

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

	Care Excellence	
Jasdeep Hayre	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 01 to 14
Joanne Holden	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 01 to 14
Ahmed Elsada	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 01 to 14
Nicola Hay	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 01 to 14
Boglarka Mikundina	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 15 to 16
Eleanor Donegan	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 15 to 16

Non-public observers:

Miriam Brazzelli	ERG Representative	Present for notes 01 to 07
Mehdi Javanbakht	ERG Representative	Present for notes 01 to 07
Aileen Nielson	ERG Representative	Present for notes 01 to 07
Graham Scotland	ERG Representative	Present for notes 01 to 07
Mr Rachid Rafia	ERG Representative	Present for notes 09 to 14
Dr Paul Tappenden	ERG Representative	Present for notes 09 to 14
Rob Hodgson	ERG Representative	Present for notes 13 to 16
Mousumi Miswas	ERG Representative	Present for notes 13 to 16
Professor Robin Choudhury	Clinical Expert	Present for notes 02 to 07
Karen Hasid	Patient Expert	Present for notes 02 to 07

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 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

32.2.1 It was agreed that this declaration would not prevent Professor Stephen O'Brien from participating in this section of the meeting.

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.**