

## Technology Appraisal Committee Meeting (Committee B)

**Minutes:** Unconfirmed

**Date and Time:** Thursday 14 May, 10.00am – 5.30pm

**Venue:** Prospero House  
241 Borough High Street  
London  
SE1 1GA

<b>Present:</b>	1. Chair, Dr Amanda Adler 2. Professor Ken Stein 3. Dr Ray Armstrong 4. Dr Jeff Aronson 5. Professor John Cairns 6. Professor Imran Chaudhry 7. Mr Matthew Campbell-Hill 8. Professor Daniel Hochhauser 9. Dr Neil Iosson 10. Mrs. Anne Joshua 11. Dr Sanjay Kinra 12. Dr Miriam McCarthy 13. Mr Christopher O'Regan 14. Professor Stephen Palmer  15. Dr Sanjeev Patel 16. Professor John Pounsford 17. Dr Danielle Preedy 18. Mr Alun Roebuck 19. Dr Marta Soares 20. Dr Nicky Welton 21. Professor Matt Stevenson	Present for all notes Present for all notes Present for all notes Present for notes 1 to 26 Present for all notes Present for all notes Present for all notes Present for notes 1 to 15 Present for notes 1 to 26 Present for notes 1 to 15 Present for all notes Present for all notes Present for notes 1 to 26 Present for notes 1 to 15 and 27 to 32 as a Committee member Present for notes 16 to 25 as an ERG member Present for all notes Present for notes 1 to 25 Present for all notes Present for all notes Present for notes 1 to 15 Present for all notes Present for notes 16 to 26
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### In attendance:

Meindert Boysen	Programme Director, National Institute for Health and Care Excellence	Present for all notes
Dr Elisabeth George	Associate Director, National Institute for Health and Care Excellence	Present for all notes
Jeremy Powell	Project Manager, National Institute for Health and Care	Present for all notes

	Excellence	
Stuart Wood	Administrator, National Institute for Health and Care Excellence	Present for all notes
Dr Mary Hughes	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 15
Fay McCracken	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 1 to 15
Ewen Cummins Craig Ramsay	Health Economist HCA Programme Director and Senior Statistician	Present for notes 1 to 14 Present for notes 1 to 14
Professor Noel Clarke	Professor of Urological Oncology nominated by British Association of Urological Surgeons	Present for notes 1 to 14
Dr Suneil Jain	Consultant clinical oncologist and clinical senior lecturer nominated by the Royal College of Physicians	Present for notes 1 to 14
Hugh Gunn	Trustee of TACKLE and nominated by TACKLE	Present for notes 1 to 14
Stuart Watson	Nominated by Prostate Cancer UK	Present for notes 1 to 14
Martyn Burke	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 16 to 26
Nicola Hay	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 16 to 26
Alexis Llewellyn Professor Stephen Palmer James Lomas	Research Fellow Professor of Health Economics Research Fellow	Present for notes 16 to 25 Present for notes 16 to 25 Present for notes 16 to 25
Professor Heinz Grunze	Professor of Clinical Psychiatry nominated by Lundbeck	Present for notes 16 to 25
Emer O'Neil	Chief Executive of Depression Alliance	Present for notes 16 to 25

**Non-public observers:**

Eleanor Donegan	NICE Appraisal Staff	Present for notes all notes
Laura Gibson	NICE Communications Staff	Present for notes all notes
Linda Grainger	NICE Editing Staff	Present for notes all notes
Michelle Van Velthoven	New member of the BMJ assessment group	Present for notes all notes
Annabelle South	MRC Clinical Trials Unit	Present for notes 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 enzalutamide for treating metastatic hormone-relapsed prostate cancer not previously treated with chemotherapy
2. Apologies were received from Mark Chapman, Dr Rebecca Kearney and Professor Ruairidh Milne

**Any other Business**

3. None

**Notes from the last meeting**

4. The minutes from the 14 April Committee meeting were approved.

**Appraisal of enzalutamide for treating metastatic hormone-relapsed prostate cancer not previously treated with chemotherapy****Part 1 – Open session**

5. The Chair welcomed the invited experts: Professor Noel Clarke, Dr Suneil Jain, Hugh Gunn, Stuart Watson, Ewen Cummins and Craig Ramsay to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from Astellas to the meeting.
7. The Chair asked all Committee members to declare any relevant interests
  - 7.1. Chair, Dr Amanda Adler, Professor Ken Stein, Dr Ray Armstrong, Dr Jeff Aronson, Professor John Cairns, Mr Matthew Campbell-Hill, Professor Daniel Hochhauser, Dr Neil Iosson, Mrs Anne Joshua, Dr Sanjay Kinra, Dr Miriam McCarthy, Mr Christopher O'Regan, Professor Stephen Palmer, Dr Sanjeev Patel, Professor John Poundsford, Dr Danielle Preedy, Mr Alun Roebuck, Dr Marta Soares and Dr Nicky Welton 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 enzalutamide

for treating metastatic hormone-relapsed prostate cancer not previously treated with chemotherapy.

7.2. Professor Imran Chaudhry stated that he had received support for travel and accommodation to attend a conference from Janssen.financial  
9.2.1 It was agreed that this was not a conflict of interest as defined by the NICE Policy on Conflicts of Interest.

8. The Chair asked all NICE Staff to declare any 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 enzalutamide for treating metastatic hormone-relapsed prostate cancer not previously treated with chemotherapy.

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

9.1. Stuart Watson, Ewen Cummins and Craig Ramsay 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 enzalutamide for treating metastatic hormone-relapsed prostate cancer not previously treated with chemotherapy.

9.2. Professor Noel Clarke declared a personal non specific financial interest as he consulted with a number of companies involved with prostate cancer and has attended lectures and seminars for these companies.  
9.2.1. It was agreed that this declaration would not prevent Professor Noel Clarke from participating in this section of the meeting

9.3. Hugh Gunn declared a non-personal non specific financial interest as TACKLE has received a grant from Astellas.  
9.3.1. It was agreed that this declaration would not prevent Hugh Gunn from participating in this section of the meeting

9.4. Dr Suneil Jain declared a personal non specific financial interest as he has given a lecture on abiraterone.  
9.4.1. It was agreed that this declaration would not prevent Dr Suneil Jain from participating in this section of the meeting

10. The Chair introduced the lead team, Professor John Cairns, Professor Daniel Hochhauser and Dr Danielle Preedy who gave presentations on the clinical effectiveness and cost effectiveness of enzalutamide for treating metastatic hormone-relapsed prostate cancer not previously treated with chemotherapy.

11. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of enzalutamide for treating metastatic hormone-relapsed prostate cancer not previously treated with chemotherapy 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:

- 11.1. Current treatment options for people with metastatic hormone-relapsed prostate cancer when chemotherapy is not yet clinically indicated in clinical practice in England, and the treatment pathway for this condition.
- 11.2. Patient experience of prostate cancer and treatments for prostate cancer.
- 11.3. The clinical effectiveness of enzalutamide for treating prostate cancer in which chemotherapy is not yet clinically indicated, the evidence for the effectiveness of abiraterone in this population and whether the trials of enzalutamide and abiraterone were similar enough to make an indirect comparison of these 2 treatments.
- 11.4. The face validity of the company's model structure and extrapolation of data in its model
- 11.5. The most appropriate cut-off of clinical data to use in the model.
- 11.6. The utility values used in the model.
- 11.7. The modelling assumptions considered by the company and ERG and the plausibility of these assumptions.
- 11.8. Whether it should take into account the consequences of the Pharmaceutical Pricing Regulation Scheme (PPRS) 2014 and in particular the PPRS payment mechanism when appraising enzalutamide noting the NICE position statement.
- 11.9. Whether enzalutamide could be considered a cost effective use of NHS resources, taking into account that it considered enzalutamide innovative and not meeting end-of-life criteria.
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, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

## **Part 2 – Closed session**

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

## **Appraisal of vortioxetine for treating major depressive disorder**

### **Part 1 – Open session**

16. The Chair welcomed the invited experts: Professor Heinz Grunze, Emer O'Neil, Alexis Llewellyn, Professor Stephen Palmer and James Lomas to the meeting and they introduced themselves to the Committee.
17. The Chair welcomed company representatives from Lundbeck to the meeting.
18. The Chair asked all Committee members to declare any relevant interests
  - 18.1. Dr Amanda Adler, Professor Ken Stein, Dr Ray Armstrong, Dr Jeff Aronson, Professor John Cairns, Professor Imran Chaudhry, Mr Matthew Campbell-Hill, Dr Neil Iosson, Mrs Anne Joshua, Dr Sanjay Kinra, Dr Miriam McCarthy, Dr Sanjeev Patel, Professor John Pounsford, Dr Danielle Preedy, Mr Alun Roebuck, Dr Nicky Welton Professor Matt Stevenson 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 vortioxetine for treating major depressive disorder.
  - 18.2. Professor Stephen Palmer and Dr Marta Soares were part of the Evidence Review Group for this appraisal
    - 18.2.1. It was agreed that Professor Palmer and Dr Soares would not participate in this section of the meeting.
  - 18.3. Chris O'Regan stated that his employer, Merck Sharp and Dohme were listed as a comparator manufacturer as they manufactured mirtazapine.
    - 9.2.1. It was agreed that since mirtazapine was a generic drug this should not be regarded as a conflict of interest.
19. The Chair asked all NICE Staff to declare any relevant interests.
  - 19.1. 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 vortioxetine for treating major depressive disorder.
20. The Chair asked all other invited guests, ERG and invited experts, not including observers, to declare their relevant interests.
  - 20.1. Emer O'Neil, Alexis Llewellyn, Professor Stephen Palmer and James Lomas 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 vortioxetine for treating major depressive disorder.
  - 20.2. Professor Heinz Grunze declared a personal non specific financial interest as he has attended advisory boards and given lectures for a number of companies involved in this appraisal.
    - 20.2.1. It was agreed that this declaration would not prevent Professor Heinz Grunze from participating in this section of the meeting

21. The Chair introduced the lead team, Professor Imran Chaudhry, Dr Danielle Preedy and Dr Nicky Welton who gave presentations on the clinical effectiveness and cost effectiveness of vortioxetine for treating major depressive disorder.
22. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of vortioxetine for treating major depressive disorder 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:
  - 22.1. The nature of the condition, and how a major depressive episode affects the quality of life of patients.
  - 22.2. The clinical management of major depressive episodes.
  - 22.3. The place of vortioxetine in the treatment pathway for people with major depressive episodes.
  - 22.4. The clinical effectiveness evidence including:
    - the adverse effects of vortioxetine and its comparators
    - the clinical trial evidence from REVIVE
    - the company's indirect comparison and other sources of evidence for estimating the relative effectiveness (for example, Pae et al 2015, Llorca et al 2014)
  - 22.5. The cost effectiveness evidence including:
    - the structural uncertainties associated with the company's economic model
    - whether the cost and healthcare resources reflected the pathway of care for people with a major depressive episode whom need second- or third-line treatment
    - the choice of utility values
    - the approaches to modelling later lines of treatment
    - the stability of the ICERs to changes in the parameters of the company's economic model
23. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
24. 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.
25. The Chair then thanked the experts, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

## **Part 2 – Closed session**

26. The Committee agreed to instruct the technical team to prepare the Appraisal Consultation Document (ACD).

## **Considering the relevance of the 2014 Pharmaceutical Pricing Regulation Scheme (PPRS) in ongoing appraisals**

## **Part 2 – Closed session**

27. The Chair asked the Committee to consider the impact of the 2014 PPRS on ongoing Committee B appraisals.
28. The Committee considered the NICE position paper on this issue.
29. The Committee instructed the technical teams to update the relevant guidance documents in line with their decisions.

## **Date, time and venue of the next meeting**

30. Thursday 11 June at Prospero House, 241 Borough High Street, SE1 1GA.