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) Present for all notes
2. Dr Lindsay Smith (Vice Chair) Present for all notes
3. Dr Nabeel Alsindi Present for all notes
4. Professor David Bowen Present for all notes
5. Dr Matthew Bradley Present for all notes
6. Professor Simon Dixon Present for all notes
7. Professor Rachel Elliott Present for all notes
8. Mrs Gillian Ells Present for all notes
9. Professor Paula Ghaneh Present for all notes
10. Dr Peter Hall Present for all notes
11. Dr Rebecca Harmston Present for all notes
12. Dr David Meads Present for all notes
13. Dr Malcolm Oswald Present for all notes
14. Professor Stephen O’Brien Present for all notes
15. Dr Paula Parvulescu Present for all notes
16. Mr William Turner Present for all notes

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kelly Cuthbertson</td>
<td>Human Resources, National Institute for Health and Care Excellence</td>
<td>Present for all notes</td>
</tr>
<tr>
<td>Henry Edwards</td>
<td>Technical Adviser, National Institute for Health and Care Excellence</td>
<td>Present for notes 30 to 52</td>
</tr>
<tr>
<td>Ann Greenwood</td>
<td>Senior Medical Editor, National Institute for Health and Care Excellence</td>
<td>Present for all notes</td>
</tr>
<tr>
<td>Linda Landells</td>
<td>Associate Director, National Institute for Health and Care Excellence</td>
<td>Present for all notes</td>
</tr>
<tr>
<td>Rachel Reid</td>
<td>Implementation Facilitator, National Institute for Health and Care Excellence</td>
<td>Present for notes 1 to 29</td>
</tr>
<tr>
<td>Maroulla Whitely</td>
<td>Business Analyst, National Institute for Health and Care Excellence</td>
<td>Present for all notes</td>
</tr>
</tbody>
</table>

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
The Chair welcomed the invited experts, Professor Martin Hoyle and David Thomson, to the meeting and they introduced themselves to the Committee.

The Chair welcomed company representatives from Bayer to the meeting.

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.

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.

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.

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.

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

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.

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 Ghanem, 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
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 Ghanem, 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.