7 October 2015
EMA/PDCO/596621/2015
Procedure Management and Committees Support Division

Paediatric Committee (PDCO)

Minutes for the meeting on 9 –11 September 2015

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

9 September 2015, 08:30 - 19:00, room 2A

10 September 2015, 08:30 - 19:00, room 2A

11 September 2015, 08:30- 13:00, room 2A

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 meeting reports once the procedures are finalised and start of referrals will also be available.

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

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 November 2015 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.

5.1. Discussions on first reports of SAWP products with paediatric interest

None

5.2. Discussions on SAWP products following a discussion meeting with companies

None

5.3. Discussions on joint reports of SAWP products

6. Discussion on the applicability of class waivers

6.1. Discussions on the applicability of class waiver for products

6.1.1. Contraloid - EMEA-38-2015

Forschungszentrum Jülich GmbH; Treatment of Alzheimer's disease/ Treatment of Alzheimer's disease

Rapporteur: Fernando de Andres Trelles

Summary of committee discussion:

The applicability of the class waiver to the planned therapeutic indication was confirmed. Potential paediatric interest of this medicine suggested by PDCO: treatment of patients with Down syndrome.

6.1.2. BI409306 - EMEA-39-2015

Boehringer Ingelheim International GmbH; Treatment of Alzheimer's disease/ Treatment of Alzheimer's disease

Rapporteur: Fernando de Andres Trelles

Summary of committee discussion:

The applicability of the class waiver to the planned therapeutic indication was confirmed during the assessment of the procedure EMEA-001742-PIP01-14 (listed in the Agenda PDCO 9-11 September 2015 under point 3.1.26)

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. Aztreonam - EMEA-000827-PIP01-09

Gilead Sciences International Limited

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.2. decitabine - EMEA-000555-PIP01-09

Janssen-Cilag International NV

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.3. N-(2,4-Di-tert-butyl-5-hydroxyphenyl)-1,4-dihydro-4- oxoquinoline-3-carboxamide - EMEA-000335-PIP01-08

Vertex Pharmaceuticals Incorporated

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.4. linagliptin - EMEA-000498-PIP01-08

Boehringer Ingelheim International GmbHd

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.5. daclatasvir - EMEA-001191-PIP01-11

Bristol-Myers Squibb International Corporation

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.6. maraviroc - EMEA-000020-PIP01-07

ViiV Healthcare UK Ltd

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.7. lacosamide - EMEA-000402-PIP02-11

UCB Pharma S.A.

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.8. Tapentadol Hydrochloride - EMEA-000018-PIP01-07

Grünenthal GmbH

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.9. Tapentadol Hydrochloride - EMEA-000325-PIP01-08

Grünenthal GmbH

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.10. Tapentadol Hydrochloride - EMEA-000485-PIP01-08

Grünenthal GmbH

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The committee noted the report.

8.1.11. Tapentadol Hydrochloride - EMEA-000486-PIP01-08

Grünenthal GmbH

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The committee noted the report.

8.1.12. Purified antigen fractions of inactivated split virion Influenza A/Vietnam/1194/... - EMEA-000160-PIP01-07

GlaxoSmithKline Biologicals S.A.

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.13. asenapine maleate - EMEA-000228-PIP01-08

N.V. Organon

Difficulties progressing the PIP? No

Summary of committee discussion:

Some studies have been completed earlier than planned. The PDCO noted the report.

8.1.14. rivaroxaban- EMEA-000430-PIP01-08

Bayer Schering Pharma AG

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

None

9.2. Coordination with EMA Scientific Committees or CMDh-v

None

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 chairperson of the Non-clinical Working Group (NcWG) of the PDCO identified relevant products for the group discussion in preparation of the October PDCO plenary discussion.

9.3.2. Formulation Working Group

PDCO member: Brian Aylward

Summary of committee discussion:

Documents tabled for information.

9.3.3. Presentation of the comments received during the public consultation phase on the Inventory of paediatric needs: Gastroenterology

PDCO member: Birka Lehmann

Summary of committee discussion:

The Committee was made aware of the comments received during the public consultation phase. The draft response document and updated Inventory will be included in the post-mail for PDCO review before adoption for final publication at the October 2015 plenary meeting.

The Committee was also made aware that the draft Inventory for Immunology will be included in the post-mail for PDCO review before adoption for public consultation at the October 2015 plenary meeting.

9.3.4. Non-clinical Working Group: Announcement of the Face to Face meeting to be held on 12-13 November 2015

PDCO member: Jacqueline Carleer

Summary of committee discussion:

The Non-clinical Working Group (NcWG) of the PDCO will hold its annual face to face meeting on 12 and 13 November 2015 at the EMA. The NcWG members will join the PDCO plenary on 12 November 2015 and will have their internal group meeting on 13 November 2015.

9.4. Cooperation within the EU regulatory network

None

9.5. Cooperation with International Regulators

None

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

None

9.7. PDCO work plan

None

9.8. Planning and reporting

None

9.9. PDCO ORGAM

None

10. Any other business

10.1.1. Presentation of Agenda for Extrapolation Workshop to be held on 30 September 2015

Summary of committee discussion:

European Medicines Agency expert workshop on extrapolation across age groups will take place 30 September 2015 at the EMA. The workshop will discuss the role of extrapolation and how it should be evaluated within a regulatory framework through the product development life cycle.

The goal of the meeting is to come with recommendations for an agreed framework by clinicians, modellers and statisticians that will result in an explicit and systematic approach for decision making alongside the product life cycle; hence optimising the chances for successful development and approval.

Participants from Paediatric Committee (PDCO), Committee for Medicinal Products for Human Use (CHMP), Scientific Advice Working Party (SAWP), Biostatistics Working Party (BSWP), PKWP Pharmacokinetics (Working Party), Modelling and Simulation Working Group (MSWG), Academia, other non-EU regulatory agencies will attend the workshop. The programme is structured in three sections: Extrapolation framework: common principles and challenges; Structure, methods and decision criteria for extrapolation and case studies.

10.1.2. Strategic Review and Learning Meeting to be held on 15-16 October 2015 in Bonn

PDCO member: Birka Lehmann

Summary of committee discussion:

The Committee was informed that Strategic Review and Learning Meeting under Luxembourg Presidency will be held on 15-16 October 2015 in Bonn at the Federal Institute for Drugs and Medical Devices. This is a joint PDCO and COMP meeting. Members were invited to register no later than on the 9th September 2015. The meeting starts on the 15th October 9 a.m. and finishes on 16 October 1 p.m. Social event will be held at the 15th and "get together" will take place on 14 October at 7 p.m in the Foyer of the BfArM.

10.1.3. Corporate Europe Observatory(CEO) report intituled 'Policy prescriptions – the firepower of the EU pharmaceutical implications for public health'

Summary of committee discussion:

Document tabled for information.

11. Breakout sessions

11.1.1. Paediatric oncology

Summary of committee discussion:

The participants discussed interactions sought with SIOP Europe (European Society for Paediatric Oncology) and recent articles on progress in outcome, care and research of children with cancer (http://jco.ascopubs.org/content/early/recent).

11.1.2. Neonatology

Summary of committee discussion:

The neonatal guideline and international activities in the field of neonatology were discussed.

11.1.3. Paediatric inventories

Summary of committee discussion:

The Committee was updated on the status of the Gastroenterology and Immunology Inventories. The working group is currently preparing a draft Respiratory Inventory. See also point 9.3.3.

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 DD Month YEAR 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-C1-000778-PIP02-12 EMEA-000430-PIP01-08-M08 EMEA-000430-PIP01-08 EMEA-001215-PIP01-11-M04
Koenraad Norga	Member (Vice-Chair)	Belgium	To be replaced for discussions, final deliberations and voting when chairing the meeting:	EMEA-000673-PIP01-09-M08 EMEA-000160-PIP01-07
Jacqueline Carleer	Alternate	Belgium	No restrictions applicable to this meeting	
Violeta Iotova	Member	Bulgaria	No participation in discussions, final deliberations and voting:	EMEA-C-000479-PIP01-08-M03 EMEA-001820-PIP01-15
Suzana Mimica Matanovic	Member	Croatia	No participation in discussions, final deliberations and voting:	EMEA-000365-PIP01-08-M07
Jaroslav Sterba	Member	Czech Republic	No interests declared	
Marianne Orholm	Member	Denmark	No interests declared	
Marta Granström	Alternate	Denmark	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	Member	Ireland	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
Aylward				
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 Grosek	Member	Slovenia	No interests declared	
Maria Jesús Fernández Cortizo	Alternate	Spain	No interests declared	
Ninna Gullberg	Member	Sweden	No restrictions applicable to this meeting	
Anna-Karin Hamberg	Alternate	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	Healthcare Professionals' Representative	No interests declared	
Johannes Taminiau	Member	Healthcare Professionals' Representative	No interests declared	
Paola Baiardi	Alternate	Patients'	No interests declared	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
		Organisation Representative		
Tsvetana Schyns-Liharska	Member	Patients' Organisation Representative	No restrictions applicable to this meeting	
Susanne Kaul	Expert - via telephone*	Germany	No interests declared	
Dominik Karres	Expert - in person*	United Kingdom	No interests declared	
A representative from the European Commission attended the meeting *For CMDh:* Ad hoc experts* and a representative from the European Commission attended the meeting				
Meeting run with support from relevant EMA staff				

* Experts were only evaluated against the product(s) they have been invited to talk about.

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/