

Technology Appraisal Committee Meeting (Committee D)

Minutes: **Confirmed**

Date and Time: **Wednesday 7 January 2015, 10am – 3.45pm**

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 (Vice Chair) 3. Dr Aomesh Bhatt 4. Dr Andrew Black 5. Professor David Bowen 6. Dr Matthew Bradley 7. Dr Ian Campbell 8. Tracey Cole 9. Dr Ian Davidson 10. Professor Simon Dixon 11. Susan Dutton 12. Dr Alexander Dyker 13. Christopher Earl 14. Gillian Ells 15. Professor Paula Ghaneh 16. Dr Susan Griffin 17. Professor Carol Haigh 18. Professor John Henderson 19. Professor John Hutton 20. Professor Steven Julious 21. Dr Tim Kinnaird 22. Warren Linley 23. Dr Malcolm Oswald 24. Professor Femi Oyebode 25. Professor Carolyn Young	Present for all notes Present for notes 1 to 28 Present for all notes Present for notes 1 to 17
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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

Kate Moore	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Carl Jackson	Administrator, National Institute for Health and Care Excellence	Present for notes 1 to 17
Dr Rosie Lovett	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 17
Boglarka Mikudina	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 17
Ian Watson	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 18 to 29
Melinda Goodall	Technical Advisor, National Institute for Health and Care Excellence	Present for notes 18 to 29
Dr Miriam Brazzelli	Aberdeen HTA Group	Present for notes 1 to 15
Professor Paul McNamee	Aberdeen HTA Group	Present for notes 1 to 15
Ms Emma Tassie	Aberdeen HTA Group	Present for notes 1 to 15
Dr Jonathan Shepherd	Southampton Health Technology Assessments Centre (SHTAC)	Present for notes 18 to 26
Dr Keith Cooper	Southampton Health Technology Assessments Centre (SHTAC)	Present for notes 18 to 26
Dr Sulleman Moreea	Consultant Hepatologist, clinical expert nominated by the British Society of Gastroenterology	Present for notes 18 to 26
Mr Andrew Langford	Chief Executive of the British Liver Trust, patient expert nominated by the British Liver Trust	Present for notes 18 to 26

Dr Debbie Shawcross	Senior Lecturer and Honorary Consultant in Hepatology, clinical expert nominated by Norgine	Present for notes 18 to 26
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Non-public observers:

Karyo Angeloudis	Technical Analyst, Health and Social Care, National Institute for Health and Care Excellence	Present for notes 1 to 29
Ms Ann Greenwood	Senior Medical Editor, Communications, National Institute for Health and Care Excellence	Present for notes 1 to 29
Ms Laura Norburn	Public Involvement Adviser, Health and Social Care, National Institute for Health and Care Excellence	Present for notes 1 to 29

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 collagenase clostridium histolyticum for treating Dupuytren's contracture and rifaximin for maintaining remission from episodes of hepatic encephalopathy
2. The Chair informed the Committee of the non-public observers at this meeting: Karyo Angeloudis, Ann Greenwood and Laura Norburn
3. Apologies were received from Professor Paula Ghaneh, Professor Steven Julious and Dr Murray Smith.

Any other Business

4. None

Notes from the last meeting

5. None

Appraisal of [Insert long form title of first topic]

Part 1 – Open session

6. The Chair welcomed the invited experts: Dr Miriam Brazzelli, Professor Paul McNamee and Ms Emma Tassie to the meeting and they introduced themselves to the Committee.
7. The Chair welcomed company representatives from Swedish Orphan Biovitrum to the meeting.
8. The Chair asked all Committee members to declare any relevant interests
 - 8.1. Dr Aomesh Bhatt, Dr Andrew Black, Professor David Bowen, Dr Matthew Bradley, Dr Ian Campbell, Ms Tracey Cole, Dr Ian Davidson, Professor Simon Dixon, Mrs Susan Dutton, Dr Alexander Dyker, Mr Christopher Earl, Mrs Gillian Ells, Dr Susan Griffin, Professor Carol Haigh, Professor John Henderson, Professor John Hutton, Dr Tim Kinnaird, Warren Linley, Professor Gary McVeigh, Dr Malcolm Oswald, Professor Femi Oyebode, Dr Mohit Sharma and Professor Carolyn Young 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 collagenase clostridium histolyticum for treating Dupuytren's contracture.
9. The Chair asked all NICE Staff to declare any 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 collagenase clostridium histolyticum for treating Dupuytren's contracture.
10. The Chair asked all other invited to declare their relevant interests.
 - 10.1. 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 collagenase clostridium histolyticum for treating Dupuytren's contracture.
11. The Chair introduced the key themes arising from the consultation responses to the Appraisal Consultation Document (ACD) received from consultees, commentators and through the NICE website.
12. The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of clostridium histolyticum for treating Dupuytren's contracture on the basis of the evidence before them. The discussions included:
 - 12.1. The responses to consultation received from consultees, commentators, and members of the public.
 - 12.2. The additional evidence submitted by the company about the number of CCH injections required and recovery time after limited fasciectomy. The Committee also discussed the Assessment Group's review of the additional evidence.

- 12.3. The additional economic analyses submitted by the company and the Assessment Group. The Committee discussed whether the assumptions reflected the available evidence and clinical experience. The following aspects of the new analyses were discussed: success rates, the use of a utility decrement to reflect recovery time, and the number of CCH injections required.
- 12.4. Whether there is a subgroup with moderate disease for whom PNF would not be a suitable treatment.
- 12.5. Whether there is a subgroup for whom CCH could be a cost-effective treatment.

13. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
14. 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.
15. The Chair then thanked the, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

16. The Committee continued to discuss the clinical and cost effectiveness of collagenase clostridium histolyticum for treating Dupuytren's contracture.
17. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of rifaximin for maintaining remission from episodes of hepatic encephalopathy

Part 1 – Open session

18. The Chair welcomed the invited experts: Dr Keith Cooper, Dr Sulleman Moreea, Mr Andrew Langford, Dr Debbie Shawcross and Dr Jonathan Shepherd to the meeting and they introduced themselves to the Committee.
19. The Chair welcomed company representatives from Norgine to the meeting.
20. The Chair asked all Committee members to declare any relevant interests
 - 20.1. Dr Aomesh Bhatt, Dr Andrew Black, Dr Matthew Bradley, Dr Ian Campbell, Ms Tracey Cole, Dr Ian Davidson, Professor Simon Dixon, Mrs Susan Dutton, Dr Alexander Dyker, Mr Christopher Earl, Mrs Gillian Ells, Dr Susan Griffin, Professor Carol Haigh, Professor John Henderson, Professor John Hutton, Dr Tim Kinnaird, Mr Warren Linley, Professor Gary McVeigh, Dr Malcolm Oswald, Professor Femi Oyebode, Dr Mohit Sharma, Dr Lindsay 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 rifaximin for maintaining remission from episodes of hepatic encephalopathy.

20.2. Professor David Bowen declared a personal non-specific non-pecuniary interest as he had attended an Advisory Board for a different product not related to this topic.
9.2.1 It was agreed that this declaration would not prevent Professor David Bowen from participating in this section of the meeting.

20.3. Professor Simon Dixon declared a personal non-specific non-pecuniary interest. Professor Dixon is the director of Health Economics Unit who have undertaken work for one of the comparator companies, but not in relation to this topic. Professor Dixon was not involved in the work.
9.3.1 It was agreed that this declaration would not prevent Professor Simon Dixon from participating in this section of the meeting.

20.4. Professor Carolyn Young was absent from the meeting due to declaring a personal non-specific pecuniary interest. She has received funding for lecturing from the company and has done paid advisory work from both the company and a comparator company.

21. The Chair asked all NICE Staff to declare any relevant interests.

21.1. 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 rifaximin for maintaining remission from episodes of hepatic encephalopathy.

22. The Chair asked all other invited guests to declare their relevant interests.

22.1. 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 rifaximin for maintaining remission from episodes of hepatic encephalopathy.

23. The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of rifaximin for maintaining remission from episodes of hepatic encephalopathy on the basis of the evidence before them. The discussions included:

23.1. The company's most recent submission, outlining evidence on the utility benefit associated with rifaximin, the effect of rifaximin on hospital admissions and the long-term effectiveness of rifaximin

23.2. The ERG's comments on the company's submission

23.3. The most appropriate assumptions for the economic model and the most plausible estimate for the cost effectiveness of rifaximin

23.4. Issues relating to equality that might affect the appraisal

24. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
25. 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.
26. 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

27. Discussion on confidential information continued. This information was supplied by the company.
28. The Committee continued to discuss the clinical and cost effectiveness of rifaximin for maintaining remission from episodes of hepatic encephalopathy.
 - 28.1. A vote was taken. The question was 'Should rifaximin be recommended, within its marketing authorisation, for preventing episodes of hepatic encephalopathy? The options were:
Option 1: Yes, recommend
Option 2: No, do not recommend
The Committee voted for Option 1: Yes, recommend
29. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Date, time and venue of the next meeting

30. Tuesday 3 February 2015 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.