Technology Appraisal Committee Meeting Committee C

Minutes: Confirmed

Date and Time: Wednesday 13 January 2016, 10:00 to 17:00

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

Present:
1. Chair Professor Andrew Stevens Present for all notes
2. Prof Kathryn Abel Present for all notes
3. David Chandler Present for all notes
4. Professor Peter Crome Present for all notes
5. Dr Nigel Langford Present for all notes
6. Dr Iain Miller Present for all notes
7. Dr Paul Miller Present for notes 01 to 12
8. Professor Eugene Milne Present for all notes
9. Professor Andrea Manca Present for notes 01 to 12
10. Dr Patrick McKiernan Present for all notes
11. Professor Stephen O’Brien Present for all notes
12. Dr Peter Selby Present for all notes
13. Prof Matt Stevenson Present for all notes
14. Dr Paul Tappenden Present for notes 01 to 08 and 13 to 16
15. Professor Robert Walton Present for all notes
16. Dr Judith Wardle Present for all notes

In attendance:

Meindert Boysen Programme Director, National Institute for Health and Care Excellence Present for all notes

Dr Frances Sutcliffe Associate Director, National Institute for Health and Care Excellence Present for all notes

Stephanie Yates Project Manager, National Institute for Health and Care Excellence Present for all notes

Joanne Ekelede Administrator, National Institute for Health and Care Excellence Present for all notes
<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
<th>Present for notes</th>
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<tbody>
<tr>
<td>Jasdeep Hayre</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>01 to 14</td>
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<tr>
<td>Joanne Holden</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>01 to 14</td>
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<tr>
<td>Ahmed Elsada</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>01 to 14</td>
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<tr>
<td>Nicola Hay</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>01 to 14</td>
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<tr>
<td>Boglarka Mikundina</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>15 to 16</td>
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<tr>
<td>Eleanor Donegan</td>
<td>Technical Adviser, National Institute for Health and Clinical Excellence</td>
<td>15 to 16</td>
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**Non-public observers:**

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<tr>
<th>Name</th>
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<tr>
<td>Miriam Brazzelli</td>
<td>ERG Representative</td>
<td>01 to 07</td>
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<tr>
<td>Mehdi Javanbakht</td>
<td>ERG Representative</td>
<td>01 to 07</td>
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<tr>
<td>Aileen Nielson</td>
<td>ERG Representative</td>
<td>01 to 07</td>
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<tr>
<td>Graham Scotland</td>
<td>ERG Representative</td>
<td>01 to 07</td>
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<tr>
<td>Mr Rachid Rafia</td>
<td>ERG Representative</td>
<td>09 to 14</td>
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<tr>
<td>Dr Paul Tappenden</td>
<td>ERG Representative</td>
<td>09 to 14</td>
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<tr>
<td>Rob Hodgson</td>
<td>ERG Representative</td>
<td>13 to 16</td>
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<tr>
<td>Mousumi Miswas</td>
<td>ERG Representative</td>
<td>13 to 16</td>
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<tr>
<td>Professor Robin Choudhury</td>
<td>Clinical Expert</td>
<td>02 to 07</td>
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<tr>
<td>Karen Hasid</td>
<td>Patient Expert</td>
<td>02 to 07</td>
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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 Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia, Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia and Ruxolitinib for disease-related splenomegaly or symptoms in adults with myelofibrosis (review of TA289)

2. Apologies were received from Dr Anna O’Neill, Gail Coster and Dr Claire Rothery

Any other Business

3. None

Appraisal of Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia

Part 1 – Open session

4. The Chair welcomed the invited experts: Professor Robin Choudhury, Karen Hasid and Simon Williams to the meeting and they introduced themselves to the Committee.

5. The Chair welcomed company representatives from Sanofi to the meeting.

6. The Chair asked all Committee members to declare any relevant interests

6.1. Dr Judith Wardle, Professor Robert Walton, Dr Paul Tappenden, Prof Matt Stevenson, Dr Peter Selby, Professor Stephen O’Brien, Dr Patrick McKiernan, Professor Andrea Manca, Professor Eugene Milne, Dr Paul Miller, Dr Iain Miller, Dr Nigel Langford, Professor Peter Crome, David Chandler and Prof Kathryn Abel 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 Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia.

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

7.1. 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 Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia.
8. The Chair asked all other invited guests ERG and invited experts, not including observers) to declare their 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 Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia.

8.2. Professor Robin Choudhury declared a personal non-specific financial interest as he has received consultancy fees from Amgen, Sanofi and MSD.

8.2.1. It was agreed that this declaration would not prevent Professor Robin Choudhury from participating in this section of the meeting.

9. The Chair introduced the lead team, Professor Stephen O’Brien, Dr Paul Tappenden and Dr Judith Wardle who gave presentations on the clinical effectiveness and cost effectiveness of Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia.

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

11. 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.

12. 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

13. The Committee continued to discuss the clinical and cost effectiveness of Alirocumab for treating primary hypercholesterolaemia and mixed dyslipidaemia.

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

Appraisal of Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia

Part 1 – Open session.

15. The Chair welcomed company representatives from Amgen to the meeting.

16. The Chair asked all Committee members to declare any relevant interests.

16.1. Dr Judith Wardle, Professor Robert Walton, Prof Matt Stevenson, Dr Peter Selby, Professor Stephen O’Brien, Dr Patrick McKiernan, Professor Andrea Manca, Professor Eugene Milne, Dr Paul Miller, Dr
Iain Miller, Dr Nigel Langford, Professor Peter Crome, David Chandler and Prof Kathryn Abel 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 Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia

16.2. Dr Paul Tappenden is conflicted. He represented the ERG at the meeting for the appraisal of Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia

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

17.1. 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 Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia

18. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.

18.1. 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 Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia

19. 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.

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

21. 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.

22. 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

23. Discussion on confidential information continued. This information was supplied by the company.

24. The Committee continued to discuss the clinical and cost effectiveness of Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia
25. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) 2 in line with their decisions.

Appraisal of Ruxolitinib for disease-related splenomegaly or symptoms in adults with myelofibrosis (review of TA289)

Part 1 – Open session

26. The Chair welcomed company representatives from Novartis to the meeting.

27. The Chair asked all Committee members to declare any relevant interests

27.1. Dr Judith Wardle, Professor Robert Walton, Dr Paul Tappenden, Prof Matt Stevenson, Dr Peter Selby, Professor Stephen O’Brien, Dr Patrick McKiernan, Professor Eugene Milne, Dr Iain Miller, Dr Nigel Langford, Professor Peter Crome, David Chandler and Prof Kathryn Abel 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 Ruxolitinib for disease-related splenomegaly or symptoms in adults with myelofibrosis (review of TA289).

27.2. Professor Stephen O’Brien declared a non-personal specific financial interest as his University have received research funding and conducted clinical trials for the company

27.3. Dr Paul Miller is conflicted, he has undertaken consultancy for a comparator company in the past 12 months

27.4. Andrea Manca is conflicted he has received fees for participating in an advisory board on one of Novartis novel drugs for haematological malignancies.

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

28.1. 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 Ruxolitinib for disease-related splenomegaly or symptoms in adults with myelofibrosis (review of TA289).

29. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
29.1. 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 Ruxolitinib for disease-related splenomegaly or symptoms in adults with myelofibrosis (review of TA289).

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.

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

31. 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.

32. 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

33. The Committee continued to discuss the clinical and cost effectiveness of Ruxolitinib for disease-related splenomegaly or symptoms in adults with myelofibrosis (review of TA289)

34. 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

35. Wednesday 10 February 2016 10:00 and to 17:00 National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.