

## Technology Appraisal Committee Meeting (Committee B)

**Minutes:** **Confirmed**

**Date and Time:** Wednesday 25 January 2017, 10am to 5pm

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

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|-----------------|--|--|
| <b>Present:</b> | 1. Dr Amanda Adler<br>2. Dr Sanjeev Patel<br>3. Dr Ray Armstrong<br>4. Professor John Cairns<br>5. Mr Mark Chapman<br>6. Dr Mark Glover<br>7. Mrs Anne Joshua<br>8. Dr Sanjay Kinra<br>9. Dr Miriam McCarthy<br>10. Professor Ruairidh Milne<br>11. Mr Christopher O'Regan<br><br>12. Professor Stephen Palmer<br><br>13. Dr Danielle Preedy<br>14. Mr Alun Roebuck<br>15. Professor Ken Stein<br>16. Dr Nicky Welton<br>17. Mr Nigel Westwood | Present for all notes<br>Present for all notes<br>Present for notes 11 to 62<br>Present for all notes<br>Present for 1 to 27, 32 to 43 and 56 to 62<br>Present for 1 to 31 and 44 to 62<br>Present for all notes<br>Present for all notes<br>Present for all notes<br>Present for all notes<br>Present for all notes |
|-----------------|--|--|

### **In attendance:**

|                 |   |                            |
|-----------------|---|----------------------------|
| Bashama Anjum   | Administrator, National Institute for Health and Care Excellence      | Present for all notes      |
| Anna Brett      | Technical Lead, National Institute for Health and Clinical Excellence | Present for notes 44 to 55 |
| Meindert Boysen | Programme Director, National Institute for Health and Care Excellence | Present for notes          |
| Ahmed Elsada    | Technical Advisor, Technology Appraisals, NICE                        | Present for 19 to 62       |
| Jenna Byers     | Project Manager,  | Present for 19 to 62       |

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|                       | National Institute for<br>Health and Care<br>Excellence  |                            |
| Rebecca Hammersley    | Administrator, National<br>Institute for Health and<br>Care Excellence   | Present for notes 1 to 18  |
| Jasdeep Hayre         | Technical Adviser,<br>National Institute for<br>Health and Clinical<br>Excellence  | Present for all notes      |
| Jeremy Powell         | Project Manager,<br>National Institute for<br>Health and Care<br>Excellence  | Present for all notes      |
| Thomas Palmer         | Technical Lead,<br>National Institute for<br>Health and Clinical<br>Excellence   | Present for notes 32 to 43 |
| Aminata Thiam         | Technical Lead,<br>National Institute for<br>Health and Clinical<br>Excellence   | Present for notes 19 to 31 |
| Miriam Brazzelli      | Evidence Review Group,<br>Senior Research Fellow,<br>Aberdeen HTA Group  | Present for notes 1 to 16  |
| Dr Ewen Cummins       | Evidence Review Group,<br>Health Economists,<br>Aberdeen HTA Group   | Present for notes 1 to 16  |
| Peter Cain            | Evidence Review Group,<br>Health Economists,<br>BMJ Evidence   | Present for notes 19 to 31 |
| Dr Steve Edwards      | Evidence Review Group,<br>Head of Health<br>Technology Assessment,<br>BMJ Evidence   | Present for notes 19 to 31 |
| Dr Victoria Wakefield | Evidence Review Group,<br>Senior HTA Analyst,<br>BMJ Evidence  | Present for notes 19 to 31 |
| Dr Adam Farmer        | Clinical specialist,<br>Consultant<br>Gastroenterologist and<br>Senior Lecturer,<br>University Hospitals of<br>North Midlands,<br>nominated by the British<br>Society of<br>Gastroenterology | Present for notes 6 to 14  |
| Dr Peter Paine        | Clinical specialist,<br>Consultant<br>Gastroenterologist,<br>Salford Royal Foundation<br>Trust, Nominated by<br>Allergan   | Present for notes 6 to 14  |
| Dr Kate Fife          | Consultant Clinical  | Present for notes 19 to 27 |

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|                          | Oncologist, Cambridge University Hospitals, nominated by Pfizer                                    |                            |
| Professor Robert Hawkins | Professor Medical Oncologist, University Manchester and The Christie Hospital, nominated by Ipsen. | Present for notes 19 to 27 |
| Professor Martin Hoyle   | Evidence Review Group, Health Economists, Peninsula Technology Assessment Group (PenTAG)           | Present for notes 32 to 43 |
| Professor Robert Wolff   | Evidence Review Group, Systematic Reviewer, Kleijnen Systematic Reviews                            | Present for notes 45 to 53 |

### **Non-public observers:**

|                   |   |                       |
|-------------------|---|-----------------------|
| Helen Barnett     | Senior Medical Editor, NICE   | Present for all notes |
| Heidi Livingstone | Senior Public Involvement Advisor, Communications, NICE             | Present for all notes |
| Edgar Masanaga    | Business Analyst - Resource Impact Assessment, Implementation, 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 eluxadoline for treating irritable bowel syndrome with diarrhoea [ID870], cabozantinib for previously treated advanced renal cell carcinoma [ID931], cetuximab and panitumumab for previously untreated metastatic colorectal cancer [ID794], ixekizumab for treating moderate to severe plaque psoriasis [ID904] and daclizumab for treating relapsing-remitting multiple sclerosis
2. The Chair informed the committee that it was Mr Alun Roebuck's last meeting.
3. The Chair informed the Committee of the non-public observers at this meeting: Helen Barnett, Heidi Livingstone and Edgar Masanaga.
4. Apologies were received from Dr Sumeet Gupta, Dr Nigel De Kare Silver and Dr Marta Soares.

### **Any other Business**

5. The Committee were given an update on the timelines and progress of other appraisals.

## **Appraisal of eluxadoline for treating irritable bowel syndrome with diarrhoea [ID870]**

### **Part 1 – Open session**

6. The Chair welcomed the invited experts: Dr Miriam Brazzelli, Dr Ewen Cummins, Dr Adam Farmer, Dr Peter Paine to the meeting and they introduced themselves to the Committee.
7. The Chair welcomed company representatives from Allergan to the meeting.
8. The Chair asked all Committee members to declare any relevant interests
  - 8.1. Dr Amanda Adler, Dr Sanjeev Patel, 5
  - 8.2. Professor John Cairns, Mr Mark Chapman, Dr Mark Glover, Mrs Anne Joshua, Dr Sanjay Kinra, Dr Miriam McCarthy, Professor Ruairidh Milne, Mr Christopher O'Regan, Professor Stephen Palmer, Dr Danielle Preedy, Mr Alun Roebuck, Professor Ken Stein, Dr Nicky Welton and Mr Nigel Westwood 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 eluxadoline for treating irritable bowel syndrome with diarrhoea [ID870].
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 eluxadoline for treating irritable bowel syndrome with diarrhoea [ID870].
10. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
  - 10.1. Dr Miriam Brazzelli and Dr Ewen Cummins 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 eluxadoline for treating irritable bowel syndrome with diarrhoea [ID870].
  - 10.2. Dr Adam Farmer declared a personal specific financial interest as he received speaker fees from Allergan and previously attended an advisory Board in the past lead UK investigator the phase III trial of this product undertaken by Furiex Pharmaceuticals.

- 10.2.1. It was agreed that this declaration would not prevent Dr Farmer from participating in this section of the meeting.
- 10.3. Dr Peter Paine declared a personal specific financial interest as he received travel expenses and honoraria from pharmaceutical companies to attend educational meetings, deliver lectures and participate in consultancy workshops. These include Allergan who are marketing the drug eluxadoline, and also Almiral and Shire.
  - 10.3.1. It was agreed that this declaration would not prevent Dr Paine from participating in this section of the meeting.
11. The Chair introduced the lead team, Mrs Anne Joshua, Professor Ruairidh Milne and Mr Nigel Westwood who gave presentations on the clinical effectiveness and cost effectiveness of eluxadoline for treating irritable bowel syndrome with diarrhoea [ID870].
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. The Committee continued to discuss the clinical and cost effectiveness of eluxadoline for treating irritable bowel syndrome with diarrhoea [ID870].
16. The Evidence Review Group representatives left the meeting.
17. The committee decision was based on consensus.
18. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD)

## **Appraisal of cabozantinib for previously treated advanced renal cell carcinoma [ID931]**

### **Part 1 – Open session**

19. The Chair welcomed the invited experts: Peter Cain, Dr Ewen Cummins, Dr Steve Edwards, Dr Kate Fife and Professor Robert Hawkins to the meeting and they introduced themselves to the Committee.
20. The Chair welcomed company representatives from Ipsen to the meeting.
21. The Chair asked all Committee members to declare any relevant interests

21.1. Dr Amanda Adler, Dr Sanjeev Patel, Dr Ray Armstrong, Professor John Cairns, Mr Mark Chapman, Dr Mark Glover, Mrs Anne Joshua, Dr Sanjay Kinra, Dr Miriam McCarthy, Professor Ruairidh Milne, Mr Christopher O'Regan, Professor Stephen Palmer, Dr Danielle Preedy, Mr Alun Roebuck, Professor Ken Stein, Dr Nicky Welton and Mr Nigel Westwood 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 Cabozantinib for previously treated advanced renal cell carcinoma [ID931].

22. The Chair asked all NICE Staff to declare any 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 Cabozantinib for previously treated advanced renal cell carcinoma [ID931].

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

23.1. Peter Cain, Dr Ewen Cummins and Dr Steve Edwards 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 Cabozantinib for previously treated advanced renal cell carcinoma [ID931].

23.2. Dr Kate Fife declared a personal specific financial interest as she received speaker fees from Roche, Novartis and Pfizer and sits on advisory boards for Pfizer.

23.2.1. It was agreed that this declaration would not prevent Dr Fife from participating in this section of the meeting.

23.3. Professor Robert Hawkins declared a personal specific financial interest as he has received honoraria and speaking fees from Pfizer, BMS, Novartis, Ipsen, GSK and Celgene.

23.3.1. It was agreed that this declaration would not prevent Professor Hawkins from participating in this section of the meeting.

24. The Chair introduced the lead team, Professor Ken Stein, Mr Mark Chapman and Dr Danielle Preedy who gave presentations on the clinical effectiveness and cost effectiveness of Cabozantinib for previously treated advanced renal cell carcinoma [ID931].

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

26. 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.

27. 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**

28. Discussion on confidential information continued. This information was supplied by the company.
29. The Committee continued to discuss the clinical and cost effectiveness of Cabozantinib for previously treated advanced renal cell carcinoma [ID931].
30. The committee decision was based on consensus.
31. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

## **Appraisal of cetuximab and panitumumab for previously untreated metastatic colorectal cancer [ID794]**

### **Part 1 – Open session**

32. The Chair welcomed the invited expert: Professor Martin Hoyle to the meeting and he introduced himself to the Committee.
33. The Chair welcomed company representatives from Amgen and Merck Serono to the meeting.
34. The Chair asked all Committee members to declare any relevant interests
  - 34.1. Dr Amanda Adler, Dr Sanjeev Patel, Dr Ray Armstrong, Professor John Cairns, Mr Mark Chapman, Dr Mark Glover, Mrs Anne Joshua, Dr Sanjay Kinra, Dr Miriam McCarthy, Professor Ruairidh Milne, Christopher O'Regan, Dr Danielle Preedy, Mr Alun Roebuck, Professor Ken Stein, Dr Nicky Welton and Mr Nigel Westwood 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 cetuximab and panitumumab for previously untreated metastatic colorectal cancer [ID794].
  - 34.2. Professor Stephen Palmer declared a personal financial interest before the meeting as he has sat on an advisory board for Amgen for a related product.
    - 9.3.1 It was agreed that this declaration would prevent Professor Palmer from participating in this section of the meeting.
35. The Chair asked all NICE Staff to declare any relevant interests.
  - 35.1. 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 cetuximab and panitumumab for previously untreated metastatic colorectal cancer [ID794].

36. The Chair asked all the Assessment Group representative to declare their relevant interests.
  - 36.1. Professor Martin Hoyle declared that he 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 cetuximab and panitumumab for previously untreated metastatic colorectal cancer [ID794].
37. The Chair introduced the key themes arising from the responses to the Final Appraisal Determination received from consultees.
38. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
39. 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.
40. The Chair then thanked the company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

## **Part 2 – Closed session**

41. Discussion on confidential information continued. This information was supplied by the company.
42. The Committee continued to discuss the clinical and cost effectiveness of cetuximab and panitumumab for previously untreated metastatic colorectal cancer [ID794].
  - 42.1. The committee decision was based on consensus.
43. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD)] in line with their decisions.

## **Appraisal of ixekizumab for treating moderate to severe plaque psoriasis [ID904]**

### **Part 1 – Open session**

44. The Vice Chair welcomed the invited Evidence Review Group representative: Dr Robert Wolff to the meeting and he introduced himself to the Committee.
45. The Chair welcomed company representatives from Eli Lilly to the meeting.

46. The Chair asked all Committee members to declare any relevant interests

Dr Amanda Adler, Dr Sanjeev Patel, Dr Ray Armstrong, Professor John Cairns, Mr Mark Chapman, Dr Mark Glover, Mrs Anne Joshua, Dr Sanjay Kinra, Dr Miriam McCarthy, Professor Ruairidh Milne, Professor Stephen Palmer, Dr Danielle Preedy, Mr Alun Roebuck, Professor Ken Stein, Dr Nicky Welton and Mr Nigel Westwood 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 ixekizumab for treating moderate to severe plaque psoriasis [ID904].

46.1. Mr Christopher O'Regan declared a personal specific financial interest before the meeting as he is employed by Merck Sharp and Dohme who manufacturer infliximab.

9.3.1 It was agreed that this declaration would prevent Christopher O'Regan from participating in this section of the meeting.

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

47.1. 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 ixekizumab for treating moderate to severe plaque psoriasis [ID904].

48. The Chair asked the Evidence Review Group representative to declare their relevant interests.

48.1. Dr Robert Wolff 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 ixekizumab for treating moderate to severe plaque psoriasis [ID904].

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.

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

50. 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.

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

## Part 2 – Closed session

52. Discussion on confidential information continued. This information was supplied by the company.
53. The Evidence Review Group representative left the meeting.
54. The Committee continued to discuss the clinical and cost effectiveness of ixekizumab for treating moderate to severe plaque psoriasis [ID904].
  - 54.1. The committee decision was based on consensus.
55. The Committee instructed the technical team to prepare the Final Appraisal Determination in line with their decisions.

#### **Appraisal of daclizumab for treating relapsing-remitting multiple sclerosis [ID827]**

56. The Chair welcomed all the attendees (Committee members and NICE staff) no experts and company representatives were invited to the meeting.
57. The Chair asked all Committee members to declare any relevant interests
  - 57.1. Dr Amanda Adler, Dr Sanjeev Patel, Dr Ray Armstrong, Professor John Cairns, Mr Mark Chapman, Dr Mark Glover, Mrs Anne Joshua, Dr Sanjay Kinra, Dr Miriam McCarthy, Professor Ruairidh Milne, Christopher O'Regan, Professor Stephen Palmer, Dr Danielle Preedy, Mr Alun Roebuck, Professor Ken Stein, Dr Nicky Welton and Mr Nigel Westwood 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 daclizumab for treating relapsing-remitting multiple sclerosis [ID827].
58. The Chair asked all NICE Staff to declare any relevant interests.
  - 58.1. 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 daclizumab for treating relapsing-remitting multiple sclerosis [ID827].
59. The Chair introduced the key issues that had arisen since the last Committee meeting.
60. The Committee continued to discuss the clinical and cost effectiveness of daclizumab for treating relapsing-remitting multiple sclerosis [ID827]
61. The committee decision was based on consensus.
62. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.