

Technology Appraisal Committee Meeting (Committee D)

Minutes: Confirmed

Date and Time: **Wednesday 30 August 2017, 10.00am – 16.00**

Venue: National Institute for Health and Care Excellence
Level 1A, City Tower
Piccadilly Plaza
Manchester
M1 4BT

Present:	1. Professor Gary McVeigh (Chair) 2. Dr Lindsay Smith (Vice Chair) 3. Dr Nabeel Alsindi 4. Professor David Bowen 5. Dr Matthew Bradley 6. Professor Simon Dixon 7. Professor Rachel Elliott 8. Mrs Gillian Ells 9. Professor Paula Ghaneh 10. Dr Peter Hall 11. Dr Rebecca Harmston 12. Dr David Meads 13. Dr Malcolm Oswald 14. Professor Stephen O'Brien 15. Dr Paula Parvulescu 16. Mr William Turner	Present for all notes Present for all notes
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Nigel Armstrong	Evidence Review Group representative, Kleijnen Systematic Reviews Ltd	Present (via telephone) for notes 42 to 49
Mariana Bacelar	Evidence Review Group representative, BMJ-TAG	Present for notes 18 to 26
Keith Cooper	Evidence Review Group representative, Southampton Health Technology Assessments Centre	Present for notes 30 to 38
Ross Dent	Technical Analyst, National Institute for Health and Clinical Excellence	Present for notes 30 to 41
Joanne Ekeledo	Project Manager, National Institute for Health and Care Excellence	Present for notes 18 to 41
Dr Geoff Frampton	Evidence Review Group representative, Southampton Health Technology Assessments Centre	Present for notes 30 - 38

Christian Griffiths	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 1 to 17
Professor Martin Hoyle	Evidence Review Group representative, PenTAG	Present for notes 1 to 14
Helen Knight	Associate Director, National Institute for Health and Care Excellence	Present for all notes
Dr John Lear	Clinical expert, Consultant Dermatologist, nominated by Roche Products Ltd	Present for notes 18 to 26
Aimely Lee	Technical Analyst, National Institute for Health and Clinical Excellence	Present for notes 18 to 29
Kate Moore	Project Manager, National Institute for Health and Care Excellence	Present for notes 1 to 17 and 42 to 52
Fatima Salih	Evidence Review Group representative, BMJ-TAG	Present for notes 18 to 26
Abitha Senthinathan	Technical Analyst, National Institute for Health and Clinical Excellence	Present for notes 1 to 17
Alex Sexton	Administrator, National Institute for Health and Care Excellence	Present for notes 1 to 17 and 42 to 52
Raisa Sidhu	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 18 to 29
David Thomson	Deputy CDF Clinical Lead, NHS England	Present for all notes
Mandy Tonkinson	Administrator, National Institute for Health and Care Excellence	Present for notes 18 to 41
Victoria Wakefield	Evidence Review Group representative, BMJ-TAG	Present for notes 18 to 26
Ian Watson	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 30 to 41
Nwamaka Umeweni	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 42 to 52
Sheela Upadhyaya	Associate Director, National Institute for Health and Care Excellence	Present for notes 30 to 41

Non-public observers:

Kelly Cuthbertson	Human Resources, National Institute for Health and Care Excellence	Present for all notes
Henry Edwards	Technical Adviser, National Institute for Health and Care Excellence	Present for notes 30 to 52
Ann Greenwood	Senior Medical Editor, National Institute for Health and Care Excellence	Present for all notes
Linda Landells	Associate Director, National Institute for Health and Care Excellence	Present for all notes
Rachel Reid	Implementation Facilitator, National Institute for Health and Care Excellence	Present for notes 1 to 29
Maroulla Whitely	Business Analyst, National Institute for Health and Care Excellence	Present for all notes

Notes**Welcome**

1. Helen Knight, Associate Director, presented NICE's position statement (https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisal-guidance/eq5d5l_nice_position_statement.pdf) on use of the EQ 5D 5L valuation set (which had been issued on 3 August 2017).
2. 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 regorafenib for treating advanced gastrointestinal stromal tumours, vismodegib for treating basal cell carcinoma, atezolizumab for treating metastatic urothelial bladder cancer after platinum-based chemotherapy, and nivolumab for treating recurrent or metastatic squamous-cell carcinoma of the head and neck after platinum-based chemotherapy.
3. The Chair welcomed Dr Nabeel Alsindi to his first meeting as a member of the Appraisal Committee.
4. Apologies were received from Dr Aomesh Bhatt, Dr Ian Davidson, Susan Dutton, Sumithra Maheswaran, and Professor Oluwafemi Oyebode.

Any other Business

5. None

Appraisal of regorafenib for treating advanced gastrointestinal stromal tumours [ID1056]**Part 1 – Open session**

6. The Chair welcomed the invited experts, Professor Martin Hoyle and David Thomson, to the meeting and they introduced themselves to the Committee.
7. The Chair welcomed company representatives from Bayer to the meeting.
8. The Chair asked all Committee members to declare any relevant interests
 - 8.1. Dr Nabeel Alsindi, Professor David Bowen, Dr Matthew Bradley, Professor Simon Dixon, Professor Rachel Elliott, Mrs Gillian Ells, Professor Paula Ghaneh, Dr Peter Hall, Dr Rebecca Harmston, Professor Gary McVeigh, Dr David Meads, Dr Malcolm Oswald, Professor Stephen O'Brien, Dr Paula Parvulescu, Dr Lindsay Smith, and Mr William Turner 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 regorafenib for treating advanced gastrointestinal stromal tumours.
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 regorafenib for treating advanced gastrointestinal stromal tumours
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 regorafenib for treating advanced gastrointestinal stromal tumours.
11. 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.
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 and company representatives 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 regorafenib for treating advanced gastrointestinal stromal tumours

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

Appraisal of vismodegib for treating basal cell carcinoma [ID1043]

Part 1 – Open session

18. The Vice Chair welcomed the invited experts: Marian Bacelar, Dr John Lear, Fatima Salih, David Thomson and Victoria Wakefield to the meeting and they introduced themselves to the Committee.
19. The Vice Chair welcomed company representatives from Roche Products to the meeting.
20. The Vice Chair asked all Committee members to declare any relevant interests
 - 20.1. Dr Nabeel Alsindi, Professor David Bowen, Dr Matthew Bradley, Professor Rachel Elliott, Mrs Gillian Ells, Professor Paula Ghaneh, Dr Peter Hall, Dr Rebecca Harmston, Professor Gary McVeigh, Dr David Meads, Dr Malcolm Oswald, Professor Stephen O'Brien, Dr Paula Parvulescu, Dr Lindsay Smith, and Mr William Turner 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 vismodegib for treating basal cell carcinoma [ID1043].
 - 20.2. Professor Simon Dixon declared a non-specific non-personal financial interest as he is director of a health economics unit that has undertaken work for the company on unrelated topics; he was not directly involved in the work and his university received payment for the work.
 - 9.2.1 It was agreed that this declaration would not prevent Professor Simon Dixon from participating in this section of the meeting.
21. The Vice 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 vismodegib for treating basal cell carcinoma [ID1043].
22. The Vice Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their 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 vismodegib for treating basal cell carcinoma [ID1043].
23. The Vice 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.
24. The Vice Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.

25. The Vice 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 Vice 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 vismodegib for treating basal cell carcinoma [ID1043].
 - 28.1. The committee decision was based on consensus.
29. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of atezolizumab for treating metastatic urothelial bladder cancer after platinum-based chemotherapy [ID939]

Part 1 – Open session

30. The Chair welcomed the invited experts: Keith Cooper, Dr Geoff Frampton and David Thomson to the meeting and they introduced themselves to the Committee.
31. The Chair welcomed company representatives from Roche Products to the meeting.
32. The Chair asked all Committee members to declare any relevant interests
 - 32.1. Dr Nabeel Alsindi, Professor David Bowen, Dr Matthew Bradley, Professor Rachel Elliott, Mrs Gillian Ells, Professor Paula Ghaneh, Dr Peter Hall, Dr Rebecca Harmston, Professor Gary McVeigh, Dr David Meads, Dr Malcolm Oswald, Professor Stephen O'Brien, Dr Paula Parvulescu, Dr Lindsay Smith, and Mr William Turner 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 atezolizumab for treating metastatic urothelial bladder cancer after platinum-based chemotherapy.
 - 32.2. Professor Simon Dixon declared a non-specific non-personal financial interest as he is the director of a health economics university that has undertaken work for the company on different topics; his university received payment for the work.
 - 32.2.1 It was agreed that this declaration would not prevent Professor Simon Dixon from participating in this section of 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 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 atezolizumab for treating metastatic urothelial bladder cancer after platinum-based chemotherapy.

34. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their 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 atezolizumab for treating metastatic urothelial bladder cancer after platinum-based chemotherapy [ID939].
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 Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
37. 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.
38. 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

39. Discussion on confidential information continued. This information was supplied by the company.
40. The Committee continued to discuss the clinical and cost effectiveness of atezolizumab for treating metastatic urothelial bladder cancer after platinum-based chemotherapy [ID939].
 - 40.1. The committee decision was based on consensus.
41. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of nivolumab for treating recurrent or metastatic squamous-cell carcinoma of the head and neck after platinum-based chemotherapy [ID971]

Following the appraisal committee meeting on 31 May 2017, the company submitted a new value proposition for nivolumab; given the confidential nature of the information, this discussion was held in a private (part 2) session.

Part 2a – Closed session

42. The Chair welcomed the invited experts, Dr Nigel Armstrong and David Thomson, to the meeting and they introduced themselves to the Committee.
43. The Chair welcomed company representatives from BMS to the meeting.
44. The Chair asked all Committee members to declare any relevant interests

44.1. Dr Nabeel Alsindi, Professor David Bowen, Dr Matthew Bradley, Professor Simon Dixon, Professor Rachel Elliott, Mrs Gillian Ells, Professor Paula Ghaneh, Dr Peter Hall, Dr Rebecca Harmston, Professor Gary McVeigh, Dr David Meads, Dr Malcolm Oswald, Dr Paula Parvulescu, Dr Lindsay Smith, and Mr William Turner 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 nivolumab for treating recurrent or metastatic squamous-cell carcinoma of the head and neck after platinum-based chemotherapy.

45.2. Professor Stephen O'Brien declared a non-specific non-personal financial interest as over the last twelve months his university and/or NHS Trust had received research funding from the company.

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

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

45.1. 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 nivolumab for treating recurrent or metastatic squamous-cell carcinoma of the head and neck after platinum-based chemotherapy.

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

46.1. 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 nivolumab for treating recurrent or metastatic squamous-cell carcinoma of the head and neck after platinum-based chemotherapy.

47. The Chair gave an overview of the additional evidence submitted by the company.

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

49. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2b – Closed session

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

51. The Committee continued to discuss the additional information.

51.1. The committee decision was based on consensus.

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

Date, time and venue of the next meeting

53. Wednesday 27 September 2017 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.