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

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

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
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<thead>
<tr>
<th>Name</th>
<th>Role and Association</th>
<th>Present For Notes</th>
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<tbody>
<tr>
<td>Martyn Burke</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>All notes</td>
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<td>Jill Colquitt</td>
<td>Evidence Review Group representative, Warwick Evidence</td>
<td>01 to 15</td>
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<tr>
<td>Danielle Conroy</td>
<td>Administrator, National Institute for Health and Care Excellence</td>
<td>All notes</td>
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<tr>
<td>Dr Iolo Doull</td>
<td>Guideline Development Group representative nominated by the National Collaborating Centre for Women’s’ and Children’s’ Health</td>
<td>01 to 15</td>
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<td>Fay McCracken</td>
<td>Technical Adviser, National Institute for Health and Care Excellence</td>
<td>All notes</td>
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<tr>
<td>Helen Knight</td>
<td>Associate Director, National Institute for Health and Care Excellence</td>
<td>All notes</td>
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<td>G.J. Melendez-Torres</td>
<td>Evidence Review Group representative, Warwick Evidence</td>
<td>01 to 15</td>
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<td>Kate Moore</td>
<td>Project Manager, National Institute for Health and Care Excellence</td>
<td>All notes</td>
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<td>Dr Edward Nash</td>
<td>Clinical Expert nominated by Vertex Pharmaceuticals</td>
<td>01 to 15</td>
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<tr>
<td>Malcolm Qualie</td>
<td>NHS Commissioning representative nominated by NHS England</td>
<td>01 to 15</td>
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**Non-public observers:**

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<tr>
<th>Name</th>
<th>Role and Association</th>
<th>Present For Notes</th>
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<tbody>
<tr>
<td>Ann Greenwood</td>
<td>Editor, National Institute for Health and Care Excellence</td>
<td>All notes</td>
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<tr>
<td>Safeer Sulehman</td>
<td></td>
<td>All notes</td>
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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 Ellis, Professor Paula Ghanem, 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.