Technology Appraisal Committee Meeting Committee C

Minutes: Confirmed

Date and Time: **Tuesday 20 October 2015**, **10:00 to 16:30**

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. Dr David Black	Present for all notes
	3. David Chandler	Present for all notes
	4. Gail Coster	Present for all notes
	5. Professor Peter Crome	Present for all notes
	6. Professor Rachel Elliott	Present for all notes
	7. Dr Iain Miller	Present for all notes
	8. Dr Paul Miller	Present for notes 10 to 14
	9. Professor Eugene Milne	Present for all notes
	10. Professor Andrea Manca	Present for notes 01 to 14
	11. Dr Patrick McKiernan	Present for all notes
	12. Stephen O'Brien	Present for all notes
	13. Dr Anna O'Neill	Present for all notes
	14. Dr Claire Rothery	Present for all notes
	15. Prof Matt Stevenson	Present for all notes
	16. Dr Paul Tappenden	Present for notes 10 to 19
	17. 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
Lori Farrar	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Joanne Ekeledo	Administrator, National Institute for Health and Care Excellence	Present for all notes

Ahmed Elsada	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 05 to 09
Nicola Hay	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 05 to 09
Chris Chesters	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 10 to 14
Joanne Holden	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 10 to 14
		Present for notes 15 to 19
Caroline Hall	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 15 to 19
Nicola Hay	Technical Adviser, National Institute for Health and Clinical Excellence	
Dr Chris Carroll	ERG Representative	Present for notes 05 to 08
Rachid Rafia	ERG Representative	Present for notes 05 to 08
Dr Paul Tappenden	ERG Representative	Present for notes 05 to 08
Dr Maiwenn Al	ERG Representative	Present for notes 10 to 13
Rob Riemsma	ERG Representative	Present for notes 10 to 13
Adeline Durand	ERG Representative	Present for notes 15 to 18
Clive Pritchard	ERG Representative	Present for notes 15 to 18
Ruben Mujica Mota	ERG Representative	Present for notes 15 to 18
Professor Anthony Wierzbicki	Clinical Expert	Present for notes 15 to 18
Dr Handrean Soran	Clinical Expert	Present for notes 15 to 18
Steve Forster	Patient Expert	Present for notes 15 to 18

Non-public observers:

Debbie Morrison	NICE Observer	Present for notes 01 to 09
Kirsty Pitt	NICE Observer	Present for notes 01 to 19
Stephanie Yates	NICE Observer	Present for notes 01 to 19
Laura Norburn	NICE Observer	Present for notes 01 to 09
Joanne Holden	NICE Observer	Present for notes 01 to 09

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 Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia, Ramucirumab for treating advanced gastric cancer or gastro-oesophageal junction adenocarcinoma after chemotherapy and Panobinostat for treating multiple myeloma in people who have received at least one prior therapy.

2. The Chair welcomed Dr Patrick McKiernan as a member of the Appraisal Committee

3. The Chair informed the Committee of the non-public observers at this meeting: Debbie Morrison, Kirsty Pitt, Stephanie Yates, Laura Norburn, and Joanne Holden

4. Apologies were received from Professor Kathryn Abel, Dr Nigel Langford, Dr Peter Selby, Professor Robert Walton, Dr Suzanne Martin and Professor Wasim Hanif

Any other Business

5. None

Appraisal of Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia

Part 1 – Open session

6. The Chair welcomed the invited experts: Professor Anthony Wierzbicki, Dr Handrean Soran, Dr Handrean Soran, Steve Forster, Dr Chris Carroll, Rachid Rafia and Dr Paul Tappenden to the meeting and they introduced themselves to the Committee.

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

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

   Dr David Black, David Chandler, Gail Coster, Professor Peter Crome, Professor Rachel Elliott, Dr Iain Miller, Professor Eugene Milne,
   Professor Andrea Manca Dr Patrick McKiernan, Stephen O'Brien, Dr Anna O'Neill, Dr Claire Rothery, Prof Matt Stevenson, Dr Judith Wardle 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.

8.1. Professor Matt Stevenson declared a non-personal specific financial interest he is employed by Evidence Review Group who produced the assessment report for this appraisal. He declared at the meeting that he had read the draft report and provided comments.

8.1.1 It was agreed that this declaration would not prevent Professor Matt Stevenson from participating in this section of the meeting.

8.2. Dr Paul Tappenden, he represented the ERG for this appraisal. Dr Paul Miller has been employed by one of the comparator company in the last 12 months

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 Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia.

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

10.1. 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

10.2. Professor Anthony Wierzbicki declared a personal non-specific financial interest as he worked on clinical trials for Amgen and Sanofi.

10.2.1. It was agreed that this declaration would not prevent Professor Anthony Wierzbicki from participating in this section of the meeting

10.3. Dr Handrean Soran personal non-specific financial interest worked on clinical trials for Amgen, Sanofi and Pfizer. He has also received research grants from MSD, Amgen and Pfizer

10.3.1. It was agreed that this declaration would not prevent Dr Handrean Soran from participating in this section of the meeting

11. The Chair introduced the lead team, Professor Rachel Elliott, Dr Anna O'Neill and Dr Judith Wardle who gave presentations on the clinical effectiveness and cost effectiveness of Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia.

12. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia on the basis of the evidence before them, and potential equality issues raised in this appraisal. They sought clarification and advice from the experts present. The discussions included:

12.1. The randomised controlled trials for evolocumab, and the generalisability of the results to clinical practice in England.
12.2. The effect of evolocumab on cardiovascular disease in people with hypercholesterolaemia.
12.3. The structure of the model developed by the company.
12.4. The consideration of the following parameters in the model: the modelled populations; the general approach to estimating the risk of cardiovascular disease; the risk equations used to predict the risks of cardiovascular disease at baseline; the estimation of the risks of cardiovascular disease for people with heterozygous-familial hypercholesterolaemia; the adjustment of the predicted risks of cardiovascular disease for the heterozygous-familial hypercholesterolaemia population; the treatment effect; and the utility data.
12.5. Whether the estimated ICERs adequately reflected the FP10 prescribing of evolocumab in primary care.

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 Evolocumab for treating primary hyperlipidaemia and mixed dyslipidaemia

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

Appraisal of Ramucirumab for treating advanced gastric cancer or gastro-oesophageal junction adenocarcinoma after chemotherapy

Part 1 – Open session

19. The Chair welcomed the invited experts: Dr Maiwenn Al and Rob Riemsma to the meeting and they introduced themselves to the Committee.

20. The Chair welcomed company representatives from Eli Lilly and Company to the meeting.

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

21.1. Dr David Black, David Chandler, Gail Coster, Professor Peter Crome, Professor Rachel Elliott, Dr Iain Miller, Dr Paul Miller, Professor Eugene Milne, Professor Andrea Manca Dr Patrick McKiernan, Stephen O'Brien, Dr Anna O'Neill, Dr Claire Rothery, Prof Matt Stevenson, Dr Paul Tappenden, Dr Judith Wardle 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 Ramucirumab for treating advanced gastric cancer or gastro-oesophageal junction adenocarcinoma after chemotherapy

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

22.1. 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 Ramucirumab for treating advanced gastric cancer or gastro-oesophageal junction adenocarcinoma after chemotherapy.

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

23.1. 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 Ramucirumab for treating advanced gastric cancer or gastro-oesophageal junction adenocarcinoma after chemotherapy

24. 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.

25. The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of Ramucirumab for treating advanced gastric cancer or gastro-oesophageal junction adenocarcinoma after chemotherapy on the basis of the evidence before them. The discussions included:

25.1. Consultation comments regarding:
- 25.1.1. Potential equality issue of the variation in second line treatment practice across England
- 25.1.2. The network meta-analysis
- 25.1.3. The appropriate comparators
- 25.1.4. End-of-life criteria
- 25.1.5. Number of eligible patients

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

27. 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.

28. 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

29. The Committee continued to discuss the clinical and cost effectiveness of Ramucirumab for treating advanced gastric cancer or gastro-oesophageal junction adenocarcinoma after chemotherapy

30. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of Panobinostat for treating multiple myeloma in people who have received at least one prior therapy

Part 1 – Open session

31. The Chair welcomed the invited experts: Adeline Durand, Clive Pritchard and Ruben Mujica Mota to the meeting and they introduced themselves to the Committee.

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

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

    33.1. Dr David Black, David Chandler, Gail Coster, Professor Peter Crome, Professor Rachel Elliott, Dr Iain Miller, Professor Eugene Milne, Professor Andrea Manca Dr Patrick McKiernan, Stephen O’Brien, Dr Anna O’Neill, Dr Claire Rothery, Prof Matt Stevenson, Dr Paul Tappenden, Dr Judith Wardle 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 Panobinostat for treating multiple myeloma in people who have received at least one prior therapy

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

    34.1. 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. Panobinostat for treating multiple myeloma in people who have received at least one prior therapy

34.2. Professor Stephen O'Brien declared a non-personal specific financial interest. Novartis funded hotel for OSA conference.

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

34.3. Dr Paul Miller has undertaken consultancy for one of the comparator companies

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

35.1. 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 Panobinostat for treating multiple myeloma in people who have received at least one prior therapy

36. 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.

37. The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of Panobinostat for treating multiple myeloma in people who have received at least one prior therapy on the basis of the evidence before them. The discussions included:

37.1. A summary of the clinical and cost effectiveness evidence presented in the company's original submission

37.2. A summary of the Committee's considerations leading to the preliminary recommendations in the ACD.

37.3. The comments/responses provided during consultation by consultees and commentators.

37.4. The additional analyses provided by the company to take account of the PAS and Committee's preferred assumptions for the economic analyses (not requested by the Committee).

37.5. Key issues including:

37.5.1. the use of time-dependent hazard ratios derived using the matching adjusted indirect comparison method

37.5.2. the use of fitted parametric models

37.5.3. the comparison with bortezomib plus dexamethasone

37.5.4. inclusion of new final overall survival data from the PANORAMA-1 clinical trial

37.6. The most plausible ICERs form panobinostat plus bortezomib and dexamethasone when compared with lenalidomide plus dexamethasone

37.7. Whether panobinostat plus bortezomib and dexamethasone met end of life criteria

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

2. 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.

3. 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

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

5. The Committee continued to discuss the clinical and cost effectiveness of Panobinostat for treating multiple myeloma in people who have received at least one prior therapy

6. 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

7. Wednesday, 18 November 2015, 10:00 until 17:00 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.