6 January 2016
EMA/PDCO/795522/2015 Corr.
Procedure Management and Committees Support Division

Paediatric Committee (PDCO)

Draft agenda 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

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 9-11 December 2015. See PDCO December 2015 minutes (to be published post PDCO January 2016 meeting).

1.2. Adoption of agenda

PDCO agenda for 9-11 December 2015 meeting.

1.3. Adoption of the minutes

PDCO minutes for 11-13 November 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

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

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

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.

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. alemtuzumab - EMEA-001072-PIP01-10

Genzyme Europe B.V.

Difficulties progressing the PIP? Yes

Action: For information

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

Celgene Europe Ltd

Difficulties progressing the PIP? Yes

Action: For information

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

Takeda Global Research and Development Centre (Europe) Ltd

Difficulties progressing the PIP? No

Action: For information

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

Bristol-Myers Squibb Pharma EEIG

Difficulties progressing the PIP? No

Action: For information

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

Gilead Sciences International Limited

Difficulties progressing the PIP? No

Action: For information

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

Action: For information

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

Almirall S.A.

Difficulties progressing the PIP? Yes

Action: For information

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

Action: For information

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

Novo Nordisk A/S

Difficulties progressing the PIP? Yes

Action: For information

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

Action: For information

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

Action: For information

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

Basilea Pharmaceutica International Ltd.

Difficulties progressing the PIP? Yes

Action: For information

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

Janssen-Cilag International NV

Difficulties progressing the PIP? No

Action: For information

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

Bristol Myers Squibb /AstraZeneca EEIG

Difficulties progressing the PIP? No

Action: For information

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

Janssen-Cilag International NV

Difficulties progressing the PIP? No

Action: For information

8.1.16. exenatide - EMEA-000689-PIP01-09

Bristol-Myers Squibb/AstraZeneca EEIG[1]

Difficulties progressing the PIP? Yes

Action: For information

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

Eli Lilly & Company

[1] Applicant name updated

Difficulties progressing the PIP? Yes

Action: For information

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

Pharming Group N.V.

Difficulties progressing the PIP? Yes

Action: For information

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

Novartis Europharm Limited

Difficulties progressing the PIP? Yes

Action: For information

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

Merck Sharp & Dohme (Europe), Inc.

Difficulties progressing the PIP? No

Action: For information

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

Action: For information

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

Janssen-Cilag International N.V.

Difficulties progressing the PIP? Yes

Action: For information

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

Action: For discussion

9.2. Coordination with EMA Scientific Committees or CMDh-v

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

Action: For information

9.2.2. Oxybutynin – KENTERA (CAP)

Applicant: Nicobrand Limited
PRAC Rapporteur: Veerle Verlinden

Scope: Signal of psychiatric disorders
Action: For discussion

9.2.3. Draft Concept Paper on a Paediatric Addendum to the CHMP Guideline on antibacterials

PDCO member: Maria Fernandez Cortizo

Action: For discussion

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

PDCO member: Brian Aylward

Action: For information

9.3.3. Formulation Working Group

PDCO member: Brian Aylward

Delegation attending the PDCO

Action: For information

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

Action: For information

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

Action: For discussion

9.7. Planning and reporting

9.7.1. Report on the 'Data Gathering Initiative'

Action: For information

9.8. PDCO ORGAM

9.8.1. PDCO ORGAM Agenda for 2 December 2015

Action: For information

9.8.2. PDCO ORGAM Draft Minutes for 2 December 2015

Action: For adoption

10. Any other business

10.1. None

11. Breakout sessions

11.1.1. Paediatric oncology

Action: For discussion on Thursday, 18:30 - 19:00, room 3L

11.1.2. Neonatology

Action: For discussion on Thursday, 18:30 - 19:00, room 3G

11.1.3. Inventory

Action: For discussion on Thursday, 18:30 - 19:00, room 3L

11.1.4. Ethics drafting group

Action: For discussion on Wednesday, 19:00 - 19:30, room tbc

12. 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/