positive opinions recommending paediatric indications during their meeting in October 2015. A new pharmaceutical form (powder for oral suspension) for Emend was approved to enable administration in younger children.

9.2.2. Fusafungine (NAP), for nasal and oral solution

Applicant: Les Laboratoires Servier, various

PDCO expert: Koenraad Norga

Scope: Review of the benefit-risk balance following notification by Italy of a referral under Article 31 of Directive 2001/83/EC, based on pharmacovigilance data

Action: For adoption

Summary of committee discussion:

The PDCO adopted the responses to PRAC questions on Fusafungine, in the context of the ongoing Article 31 referral. The PDCO responses were drafted taking into account the analysis of EudraVigilance data for paediatric cases related to Fusafungine (EV paediatric query). The PDCO expert and the Chair highlighted the importance of the EV paediatric query as a methodological tool to inform PDCO views on the specific questions.

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

Action: For information

Summary of committee discussion:

Relevant products for Non-clinical Working Group (NcWG) discussion were identified by the chairperson of the NcWG .

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Summary of committee discussion:

Documents tabled for information.

9.3.3. Non-clinical Working Group

PDCO member: Jacqueline Carleer

Delegation attending the PDCO

Summary of committee discussion:

PDCO/NcWG common plenary session:

It was agreed to look into organising a pre-clinical training session for PDCO members on the basic elements of a pre-clinical review in the context of paediatric clinical drug development.

Some PDCO members expressed interest in participating to the monthly TCs when their respective products are discussed. It was agreed to also send the NcWG agenda to the PDCO members.

As regards to the NcWG expert contributions to paediatric SAWP procedures, it was agreed to possibly limit this only to those cases with a previous PIP/NcWG evaluation or where the SAWP would see a value/need for additional NcWG feedback. This will be decided on a case by case basis.

9.3.4. European Medicines Agency Human Scientific Committees' Working Party with Patients' and Consumers' Organisations (PCWP) Work Plan for 2016

Summary of committee discussion:

Work Plan adopted with no comments.

9.3.5. European Medicines Agency Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP) Work Plan for 2016

Summary of committee discussion:

Work Plan adopted with no comments.

9.3.6. Report from PDCO-COMP Strategic Review and Learning Meeting held in Bonn on 14-16 October 2015

PDCO Chair: Dirk Mentzer; PDCO member: Birka Lehmann

Summary of committee discussion:

Report postponed to PDCO December 2015 meeting.

9.3.7. Guideline on Clinical investigation of recombinant and Human plasma-derived factor IX products (replacing EMA/CHMP/BPWP/144552/2009)

Summary of committee discussion:

The PDCO noted the final guideline. The PDCO was in agreement with the content of the final guideline which included comments and input provided by PDCO members. The guideline provides applicants and regulators with harmonised requirements for applications for marketing authorisation for recombinant or plasma-derived factor IX products.

9.3.8. Guideline on Clinical investigation of recombinant and human plasma-derived factor VIII products (Rev. 1)

Summary of committee discussion:

The PDCO was in general agreement with the content of the draft guideline providing applicants and regulators with harmonised requirements for applications for marketing authorisation for recombinant or plasma-derived factor VIII products. Additional PDCO comments may be provided in advance of the guideline adoption.

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. Results of survey project 'Questionnaire to children about taking medicines and participation in clinical trials'

Expert: Sofia Nordenmalm

Summary of committee discussion:

The results of the survey on the views of the paediatric population (from 10 to less than 18 years of age) on taking medicines and participation in clinical trials carried out in some EU countries were presented by the expert Sofia Nordenmalm. As a following step it was highlighted the opportunity to publish these results in a scientific paper and to the extent the survey to the EU countries not included in the research.

9.4.3. Debriefing from the meeting with the ENVI Committee of the EP on 10 November 2015

Summary of committee discussion:

The committee was debriefed on the exchange of views between members of the ENVI (Environment, Public Health and Food Safety) Committee of the European Parliament, representatives of the European Commission and of the Agency on the condition and scope of Paediatric investigation plans and waivers.

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

PDCO member: Birka Lehmann; Expert: Elke Maneke

Summary of committee discussion:

Postponed to PDCO December 2015 meeting.

9.5. Cooperation with International Regulators

9.5.1. Overview of extrapolation activities at EU and ICH level

PDCO Chair: Dirk Mentzer

Summary of committee discussion:

Postponed to PDCO December 2015 meeting.

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

None

9.7. PDCO work plan

9.7.1. 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 comments in advance of the PDCO December 2015 meeting were the document will be finalised. The final work plan is expected to be adopted in January 2016.

9.8. Planning and reporting

None

9.9. PDCO ORGAM

9.9.1. PDCO ORGAM Agenda for 4 November 2015

Summary of committee discussion:

Noted.

9.9.2. PDCO ORGAM Draft Minutes for 4 November 2015

Summary of committee discussion:

Noted.

10. Any other business

None

11. Breakout sessions

11.1.1. Paediatric oncology

Summary of committee discussion:

The following topics were discussed: the exchange of views with the ENVI committee on 2015-11-10 on the "Policy on the Conditions for a Paediatric Investigation Plan/Waiver" and the International Society of Paediatric Oncology (SIOP) Europe strategic plan.

11.1.2. Deferrals in paediatric only development

Summary of committee discussion:

Session postponed.

11.1.3. Neonatology

Summary of committee discussion:

The group discussed general neonatology related issues in PIPs and participation at the International Neonatal Consortium.

11.1.4. White Paper Drafting Group

Summary of committee discussion:

Session cancelled.

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 11-13 November 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 discussions, final deliberations and voting	EMEA-000480-PIP01-08-M08 EMEA-000788-PIP02-11-M04 EMEA-001229-PIP01-11-M02 EMEA-C2-001215-PIP01-11-M04 EMEA-001839-PIP01-15 EMEA-001139-PIP01-11-M02 EMEA-001296-PIP01-12-M03
Koenraad Norga	Member (Vice-Chair)	Belgium	No restrictions applicable to this meeting	
Jacqueline Carleer	Alternate	Belgium	No restrictions applicable to this meeting	
Suzana Mimica Matanovic	Member	Croatia	No interests declared	
Georgios Savva	Member	Cyprus	No interests declared	
Jaroslav Sterba	Member	Czech Republic	No interests declared	
Peter Szitanyi	Alternate	Czech Republic	No interests declared	
Marianne Orholm	Member	Denmark	No interests declared	
Marta Granström	Alternate	Denmark	No interests declared	
Irja Lutsar	Member - via telephone*	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	Member	France	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Benchetrit				
Birka Lehmann	Member	Germany	No interests declared	
Immanuel Barth	Alternate	Germany	No interests declared	
Grigorios Melas	Member	Greece	No interests declared	
Stefanos Mantagos	Alternate	Greece	No interests declared	
Ágnes Gyurasics	Member (CHMP member)	Hungary	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	
Herbert Lenicker	Alternate	Malta	No interests declared	
Hendrik van den Berg	Member	Netherlands	No interests declared	
Siri Wang	Member	Norway	No interests declared	
Ine Skottheim Rusten	Alternate	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	Member	Slovenia	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Grosek				
Fernando de Andrés Trelles	Member	Spain	No interests declared	
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 restrictions applicable to this meeting	
Paolo Paolucci	Alternate - via telephone*	Healthcare Professionals' Representative	No interests declared	
Johannes Taminiau	Member	Healthcare Professionals' Representative	No interests declared	
Doina Plesca	Alternate	Healthcare Professionals' Representative	No participation in discussions, final deliberations and voting	EMEA-001617-PIP01-14 EMEA-001714-PIP01-14 EMEA-C2-000402-PIP02-11-M02 EMEA-001812-PIP01-15
Günther Auerswald	Member	Patients' Organisation Representative	No participation in discussions, final deliberations and voting	EMEA-001229-PIP01-11-M02 EMEA-C2-001215-PIP01-11-M04 EMEA-001839-PIP01-15 EMEA-001139-PIP01-11-M02 EMEA-001296-PIP01-12-M03
Paola Baiardi	Alternate	Patients' Organisation Representative	No interests declared	
Tsvetana Schyns-Liharska	Member	Patients' Organisation Representative	No restrictions applicable to this meeting	
Dominik Sturm	Expert - via telephone*		No interests declared	
Sofia	Expert - via		No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Nordenmalm	telephone*			
Lutz Wiesner	Member	Non-clinical Working Group	No interests declared	
Sabine Kudicke	Member	Non-clinical Working Group	No interests declared	
Fabien Lavergne	Member	Non-clinical Working Group	No interests declared	
Fernando Méndez Hermida	Member	Non-clinical Working Group	No interests declared	
Claire Beuneu	Member	Non-clinical Working Group	No interests declared	
Jan Willem van der Laan	Member	Non-clinical Working Group	No interests declared	
Dinah Duarte	Member	Non-clinical Working Group	No interests declared	
A representative from the European Commission attended the meeting				
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/