

Technology Appraisal Committee Meeting (Committee D)

Minutes: Confirmed

Date and Time: Thursday 28 April 2016, 10:40-15:00

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. Dr Matthew Bradley 6. Dr Ian Campbell 7. Dr Ian Davidson 8. Professor Simon Dixon 9. Mrs Susan Dutton 10. Mrs Gillian Ells 11. Professor Paula Ghaneh 12. Dr Susan Griffin 13. Professor Carol Haigh 14. Mr Malcolm Oswald 15. Professor Oluwafemi Oyebode 16. Dr Paula Parvulescu 17. Dr Mohit Sharma	Present for all notes Present for notes 01 to 16 Present for all notes Present for all notes Present for all notes 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
Martyn Burke	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 17 to 26
Danielle Conroy	Administrator, National Institute for Health and Care Excellence	Present for all notes
Dr Jesme Fox	Patient expert nominated by Roy Castle Lung Cancer Foundation	Present for notes 05 to 13

Helen Knight	Associate Director, National Institute for Health and Care Excellence	Present for all notes
Professor Jo Lord	ERG representative from Southampton Health Technology Assessments Centre	Present for notes 05 to 13
Professor Gary Middleton	Clinical expert nominated by Eli Lilly UK	Present for notes 05 to 13
Fay McCracken	Technical Adviser, National Institute for Health and Care Excellence	Present for notes 17 to 26
Kate Moore	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Dr Thomas Newsom- Davis	Clinical expert nominated by Royal College of Physicians	Present for notes 05 to 13
Dr Karen Pickett	ERG representative from Southampton Health Technology Assessments Centre	Present for notes 05 to 13
Nwamaka Umeweni	Technical Adviser, National Institute for Health and Care Excellence	Present for notes 01 to 16
Ian Watson	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 01 to 16
Non-public observers:		
Ann Greenwood	Editor, National Institute for Health and Care Excellence	Present for notes all notes
Bas Knoop	Journalist, Medisch Contact	Present for notes all notes
Harmeet Rehan	Durham University	Present for notes all notes
Safeer Sulehman	Finance Trainee, National Institute for	Present for notes all notes

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 necitumumab for untreated advanced metastatic squamous non-small-cell lung cancer and lumacaftor and ivacaftor combination therapy for treating cystic fibrosis homozygous for the F508del mutation.
2. The Chair informed the Committee of the non-public observers at this meeting: Ann Greenwood, Bas Knoop, Harmeet Rehan and Safeer Sulehman.
3. Apologies were received from Professor David Bowen, Ms Tracey Cole, Dr Alexander Dyker, Professor John Henderson and Dr Tim Kinnaird.

Any other Business

4. The committee were given updates on research recommendations and the Cancer Drugs Fund

Appraisal of necitumumab for untreated advanced metastatic squamous non-small-cell lung cancer

Part 1 – Open session

5. The Chair welcomed the invited experts: Dr Jesme Fox, Professor Jo Lord, Professor Gary Middleton, Dr Thomas Newsom-Davis and Karen Pickett to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from Eli Lilly UK to the meeting.
7. The Chair asked all Committee members to declare any relevant interests
 - 7.1. Professor Gary McVeigh, Dr Lindsay Smith, Dr Aomesh Bhatt, Dr Andrew Black, Dr Matthew Bradley, Dr Ian Campbell, Dr Ian Davidson, Professor Simon Dixon, Mrs Susan Dutton, Mrs Gillian Ells, Professor Paula Ghaneh, Dr Susan Griffin, Professor Carol Haigh, Mr Malcolm Oswald, Professor Oluwafemi Oyebode, Dr Paula Parvulescu and Dr Mohit Sharma all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial 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 necitumumab for untreated advanced metastatic squamous non-small-cell lung cancer.
8. The Chair asked all NICE Staff to declare any relevant interests.

- 8.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial 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 necitumumab for untreated advanced metastatic squamous non-small-cell lung cancer.
9. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
 - 9.1. Dr Jesme Fox, Professor Jo Lord, Professor Gary Middleton and Dr Karen Pickett declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial 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 necitumumab for untreated advanced metastatic squamous non-small-cell lung cancer.
 - 9.2. Dr Thomas Newsom-Davis declared a personal non-specific financial interest as he has carried out advisory work for Eli Lilly. This was unrelated to the technology under appraisal but Dr Newsom-Davis did receive payment for this work.
 - 9.2.1. It was agreed that this declaration would not prevent Dr Newsom-Davis from participating in this section of the meeting
10. The Chair introduced the lead team, Professor Simon Dixon, Professor Paula Ghaneh and Mr Malcolm Oswald who gave presentations on the clinical effectiveness and cost effectiveness of necitumumab for untreated advanced metastatic squamous non-small-cell lung cancer.
11. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
12. 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.
13. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

14. Discussion on confidential information continued. This information was supplied by the company.
15. The Committee continued to discuss the clinical and cost effectiveness of necitumumab for untreated advanced metastatic squamous non-small-cell lung cancer.
 - 15.1. The committee decision was based on consensus.

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

Appraisal of lumacaftor and ivacaftor combination therapy for treating cystic fibrosis homozygous for the F508del mutation

Part 1 – Open session

17. The Chair welcomed company representatives from Vertex Pharmaceuticals to the meeting.
18. The Chair asked all Committee members to declare any relevant interests
 - 18.1. Professor Gary McVeigh, Dr Lindsay Smith, Dr Aomesh Bhatt, Dr Andrew Black, Dr Matthew Bradley, Dr Ian Campbell, Dr Ian Davidson, Mrs Susan Dutton, Mrs Gillian Ells, Professor Paula Ghaneh, Dr Susan Griffin, Mr Malcolm Oswald, Professor Oluwafemi Oyebode, Dr Paula Parvulescu and Dr Mohit Sharma all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial 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 lumacaftor and ivacaftor combination therapy for treating cystic fibrosis homozygous for the F508del mutation.
 - 18.2. Professor Simon Dixon, declared a non-personal non-specific financial interest as he is the Director of Health Economics Unit that has undertaken work for Roche, who is a comparator in this appraisal. This work was for an unrelated topic and the University of Sheffield received payment for this work.
 - 9.2.1 It was agreed that this declaration would not prevent Professor Dixon participating in this section of the meeting.
19. The Chair asked all NICE Staff to declare any relevant interests.
 - 19.1. All declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, non-personal non-specific financial 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 lumacaftor and ivacaftor combination therapy for treating cystic fibrosis homozygous for the F508del mutation.
20. 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.
21. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
22. 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.

23. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

24. Discussion on confidential information continued. This information was supplied by the company.
25. The Committee continued to discuss the clinical and cost effectiveness of lumacaftor and ivacaftor combination therapy for treating cystic fibrosis homozygous for the F508del mutation.
 - 25.1. The committee decision was based on consensus.

26. 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

27. Thursday 26 May 2016, 10:00 to 17:00, at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.