



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Procedure Management and Committees Support Division

Paediatric Committee (PDCO)

Draft agenda 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

Health and safety information

In accordance with the Agency's health and safety policy, delegates are to be briefed on health, safety and emergency information and procedures prior to the start of the meeting.

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

Pre-meeting list of participants and restrictions in relation to declarations of interests applicable to the items of the agenda for the PDCO plenary session to be held 20-22 May 2015. See May 2015 PDCO minutes (to be published post June 2015 PDCO meeting).

1.2. Adoption of agenda

PDCO agenda for 20-22 May 2015.

1.3. Adoption of the minutes

PDCO minutes for 15-17 April 2015.

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 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 July 2015 for Nomination of Rapporteur and Peer reviewer

Action: For adoption

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

Action: For adoption

4.3. Nominations for other activities

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

Action: For adoption

4.3.2. Nomination of PDCO members for other activities

Action: For adoption

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

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

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

Action: For information

8.1.2. Apixaban - EMEA-000183-PIP01-08

Bristol-Myers Squibb International Corporation

Difficulties progressing the PIP? No

Action: For information

8.1.3. Apixaban - EMEA-000183-PIP02-12

Bristol-Myers Squibb / Pfizer EEIG

Difficulties progressing the PIP? No

Action: For information

8.1.4. [pixantrone dimaleate - Orphan - EMEA-000713-PIP02-10](#)

CTI Life Sciences Limited

Difficulties progressing the PIP? No

Action: For information

8.1.5. [rituximab - EMEA-000308-PIP01-08-M02](#)

Roche Products Ltd

Difficulties progressing the PIP? Yes

Action: For information

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

Action: For information

8.1.7. [Abatacept - EMEA-000118-PIP02-10](#)

Bristol-Myers Squibb Pharma EEIG

Difficulties progressing the PIP? No

Action: For information

8.1.8. [simeprevir - EMEA-000625-PIP01-09](#)

Tibotec BVBA

Difficulties progressing the PIP? No

Action: For information

8.1.9. [Sitagliptin phosphate monohydrate - EMEA-000471-PIP01-08](#)

Merck Sharp and Dohme (Europe), Inc.

Difficulties progressing the PIP? No

Action: For information

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

Merck Sharp and Dohme (Europe), Inc.

Difficulties progressing the PIP? No

Action: For information

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

Merck Sharp and Dohme (Europe), Inc.

Difficulties progressing the PIP? No

Action: For information

8.1.12. Telbivudine - EMEA-000065-PIP01-07

Novartis Europharm Limited

Difficulties progressing the PIP? Yes

Action: For information

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

Roche Registration Ltd

Difficulties progressing the PIP? Yes

Action: For information

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

Gilead Sciences International Limited

Difficulties progressing the PIP? No

Action: For information

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

Action: For information

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

Action: For information

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

Sanofi Pasteur

Difficulties progressing the PIP? No

Action: For information

9. Organisational, regulatory and methodological matters

9.1. Mandate and organisation of the PDCO

9.1.1. Procedure for re-examination of PDCO Opinions

Action: For information

9.1.2. Draft PDCO Opinion on revision of class waiver list

Rapporteur: Hendrik van den Berg, Koenraad Norga

Action: Discussion and adoption

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

Action: For information

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

Action: For discussion and possible written procedure

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

9.3.2. Formulation Working Group : D30 Products identified

PDCO member: Brian Aylward

Action: 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

Action: For discussion and possible written procedure

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

PDCO member: Siri Wang

Action: For information and discussion

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

Action: For information

9.7. PDCO work plan

9.7.1. Draft PDCO work plan 2015

Action: For adoption

9.8. Planning and reporting

None

9.9. PDCO ORGAM

None

9.10. Others

9.10.1. Presentation of Global Research in Paediatrics (GRIP)

Action: For information

10. Any other business

10.1. None

11. Breakout sessions

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

Action: For discussion on Thursday, room 3G

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/