

Technology Appraisal Committee Meeting (Committee [A])

Minutes: Confirmed

Date and Time: Thursday 6 April 2017, 10am

Venue:

National Institute for Health and Care Excellence
10 Spring Gardens
SW1A 2BU

Present:		
1.	Chair Jane Adam	Present for all notes
2.	Professor Ian Squire	Present for all notes
3.	Dr Graham Ash	Present for all notes
4.	Dr Justin Daniels	Present for all note
5.	Dr Andrew England	Present for all notes
6.	Dr Rachel Hobson	Present for notes 1 to 28
7.	Dr Anne McCune	Present for all notes
8.	Dr Mohit Misra	Present for all notes
9.	Dr Mohit Sharma	Present for all notes
10.	Dr Ian Bernstein	Present for all notes
11.	Ms Pamela Rees	Present for all notes
12.	Mr David Evans	Present for all notes
13.	Dr Paul Robinson	Present for all notes
14.	Ms Ellen Rule	Present for notes 1 to 17
15.	Dr John Watkins	Present for all notes
16.	Professor Olivia Wu	Present for all notes
17.	Dr Nerys Woolacott	Present for all notes
18.	Dr Rita Faria	Present for all notes

In attendance:

Meindert Boysen	Programme Director, National Institute for Health and Care Excellence	Present for all notes
Janet Robertson	Associate Director, National Institute for Health and Care Excellence	Present for all notes
Liv Gualda	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Marcia Miller	Technology	Present for all notes

	Administrator, National Institute for Health and Care Excellence	
Orsoyla Balogh	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 17
Eleanor Donegan	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 1 to 17
Hamish Lunagaria	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 18 to 28
Zoe Charles	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 8 to 28
Christian Griffith	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 29 to 40
Joanna Richardson	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 29 to 40

Evidence Review Group

Tracey Jones Hughes	Research Fellow Penninsula Technology Assessment Group PenTAG, University of Exeter	Present for notes 1 to 14
Irina Tikhonova	Research Fellow Penninsula Technology Assessment Group PenTAG, University of Exeter	Present for notes 1 to 14

James Dunham	Research Fellow Pennisula Technology Assessment Group PenTAG, University of Exeter	Present for notes 1 to 14
Rob Riemsma	Kleijnen Systematic Reviews	Present for notes 18 -26
Sabrine Grimme	Kleijnen Systematic Reviews	Present for notes 18 - 26
Jonathan Shepherd	Southampton Health Technology Assessment Centre, University of Southampton (SHTAC)	Present for notes 29 to 37
Jo Lord	Southampton Health Technology Assessment Centre, University of Southampton (SHTAC)	Present for notes 29 to 37

Experts

Dr Peter Clarke	NHS England Commissioning Clinical Lead	Present for notes 1 to 17
Dr Charlotte Benson	Consultant Medical Oncologist/NCRI Sarcoma CSG member nominated by RCP	Present for notes 1 to 14
Dr Robin Jones	Consultant Medical Oncologist nominated by Eli Lilly	Present for notes 1 to 14
Mrs Anjula Thompson	Carer nominated by Sarcoma UK	Present for notes 1 to 14
Sam Hackett	Specialist Nurse nominated by Sarcoma UK	Present for notes 1 to 14
Sarah LeBrocq	Director/Trustee of HOOP nominated by Helping Overcome Obesity Problems	Present for notes 18 to 26

Non-public observers:

Joshua South	NICE, Corp Office	Present for all notes
Chloe Kastoryano	NICE, Public Involvement Programme	Present for all notes
Aimely Lee	NICE	Present for notes 29 to 37
Adam Storrow	NICE	Present for 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 appraisals of Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma
2. The Chair welcomed Mr David Evans to his first meeting as a member of the Appraisal Committee
3. The Chair informed the Committee of the non-public observers at this meeting: Joshua South, Chloe Kastoryano, Adam Storrow
4. Apologies were received from: Dr Jeremy Braybrooke, Mr Stephen Sharp, Professor John McMurray and Dr Brian Shine.

Notes from the last meeting

5. The minutes from the last meeting were agreed.

Appraisal of Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma**Part 1 – Open session**

6. The Chair welcomed the invited experts and ERG representatives: Dr Charlotte Benson, Dr Robin Jones, Dr Peter Clark, Anjula Thompson, Sam Hackett, James Dunham, Irina Tikhonova and Tracey Jones Hughes to the meeting and they introduced themselves to the Committee.
7. The Chair welcomed company representatives from Eli Lilly to the meeting.
8. The Chair asked all Committee members to declare any relevant interests

- 8.1. Chair Jane Adam, Professor Iain Squire, Dr Ian Bernstein, Dr Justin Daniels, Dr Andrew England, Mr David Evans, Dr Rita Faria, Dr Rachel Hobson, Dr Anne McCune, Dr Mohit Misra, Dr Mohit Sharma, Ms Pamela Rees, Dr Paul Robinson, Ms Ellen Rule, Dr John Watkins, Professor Olivia Wu, Dr Nerys Woolacott 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 Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma.
- 8.2. Dr Graham Ash declared a non-personal specific financial interest as he is an investigator on a study sponsored by the comparator company Janssen in mental health.
 - 9.2.1. It was agreed that this declaration would not prevent Dr Graham Ash from participating in this section of the meeting.
- 8.3. Mr Adrian Griffin declared a personal specific pecuniary interest as the comparator company Janssen are part of Johnson and Johnson. It was agreed that this declaration would prevent Mr Adrian from participating in this section of the meeting and he was absent from 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 Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma

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

- 10.1. James Dunham, Tracey Jones Hughes, Irina Tikhonova, Sam Hackett and Mrs Anjula Thompson 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 Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma
- 10.2. Dr Charlotte Benson declared a personal non-specific financial interest as she is an investigator on the Phase III trial.
 - 10.2.1. It was agreed that this declaration would not prevent Dr Charlotte Benson from participating in this section of the meeting
- 10.3. Dr Robin Jones declared a personal non-specific financial interest as he is an investigator on the Phase II and III olaratumab trials and has been

a consultant for Eli Lilly. It was agreed that this would not prevent him from participating in this part of the meeting

11. The Chair introduced the lead team, Dr Graham Ash, Ellen Rule and Pamela Rees who gave presentations on the clinical effectiveness and cost effectiveness of Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma.
12. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
13. 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.
14. The Chair then thanked the experts for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

15. Discussion on confidential information continued. This information was supplied by the company.
16. The Committee continued to discuss the clinical and cost effectiveness of Olaratumab in combination with doxorubicin for treating advanced soft tissue sarcoma
17. The Committee agreed that olaratumab should be recommended for the cancer drugs fund and instructed the technical team to prepare the Final Appraisal Determination (FAD)

Appraisal of Naltrexone–bupropion (prolonged-release) for overweight and obesity [ID757]

Part 1 – Open session

18. The Chair welcomed the invited experts: Sabine Grimme, Rob Riemsma, Professor Wilding and Sarah LeBrocq the meeting and they introduced themselves to the Committee.
19. The Chair welcomed company representatives from Orexigen Therapeutics to the meeting.
20. The Chair asked all Committee members to declare any relevant interests
 - 20.1. Jane Adam, Professor Iain Squire, Dr Graham Ash, Dr Ian Bernstein, Dr Justin Daniels, Dr Andrew England, Dr Rita Faria, Dr Rachel Hobson, Dr Anne McCune, Dr Mohit Misra, Dr Mohit Sharma, Ms Pamela Rees , Dr Paul Robinson, Ellen Rule, Dr John Watkins, Professor Olivia Wu, Dr Nerys Woolacott 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 Naltrexone–bupropion (prolonged-release) for overweight and obesity.

- 20.2. Mr David Evans declared a personal specific financial interest as he holds shares in healthcare industries for GSK a comparator company in this appraisal. It was agreed that this declaration would prevent Mr David Evans from participating in this section of the meeting and he observed part 1 of the meeting only.
21. The Chair asked all NICE Staff to declare any relevant interests.
 - 21.1. 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 Naltrexone–bupropion (prolonged-release) for overweight and obesity
22. The Chair asked the ERG and invited experts, not including observers) to declare their relevant interests.
 - 22.1. **Sabine Grimme and Rob Riemsma 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 Naltrexone–bupropion (prolonged-release) for overweight and obesity**
 - 22.2. Sarah Le Brocq declared a personal non-specific financial interest as she works for the comparator company Roche in the oncology devision and has not involvement with the technology being discussed.
 - 22.2.1. It was agreed that this declaration would not prevent Sarah Le Brocq from participating in this section of the meeting
 - 22.3. Dr John Wilding declared a personal non-specific financial interest as he has been paid for providing educational sessions and attending advisory boards from the comparator companies. He has received travel grants to attend conferences from the comparator companies. He has received research grant to University of Liverpool, Consultancy and lecture fees and funding
 - 22.3.1. It was agreed that this declaration would not prevent Dr John Wilding from participating in this section of the meeting
23. The Chair introduced the lead team, Dr Mohit Misra, Dr Rita Faria and Ms Pamela Rees gave presentations on the clinical effectiveness and cost effectiveness of Naltrexone–bupropion (prolonged-release) for overweight and obesity.
24. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

25. 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.
26. 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

27. Discussion on confidential information continued. This information was supplied by the company.
28. The Committee continued to discuss the clinical and cost effectiveness of Naltrexone–bupropion (prolonged-release) for overweight and obesity

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

Appraisal of Etelcalcetide for treating secondary hyperparathyroidism [ID908]

Part 1 – Open session

29. The Chair welcomed the invited ERG: Jonathan Shepherd and Jo Lord to the meeting and they introduced themselves to the Committee.
30. The Chair welcomed company representatives from Amgen to the meeting.
31. The Chair asked all Committee members to declare any relevant interests
 - 31.1. Dr Jane Adam, Dr Graham Ash Dr Ian Bernstein, Dr Justin Daniels, Dr Andrew England, Dr Rita Faria Dr Rachel Hobson, Dr Anne McCune, Dr Mohit Misra, Dr Mohit Sharma, Ms Pamela Rees , Dr Paul Robinson, Ms Ellen Rule, Dr John Watkins, Professor Olivia Wu, Dr Nerys Woolacott 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 Naltrexone–bupropion (prolonged-release) for overweight and obesity
 - 31.2. Professor Iain Squire declared a personal non-specific financial interest as he has been an investigator in trials sponsored by Amgen in cardiovascular disease.
 - 3.2.1 It was agreed that this declaration would not prevent Professor Iain Squired from participating in this section of the meeting and he remained absent
32. The Chair asked all NICE Staff to declare any relevant interests.

- 32.1. 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 Naltrexone–bupropion (prolonged-release) for overweight and obesity
33. The Chair asked the ERG (not including observers) to declare their relevant interests.
 - 33.1. 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 Naltrexone–bupropion (prolonged-release) for overweight and obesity
34. The Chair introduced the key themes arising from the responses to the Appraisal Consultation Document (ACD) received from consultees, commentators and through the NICE website.
35. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
36. 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.
37. 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

38. Discussion on confidential information continued. This information was supplied by the company.
39. The Committee continued to discuss the clinical and cost effectiveness of Etelcalcetide for treating secondary hyperparathyroidism [ID908]

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

40. Thursday 8 June 2017, 10am at NICE London Office, Prince of Wales Suite 10 Spring Gardens SW1A 2BU .