

Technology Appraisal Committee Meeting (Committee D)

Minutes: Unconfirmed

Date and Time: Wednesday 4 March 2015, 10:03-13:53

Venue: National Institute for Health and Care Excellence
Level 1A, City Tower
Piccadilly Plaza
Manchester
M1 4BT

Present:	1. Professor Gary McVeigh, Chair 2. Dr Lindsay Smith 3. Dr Aomesh Bhatt 4. Dr Andrew Black 5. Professor David Bowen 6. Dr Matthew Bradley 7. Mrs Tracey Cole 8. Dr Ian Davidson 9. Professor Simon Dixon 10. Mrs Susan Dutton 11. Dr Alexander Dyker 12. Professor Paula Ghaneh 13. Professor Carol Haigh 14. Professor John Henderson 15. Professor John Hutton 16. Dr Warren Linley 17. Mr Malcolm Oswald 18. Dr Murray Smith	Present for all notes Present for all notes
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In attendance:

Meindert Boysen	Programme Director, National Institute for Health and Care Excellence	Present for all notes
Helen Knight	Associate Director, National Institute for Health and Care Excellence	Present for all notes
Lori Farrar	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Joanne Ekeledo	Administrator, National Institute for Health and Care Excellence	Present for all notes

Amhed Elsada	Technical Analyst, National Institute for Health and Care Excellence	Present for all notes
Melinda Goodall	Technical Adviser, National Institute for Health and Clinical Excellence	Present for all notes
Dr Susan Griffin	Centre for Reviews and Dissemination and Centre for Economics - York	Present for notes 4 to 14
Beth Woods	Centre for Reviews and Dissemination and Centre for Economics - York	Present for notes 4 to 14
Mark Simmonds	Centre for Reviews and Dissemination and Centre for Economics - York	Present for notes 4 to 14
Alexis Llewelyn	Centre for Reviews and Dissemination and Centre for Economics - York	Present for notes 4 to 14
Professor Geoff Dusheiko	Clinical expert nominated by Bristol-Myers Squibb Pharmaceuticals	Present for notes 4 to 14
Dr Terence Wong	Clinical expert nominated by the British Society of Gastroenterology	Present for notes 4 to 14
Charles Gore	Patient expert nominated by The Hepatitis C Trust	Present for notes 4 to 14
Robert James	Patient expert nominated by the British HIV Association and British Association for Sexual Health and HIV	Present for notes 4 to 14
Professor Matthew Hickman	National Clinical Guideline Centre	Present for notes 4 to 14

Notes

Welcome

1. The Chair welcomed all members of the Committee and other attendees present to the meeting. The Chair reviewed the agenda and timescales for the meeting, which included the appraisals of Daclatasvir for treating chronic hepatitis C.
2. Apologies were received from Dr Ian Campbell, Mrs Gillian Ells, Professor Steven Julius, Dr Tim Kinnaird and Professor Oluwafemi Oyebode and Dr Mohit Sharma.

Any other Business

3. None.

Appraisal of Daclatasvir for treating chronic hepatitis C.

Part 1 – Open session

4. The Chair welcomed the invited experts: Geoff Dusheiko, Terrence Wong, Charles Gore, Robert James, Susan Griffin, Beth Woods, Mark Simmonds, Alexis Llewelyn, Matthew Hickman and Ursula People to the meeting and they introduced themselves to the Committee.
5. The Chair welcomed company representatives from Bristol-Myers Squibb Pharmaceuticals Ltd (BMS) to the meeting.
6. The Chair asked all Committee members to declare any relevant interests
 - 6.1. Professor Gary McVeigh, Dr Lindsay Smith, Dr Aomesh Bhatt, Dr Andrew Black, Professor David Bowen, Dr Matthew Bradley, Mrs Tracey Cole, Dr Ian Davidson, Professor Simon Dixon, Mrs Susan Dutton, Dr Alexander Dyker, Professor Paula Ghaneh, Professor Carol Haigh, Professor John Henderson, Professor John Hutton, Dr Warren Linley, Mr Malcolm Oswald and Dr Murray Smith all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of Daclatasvir for treating chronic hepatitis C.
7. The Chair asked all NICE Staff to declare any relevant interests.
 - 7.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary interest,

personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of Daclatasvir for treating chronic hepatitis C.

8. The Chair asked the Guidance Development Group to declare any relevant interests.
 - 8.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of Daclatasvir for treating chronic hepatitis C.
9. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their relevant interests.
 - 9.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary interest, personal specific family interest or personal non-specific family interest for any of the technologies to be considered as part of the appraisal of Daclatasvir for treating chronic hepatitis C.
10. The Chair introduced the lead team, Professor Carol Haigh, Dr Murray Smith and Mr Malcolm Oswald who gave presentations on the clinical effectiveness and cost effectiveness of Daclatasvir for treating chronic hepatitis C.
11. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of Daclatasvir for treating chronic hepatitis C on the basis of the evidence before them, and potential equality issues raised in this appraisal. They sought clarification and advice from the experts present. The discussions included:
 - 11.1. The clinical management of chronic hepatitis C in adults, and the role of the new technologies in treatment
 - 11.2. The alternative treatment durations and regimens recommended in the marketing authorisation for genotypes 1 and 4 hepatitis C virus
 - 11.3. The quality of the clinical trial evidence for daclatasvir
 - 11.4. The efficacy of daclatasvir in clinical trials
 - 11.5. The subgroups of people co-infected with HIV, and those who had, or were yet to have, a liver transplant
 - 11.6. The appropriate population for the consideration of the cost effectiveness of daclatasvir
 - 11.7. The transition probabilities in the company's model
 - 11.8. The appropriate comparators for daclatasvir in the economic model

- 11.9. The SVR rates used in the model for daclatasvir and its comparators, and the robustness of these estimates
- 11.10. The utility increments in the model for having an SVR
- 11.11. The costs included in the model
- 11.12. The best source of evidence on the cost effectiveness of daclatasvir
- 11.13. The ICERs for each relevant subgroup of patients

12. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
13. The Chair explained that "representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest" (Section 1(2) Public Bodies (Admission to Meetings) Act 1960)" and all public attendees left the meeting.
14. The Chair then thanked the experts, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

15. Discussion on confidential information continued. This information was supplied by the company.
16. The Committee continued to discuss the clinical and cost effectiveness of Daclatasvir for treating chronic hepatitis C.

17. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

Date, time and venue of the next meeting

17. Wednesday 1 April 2015, 10:00 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.