17 June 2015
EMA/PDCO/340491/2015
Procedure Management and Committees Support Division

Paediatric Committee (PDCO)

Minutes for the meeting on 20-22 May 2015

Chair: Dirk Mentzer – Vice-Chair: Koenraad Norga

20 May 2015, 08:30- 19:00, room 3A

21 May 2015, 08:30- 19:00, room 3A

22 May 2015, 08:30- 13:00, room 3A

Disclaimers

Some of the information contained in this agenda 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).

Note on access to documents

Some documents mentioned in the agenda 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

2.1. Opinions on Products

2.2. Opinions on Compliance Check

2.3. Opinions on Modification of an Agreed Paediatric Investigation Plan

2.4. Opinions on Re-examinations

2.5. Finalisation and adoption of opinions

The opinions adopted during the Paediatric Committee meeting of May 2015 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

3. Discussion of applications

The PDCO discussed 92 procedures in total[1], of which:

- 33 paediatric investigation plan applications;
- 9 product-specific waiver applications;
- 14 compliance check procedures (interim and final);
- 34 requests for modifications of an agreed paediatric investigation plan;
- 2 re-examination requests.

[1] The procedures discussed by the PDCO are on-going and therefore are considered confidential. Additional details on these procedures will be disclosed in the PDCO Committee meeting reports (after the PDCO Opinion is adopted), and on the Opinions and decisions on paediatric investigation plans webpage (after the EMA Decision is issued).

4. Nominations

4.1. List of letters of intent received for submission of applications with start of procedure July 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 list of Rapporteurs.

4.3. Nominations for other activities

4.3.1. Nomination of Anne-Laure Camara as FWG – PDCO member

Summary of committee discussion:

Anne Laure Camara was nominated as FWG – PDCO member

4.3.2. Nomination of PDCO members 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

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

6. Discussion on the applicability of class waivers

6.1. Discussions on the applicability of class waiver for products

6.1.1. Telotristat (etiprate) - EMEA-10-2015

IPSEN PHARMA; Treatment of patients with carcinoid syndrome/Treatment of gastroenteropancreatic neuroendocrine tumours (excluding neuroblastoma, neuroganglioblastoma, phaeochromocytoma)

Rapporteur: Herbert Lenicker

Summary of committee discussion:

The applicability of the class waiver to the planned therapeutic indication was not confirmed. Potential paediatric interest of this medicine suggested by PDCO: neuro-endocrine tumours secreting vasoactive substances causing symptoms of carcinoid syndrome.

6.1.2. Octreotide (hydrochloride) - EMEA-14-2015

Novartis Europharm Limited; Treatment of adult patients with functional neuroendocrine tumours of gastrointestinal origin/Treatment of gastroenteropancreatic neuroendocrine tumours (excluding neuroblastoma, neuroganglioblastoma, phaeochromocytoma)

Rapporteur: Koenraad Norga

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: acromegaly.

6.1.3. LY2835219 - EMEA-17-2015

Eli Lilly and Company Ltd.; Treatment of metastatic breast cancer/Treatment of breast carcinoma, Treatment of non-small cell lung cancer/Treatment of lung carcinoma (small cell and non-small cell carcinoma)

Rapporteur: Paolo Paolucci

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: MLL-rearranged acute lymphoblastic leukaemia, T-cell leukaemia/lymphoma, osteosarcoma, neuroblastoma, rabdomyosarcoma.

6.1.4. Cabozantinib- EMEA-18-2015

Exelixis International (UK) Limited; Treatment of adult patients with advanced renal cell carcinoma who have received one prior therapy/ Treatment of kidney and renal pelvis carcinoma (excluding nephroblastoma, nephroblastomatosis, clear cell sarcoma, mesoblastic nephroma, renal medullary carcinoma and rhabdoid tumour of the kidney

Rapporteur: Koenraad Norga

Summary of committee discussion:

The applicability of the class waiver to the planned therapeutic indication was confirmed. The PDCO noted that a paediatric development of cabozantinib had been agreed in a PIP.

6.1.5. Ezetimibe / atorvastatin (calcium trihydrate) - EMEA-22-2015

Merck Sharp & Dohme Ltd; Treatment of coronary heart disease/ Treatment of coronary atherosclerosis

Rapporteur: Birka Lehmann

Summary of committee discussion:

The applicability of the class waiver to the planned therapeutic indication was confirmed.

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. Pazopanib - Orphan - EMEA-000601-PIP01-09

Glaxo Group Limited

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted that a clinical study is not proceeding as planned and that the applicant is planning to request a modification of the agreed PIP.

8.1.2. Apixaban - EMEA-000183-PIP01-08

Bristol-Myers Squibb International Corporation

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.3. Apixaban - EMEA-000183-PIP02-12

Bristol-Myers Squibb / Pfizer EEIG

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.4. pixantrone dimaleate - Orphan - EMEA-000713-PIP02-10

CTI Life Sciences Limited

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.5. rituximab - EMEA-000308-PIP01-08-M02

Roche Products Ltd

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.6. Clostridium Botulinum neurotoxin type A (150 kD), free of complexing proteins - EMEA-001039-PIP02-12

Merz Pharmaceuticals GmbH

Difficulties progressing the PIP? Yes

Summary of committee discussion:

Delays for study MRZ60201_3091_1 (EudraCT 2013-004532-30). A request for modification of the agreed PIP is planned to be submitted.

8.1.7. Abatacept - EMEA-000118-PIP02-10

Bristol-Myers Squibb Pharma EEIG

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.8. simeprevir - EMEA-000625-PIP01-09

Tibotec BVBA

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.9. Sitagliptin phosphate monohydrate - EMEA-000471-PIP01-08

Merck Sharp and Dohme (Europe), Inc.

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.10. Sitagliptin phosphate monohydrate - EMEA-000470-PIP01-08

Merck Sharp and Dohme (Europe), Inc.

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.11. Sitagliptin phosphate monohydrate - EMEA-000472-PIP01-08

Merck Sharp and Dohme (Europe), Inc.

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report.

8.1.12. Telbivudine - EMEA-000065-PIP01-07

Novartis Europharm Limited

Difficulties progressing the PIP? Yes

Summary of committee discussion:

Delays in study CLDT600A2306 due to NCA requests. A modification will be submitted once extent of delay is understood.

8.1.13. Oseltamivir phosphate - EMEA-000365-PIP01-08

Roche Registration Ltd

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report.

8.1.14. elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil (as fumarate) - EMEA-000970-PIP01-10

Gilead Sciences International Limited

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report. The PIP is progressing according to plan.

8.1.15. (2S,3R,4R,5S,6R)-2-(4-Chloro-3-{3-[(S)-(tetrahydrofuran-3-yl)oxy]-benzyl}-phenyl...- EMEA-000828-PIP01-09

Boehringer Ingelheim International GmbH

Difficulties progressing the PIP? Yes

Summary of committee discussion:

The PDCO noted the report. The applicant has encountered recruitment problems. A request for modification of the agreed PIP has been received.

8.1.16. N. meningitidis serogroup Y polysaccharide conjugated to tetanus toxoid / N. men...- EMEA-000429-PIP01-08

GlaxoSmithKline Biologicals s.a

Difficulties progressing the PIP? Yes

Summary of committee discussion:

Delay in MenACWY-TT-084 which has been discussed and accepted M04.

8.1.17. Haemophilus influenzae type b polysaccharide conjugated to tetanus protein / Hep...- EMEA-001201-PIP01-11

Sanofi Pasteur

Difficulties progressing the PIP? No

Summary of committee discussion:

The PDCO noted the report. PIP studies are progressing according to plan.

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. Procedure for re-examination of PDCO Opinions

Summary of committee discussion:

The committee heard a presentation on the principles and procedural details on the re-examination of PDCO opinions.

9.1.2. PDCO revision of class waiver list

Rapporteur: Hendrik van den Berg, Koenraad Norga

Summary of committee discussion:

The PDCO was informed on the proceedings of the first EMA Industry stakeholder platform meeting on paediatric medicines, held on 11 May 2015, during which this topic was discussed.

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

CHMP update on paediatric topics

Summary of committee discussion:

The PDCO members were informed about two products, Tygacil and Orfadin, with paediatric indication and paediatric pharmaceutical form (oral suspension) respectively, recommended by the CHMP April 2015 plenary meeting.

9.2.2. Pharmacovigilance Risk Assessment Committee (PRAC)

Signal of decreased bone density with warfarin in children – PDCO conclusions and recommendations to PRAC

Rapporteur: Christoph Male

Summary of committee discussion:

Further to written comments received from PDCO members on the PRAC questions, a drafted response with conclusions and recommendations to the PRAC was presented to the PDCO

members. This response will be adopted by written procedure the week following the PDCO, and sent back to the PRAC.

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 report was noted.

9.3.2. Formulation Working Group : D30 Products identified

PDCO member: Brian Aylward

Summary of committee discussion:

Documents tabled for information.

9.4. Cooperation within the EU regulatory network

9.4.1. Agendas of the three Enpr-EMA meetings to take place on 28 and 29 May 2015

PDCO member: Christoph Male

Summary of committee discussion:

The agenda of the upcoming Enpr-EMA meeting was presented to the committee and will be included in the post-mail. In addition, the committee was informed about the planning of next year Enpr-EMA workshop.

9.4.2. Update on European Directorate for the Quality of Medicines (EDQM) project PaedForm

PDCO member: Siri Wang

Summary of committee discussion:

The Committee was informed of the activities carried out for the development of a pan-European paediatric formulary.

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

9.6.1. Report from EMA Industry stakeholder platform meeting on paediatric medicines held on 11 May 2015

Summary of committee discussion:

The PDCO was informed on the proceedings of the recent first EMA Industry stakeholder platform meeting on paediatric medicines. The interactions during this first platform meeting were considered useful and follow-up meeting are planned, on an annual basis or more often.

9.7. PDCO work plan

9.7.1. PDCO work plan 2015

Summary of committee discussion:

The Committee adopted the PDCO work plan 2015 with minor editorial amendments. The work plan will be published on the EMA public website.

9.8. Planning and reporting

None

9.9. PDCO ORGAM

None

9.10. Others

9.10.1. Presentation of Global Research in Paediatrics (GRIP)

Summary of committee discussion:

The PDCO was informed on the progress and deliverables of this project.

10. Any other business

10.1. None

11. Breakout sessions

11.1.1. PDCO contribution to the Cross Committee Task Force on registry

Summary of committee discussion:

A breakout session took place to plan next steps of PDCO contribution to this Cross Committees activity.

12. List of participants

including any restrictions with respect to involvement of members / alternates / experts following evaluation of declared interests for the 20-22 May 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-C-000312-PIP01-08-M07 EMEA-001215-PIP01-11-M03 EMEA-C1-000914-PIP01-10-M02
Koenraad Norga	Member (Vice-Chair)	Belgium	To be replaced for discussions, final deliberations and voting on products when chairing the meeting	EMEA-000069-PIP02-10-M05 EMEA-000431-PIP01-08-M08 EMEA-001749-PIP01-15
Jacqueline Carleer	Alternate	Belgium	No restrictions applicable to this meeting	
Violeta Iotova	Member	Bulgaria	No participation in discussions, final deliberations and voting	EMEA-001517-PIP02-14 EMEA-001755-PIP01-15 EMEA-000828-PIP03-14
Bernard Kaić	Alternate	Croatia	No interests declared	
Georgios Savva	Member	Cyprus	No interests declared	
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	Member	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	

Name	Role	Member state or affiliation	Outcome restriction following evaluation of e-DoI	Topics on agenda for which restrictions apply
			meeting	
Francesca Rocchi	Alternate	Italy	No restrictions applicable to this meeting	
Dina Apele-Freimane	Member	Latvia	No interests declared	
John-Joseph Borg	Member	Malta	No interests declared	
Maaike van Dartel	Alternate	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	
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	Healthcare Professionals' Representative	No interests declared	
Johannes Taminiau	Member	Healthcare Professionals' Representative	No interests declared	
Günther Auerswald	Member	Patients' Organisation Representative	No participation in discussions, final deliberations and voting	EMEA-C-000312-PIP01-08-M07 EMEA-001215-PIP01-11-M03 EMEA-C1-000914-PIP01-10-M02
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	
Sabine Scherer	Expert - via telephone*	Germany	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 product(s) they have been invited to talk about.

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/