

Technology Appraisal Committee Meeting (Committee A)

Minutes: Confirmed

Date and Time: 30th June 2015

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

Present:	1. Dr Jane Adam	Present for all notes
	2. Professor Iain Squire	Present for all notes
	3. Dr Anne McCune	Present for all notes
	4. Dr Jeremy Braybrooke	Present for notes 1 - 39
	5. Dr Gerardine Bryant	Present for all notes
	6. Dr Mohit Misra	Present for all notes
	7. Dr Eldon Spackman	Present for notes 17-42
	8. Dr Nerys Woolacott	Present for notes 17 - 42
	9. Professor Olivia Wu	Present for all notes
	10. Dr Brian Shine	Present for all notes
	11. Mr David Thomson	Present for all notes
	12. Mrs Pamela Rees	Present for all notes
	13. Miss Ellen Rule	Present for all notes
	14. Dr Andrew England	Present for all notes
	15. Dr Paul Robinson	Present for notes
	16. Dr Graham Ash	Present for all notes
	17. Professor Aileen Clarke	Present for all note

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
Bijal Joshi	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Marcia Miller	Technology Appraisal Administrator, National Institute for Health and Care Excellence	Present for all notes
Caroline Hall	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 - 16
Joanna Richardson	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 1 - 16
	Technical Analyst, National	Present for notes 17 - 29

Christian Griffiths	Institute for Health and Care Excellence	
Eleanor Donegan	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 17 - 29
Helen Tucker	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 30 - 42
Zoe Charles	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 30 - 42

Assessment Group

Evidence Review Group

Angela Boland	Liverpool Reviews and Implementation Group	Present for notes 17 - 29
Dr Janette Greenhalgh	Liverpool Reviews and Implementation Group	Present for notes 17 - 29
Dr Louise Longworth	Liverpool Reviews and Implementation Group	Present for notes 17 - 29
Susan Harnan	School of Health and Related Research	Present for notes 17 - 29
Paul Tappenden	School of Health Related Research	Present for notes 17 - 29

Non-public observers:

Professor Terrance Chua	Medical Director, National Health Centre	Present for notes 1 - 16
Mr Ng Kwong Hoe	Head (Evaluation & Appraisal), Agency for Care Effectiveness, Ministry of Health	Present for notes 1 - 16
Professor Benjamin Ong	Director of Medical Services, Ministry of Health Singapore	Present for notes 1 - 16
Dr Daphne Khoo	Group Director (Healthcare performance Group, Ministry of Health, Singapore)	Present for notes 1- 16
Dr Lim Eng Kok	Director Performance & Technology Assessment Division, Ministry of Health, Singapore	Present for notes 1- 16
Professor Kenneth Mak	Chairman, Medical Board, Khoo Teck Puat Hospital, Singapore	Present for notes 1- 16
Professor Dan Yock Young	Chair and Head of Medicine, National University Hospital, Singapore	Present for notes 1- 16
Heidi Livingstone	NICE, PPIP	Present for all notes
Manisha Young	NICE, Corporate Office	Present for all notes
Sophie Laurenson	NICE, CHTE	Present for all notes
Ria Skelton	NICE, Comms	Present for notes 1- 16

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 **TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis (including a review of TA143 and TA233) [ID694]**
2. The Chair informed the Committee of the non-public observers at this meeting: Professor Terrance Chua, Mr Ng Kwong Hoe, Professor Benjamin Ong, Dr Daphne Khoo, Dr Lim Eng Kok, Professor Kenneth Mak, Professor Dan Yock Young, Heidi Livingstone, Manisha Young, Sophie Laurenson, Ria Skelton, Gabriel Rogers, Sophie Laurenson, Heidi Livingstone, Ria Skelton and Gabriel Rogers.
3. Apologies were received from: Professor John McMurray, Mrs Sarah Parry, Mr Stephen Sharp and Dr John Watkins

Notes from the last meeting

4. Minute of the last meeting were confirmed

Appraisal of TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis (including a review of TA143 and TA233) [ID694]

Part 1 – Open session

5. The Chair welcomed the invited experts: Mrs Debbie Cook, Dr Karl Gaffney, Dr Raj Sengupta and Mr Roger Stevens to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from AbbVie, Hospira, Merck Sharpe & Dohme and Napp to the meeting.
7. The Chair asked all Committee members to declare any relevant interests
Dr Jane Adam, Professor Iain Squire, Dr Anne McCune, Dr Jeremy Braybrook, Dr Gerardine Bryant, Dr Mohit Misra, Dr Eldon Spackman, Dr Nerys Woolcott, Professor Olivia Wu, Dr Brian Shine, Mr David Thomson, Mrs Pamela Rees, Miss Ellen Rule, Mr Andrew England, Dr Graham Ash, Professor Aileen Clarke all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 **TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis (including a review of TA143 and TA233) [ID694]**.
 - 7.1. Mr Adrian Griffin declared a personal specific pecuniary interest as Johnson and Johnson has rights to the comparator drug infliximab
 - 7.1.1 It was agreed that this declaration would Mr Adrian Griffin from participating in the meeting and he remained absent.
 - 7.2. Dr Eldon Spackman declared a personal specific pecuniary interest as his team had produced the assessment report for this appraisal, which he was directly involved.

- 7.2.1 It was agreed that this declaration would prevent Dr Eldon Spackman from participating in this section of the meeting.
- 7.3. Dr Paul Robinson declared a personal specific pecuniary interest as he works for Merck Sharpe and Dohme, one of the manufacturers of the technology under discussion
- 7.3.1 It was agreed that this declaration would prevent Dr Paul Robinson from participating in this section of the meeting and he observed part 1 of the meeting only.
- 7.4. Dr Nerys Woolacott declared a personal specific pecuniary interest as her team had produced the assessment report for this appraisal, which she was directly involved.
- 7.4.1 It was agreed that this declaration would prevent Dr Nerys Woolacott from participating in this section of the meeting.
8. The Chair asked all NICE Staff to declare any relevant interests.
- 8.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis (including a review of TA143 and TA233)].
9. The Chair asked all other invited experts to declare their relevant interests.
- 9.1. Debbie Cook and Roger Stevens declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 [TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis (including a review of TA143 and TA233
- 9.2. Dr Karl Gaffney declared a personal specific pecuniary interest as he has received research funding, attended advisory board and received speaker's fees.
- 9.2.1. It was agreed that this declaration would not prevent Dr Karl Gaffney from participating in this section of the meeting
- 9.3. Dr Raj Sengupta declared a personal specific pecuniary interest as he has sat on advisory board and received speaker fees from AbbVie, MSD, Pfizer and UCB
- 9.3.1. It was agreed that this declaration would not prevent Dr Raj Sengupta from participating in this section of the meeting
10. 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.
11. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis (including a review of TA143 and TA233) 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. 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 continued to discuss the clinical and cost effectiveness of **TNF-alpha inhibitors for ankylosing spondylitis and non-radiographic axial spondyloarthritis (including a review of TA143 and TA233)**
16. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of Edoxaban tosylate for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation

Part 1 – Open session

17. The Chair welcomed the invited experts: Dr Ameet Bakhai, Vicki Hill, Miss Nazish Khan, Laura Wood to the meeting and they introduced themselves to the Committee.
18. The Chair welcomed company representatives from Daiichi Sankyo to the meeting.
19. The Chair asked all Committee members to declare any relevant interests
 - 19.1. Dr Jane Adam, Professor Iain Squire, Dr Anne McCune, Dr Jeremy Braybrooke, Dr Geraradine Bryant, Dr Mohit Misra, Dr Eldon Spackman, Dr Nerys Woolacott, Professor Olivia Wu, Dr Brian Shine, Mr David Thomson, Mrs Pamela Rees Miss Ellen Rule, Mr Andrew England, Dr Paul Robinson, Dr Graham Ash, Professor Aileen Clarke all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 **Edoxaban tosylate for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation**
 - 19.2. Professor John McMurray declared a personal specific pecuniary interest as he has worked with representatives of the company to prepare the edoxaban submission to the EMA
 - 19.2.1 It was agreed that this declaration would prevent Professor John McMurray from participating in this section of the meeting and he was absent from the meeting
 - 19.3. Mr Adrian Griffith declared a personal specific pecuniary interest as his company Johnson and Johnson has rights to the comparator drug rivaroxaban.

19.3.1 It was agreed that this declaration would prevent Mr Adrian Griffin from participating in this section of the meeting and was absent from the meeting.

20. The Chair asked all NICE Staff to declare any relevant interests.
 - 20.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 **Edoxaban tosylate for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation**
21. The Chair asked the ERG and invited experts, not including observers) to declare their relevant interests.
 - 21.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 **Edoxaban tosylate for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation**
22. The Chair introduced the lead team, Dr Jeremy Braybrooke, Ellen Rule and Mr David Thomas who gave presentations on the clinical effectiveness and cost effectiveness Edoxaban tosylate for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation
23. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of Edoxaban tosylate for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation 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:
 - 23.1. Clinical features of atrial fibrillation
 - 23.2. Patient perspective of atrial fibrillation
 - 23.3. Evidence on clinical effectiveness of edoxaban from the company's submission and ERG report and addendum
 - 23.4. Generalisability of the ENGAGE AF-TIMI48 trial to clinical practice in England and Wales.
 - 23.5. Uncertainties around the company's network meta-analysis for the comparison with other newer oral anticoagulants
 - 23.6. Potential subgroups relating to centre level time in therapeutic range, renal function and stroke risk.
 - 23.7. Evidence on cost effectiveness of edoxaban from the company submission and critique by the ERG.
 - 23.8. Consideration of the ERG's exploratory analyses
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, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

27. Discussion on confidential information AstraZeneca. This information was supplied by the company.
28. The Committee continued to discuss the clinical and cost effectiveness of Edoxaban tosylate for preventing stroke and systemic embolism in people with non-valvular atrial fibrillation
29. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD)] in line with their decisions.

Appraisal of Olaparib for maintenance treatment of BRCA 1 or 2 mutated, relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer in people whose relapsed disease has responded to platinum-based chemotherapy

Part 1 – Open session

30. The Chair welcomed the invited experts: Susan Harnan, Dr Simon Newman, Paul Tappenden to the meeting and they introduced themselves to the Committee.
31. The Chair welcomed company representatives from **AstraZeneca** to the meeting.
32. The Chair asked all Committee members to declare any relevant interests
 - 32.1. Dr Jane Adam, Professor Iain Squire, Dr Anne McCune, Dr Jeremy Braybrooke, Dr Geraradine Bryant, Dr Mohit Misra, Dr Eldon Spackman, Dr Nerys Woolacott, Professor Olivia Wu, Dr Brian Shine, Mr David Thomson, Mrs Pamela Rees Miss Ellen Rule, Mr Andrew England, Dr Paul Robinson, Dr Graham Ash, Professor Aileen Clarke all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 **Olaparib for maintenance treatment of BRCA 1 or 2 mutated, relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer in people whose relapsed disease has responded to platinum-based chemotherapy.**
 - 32.2. Dr Jeremy Braybrooke declared a personal specific pecuniary interest **as** he currently a co-investigator on a clinical trial with Olaparib in breast cancer. I have also sat on and received payment for an advisory board for Astra Zeneca on another breast cancer drug – Fulvestrant
 - 9.2.1 It was agreed that this declaration would prevent Dr Jeremy Braybrooke from participating in this section of the meeting and he was absent from the meeting.
33. The Chair asked all NICE Staff to declare any relevant interests.
 - 33.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 **Olaparib for maintenance treatment of**

BRCA 1 or 2 mutated, relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer in people whose relapsed disease has responded to platinum-based chemotherapy

34. The Chair asked all other invited guests, ERG and invited experts, not including observers) to declare their relevant interests.
 - 34.1. Susan Harnan, Professor Jonathan Ledermann, Dr Simon Newman and Paul Tappenden declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 **Olaparib for maintenance treatment of BRCA 1 or 2 mutated, relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer in people whose relapsed disease has responded to platinum-based chemotherapy.**
 - 34.2. Professor Charlie Gourley declared a personal specific pecuniary interest in AstraZeneca, GlaxosmithKline and Roche
 - 34.2.1. It was agreed that this declaration would not prevent Professor Charlie Gourley from participating in this section of the meeting
35. 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.
36. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of **Olaparib for maintenance treatment of BRCA 1 or 2 mutated, relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer in people whose relapsed disease has responded to platinum-based 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:
 - 36.1. The comments from consultees, commentators and from the website on the Appraisal Consultation Document
 - 36.2. The further cost effectiveness analysis submitted by the company in response to the ACD
 - 36.3. Estimates of life expectancy for patients with relapsed BRCA mutated ovarian cancer obtained from the ICON-6 trial and an Australian observational study
 - 36.4. Whether the end-of life criteria would apply to a subgroup of patients in Study 19 who received three or more previous courses of platinum-based chemotherapy
37. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
38. 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.
39. 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

40. Discussion on confidential information continued. This information was supplied by the company.
41. The Committee continued to discuss the clinical and cost effectiveness of Olaparib for maintenance treatment of BRCA 1 or 2 mutated, relapsed, platinum-sensitive ovarian, fallopian tube and peritoneal cancer in people whose relapsed disease has responded to platinum-based chemotherapy.
42. The Committee instructed the technical team to prepare the **Appraisal Consultation Document (ACD)** in line with their decisions.