

## Technology Appraisal Committee Meeting (Committee D)

**Minutes:** Confirmed

**Date and Time:** Thursday 25 February 2016, 10:00-14:15

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

<b>Present:</b>	1. Professor Gary McVeigh, Chair 2. Dr Lindsay Smith, Vice Chair 3. Dr Aomesh Bhatt 4. Dr Andrew Black 5. Dr Matthew Bradley 6. Ms Tracey Cole 7. Dr Ian Davidson 8. Professor Simon Dixon 9. Mrs Susan Dutton 10. Dr Alexander Dyker 11. Mrs Gillian Ells 12. Professor Paula Ghaneh 13. Dr Susan Griffin 14. Professor Carol Haigh 15. Mr Malcolm Oswald 16. Dr Paula Parvulescu	Present for all notes Present for all notes
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### In attendance:

Vicky Armstrong	Patient Expert nominated by The Cystic Fibrosis Trust	Present for notes 01 to 15
Dr Ian Balfour-Lynn	NHS Commissioning representative nominated by NHS England	Present for notes 01 to 15
Dr Peter Barry	Clinical Expert nominated by Vertex Pharmaceuticals	Present for notes 01 to 15
Lynsey Beswick	Patient Expert nominated by The Cystic Fibrosis Trust	Present for notes 01 to 15
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 all notes
Jill Colquitt	Evidence Review Group representative, Warwick Evidence	Present for notes 01 to 15
Danielle Conroy	Administrator, National Institute for Health and Care Excellence	Present for all notes
Dr Iolo Doull	Guideline Development Group representative nominated by the National Collaborating Centre for Women's and Children's Health	Present for notes 01 to 15
Fay McCracken	Technical Adviser, 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
G.J. Melendez-Torres	Evidence Review Group representative, Warwick Evidence	Present for notes 01 to 15
Kate Moore	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Dr Edward Nash	Clinical Expert nominated by Vertex Pharmaceuticals	Present for notes 01 to 15
Malcolm Qualie	NHS Commissioning representative nominated by NHS England	Present for notes 01 to 15

**Non-public observers:**

Ann Greenwood	Editor, National Institute for Health and Care Excellence	Present for all notes
Safeer Sulehman		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 appraisal of 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 and Safeer Sulehman.
3. Apologies were received from Professor David Bowen, Dr Ian Campbell, Professor John Henderson, Dr Tim Kinnaird, Professor Oluwafemi Oyebode, Dr Mohit Sharma and Dr Murray Smith.

### Any other Business

4. None.

### Notes from the last meeting

5. Agreement of the minutes from the last committee meeting on 27 January 2016.

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

#### **Part 1 – Open session**

6. The Chair welcomed the invited experts: Vicky Armstrong, Dr Peter Barry, Dr Ian Balfour-Lynn, Lynsey Beswick, Jill Colquitt, Dr Iolo Duoll, G.J. Melendez-Torres, Dr Edward Nash, Joshua Pink and Malcolm Qualie to the meeting and they introduced themselves to the Committee.
7. The Chair welcomed company representatives from Vertex Pharmaceuticals to the meeting.
8. The Chair asked all Committee members to declare any relevant interests
  - 8.1. Dr Aomesh Bhatt, Dr Andrew Black, Dr Matthew Bradley, Ms Tracey Cole, Dr Ian Davidson, Mrs Susan Dutton, Dr Alexander Dyker, Mrs Gillian Ells, Professor Paula Ghaneh, Dr Susan Griffin, Professor Carol Haigh, Professor Gary McVeigh, Mr Malcolm Oswald, Dr Paula Parvulescu and Dr Lindsay Smith 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.

- 8.2. Professor Simon Dixon declared a non-personal non-specific financial interest as he is the Director of a Health Economics Unit that has undertaken work for Roche who are a comparator in this appraisal. This was unrelated to the topic under consideration but the University did receive payment for this work.
- 8.2.1 It was agreed that this declaration would not prevent Professor Dixon from participating in this section of the meeting.
9. The Chair asked all NICE Staff to declare any relevant interests.
- 9.1. 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.
10. The Chair asked the Guidance Development Group representative to declare any relevant interests.
- 10.1. Dr Iolo Doull declared a personal specific non-financial interest as he has provided expert advice to the MHRA on this technology. Dr Duoll did not receive payment.
- 10.1.1. It was agreed that this declaration would not prevent Dr Duoll from participating in this section of the meeting.
11. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their relevant interests.
- 11.1. 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.
- 11.2. Dr Peter Barry declared a personal non-specific non-financial interest as he is Principle Investigator on 2 trials sponsored by the manufacturer in this appraisal. These were not for the technology under consideration and Dr Barry did not receive payment for this work.
- 11.2.1. It was agreed that this declaration would not prevent Dr Barry from participating in this section of the meeting
12. The Chair introduced the lead team, Dr Matthew Bradley, Ms Tracey Cole and himself who gave presentations on the clinical effectiveness and cost effectiveness of lumacaftor and ivacaftor combination therapy for treating cystic fibrosis homozygous for the F508del mutation
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 experts and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

## **Part 2 – Closed session**

16. Discussion on confidential information continued. This information was supplied by the company.
17. 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.
18. 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**

19. Wednesday 23 March 2016, 10:00-17:00 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.