

Technology Appraisal Committee Meeting (Committee D)

Minutes: Confirmed

Date and Time: Wednesday 4 November 2015, 10:10-16:17

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 notes 01 to 31
	3. Dr Aomesh Bhatt	Present for all notes
	4. Dr Andrew Black	Present for all notes and acting as Vice Chair for notes 32 to 45
	5. Professor David Bowen	Present for all notes
	6. Dr Matthew Bradley	Present for notes 01 to 31
	7. Ms Tracey Cole	Present for all notes
	8. Dr Ian Davidson	Present for all notes
	9. Professor Simon Dixon	Present for all notes
	10. Mrs Susan Dutton	Present for all notes
	11. Dr Alexander Dyker	Present for all notes
	12. Mrs Gillian Ells	Present for all notes
	13. Professor Paula Ghaneh	Present for all notes
	14. Dr Susan Griffin	Present for all notes
	15. Professor John Henderson	Present for all notes
	16. Dr Tim Kinnaird	Present for all notes
	17. Dr Mohit Sharma	Present for all notes
	18. Dr Murray Smith	Present for all notes

In attendance:

Rob Anderson	Assessment Group Representative, Peninsula Technology Assessment Group (PenTAG)	Present for notes 06 to 14 and notes 18 to 28
Meindert Boysen	Programme Director, National Institute for Health and Care Excellence	Present for all notes
Danielle Conroy	Administrator, National Institute for Health and Care Excellence	Present for all notes

Sally Doss	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 01 to 31
Dr John Graham	Guideline Development Group Representative, nominated by National Collaborating Centre for Cancer	Present for notes 32 to 42
Christian Griffiths	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 01 to 31
Marcela Haasova	Assessment Group Representative, Peninsula Technology Assessment Group (PenTAG)	Present for notes 06 to 14 and notes 18 to 28
Sarah-Louise Harwood	Patient Expert, nominated by Kidney Research UK	Present for notes 18 to 28
Tracey Jones-Hughes	Assessment Group Representative, Peninsula Technology Assessment Group (PenTAG)	Present for notes 06 to 14 and notes 18 to 28
Helen Knight	Associate Director, National Institute for Health and Care Excellence	Present for all notes
Fay McCracken	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 32 to 45
Dr David Milford	Clinical Expert, nominated by British Association for Paediatric Nephrology	Present for notes 18 to 28
Liesl Miller	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 01 to 17
Kate Moore	Project Manager, National Institute for Health and Care Excellence	Present for all notes

Ruben Mujica-Mota	Assessment Group Representative, Peninsula Technology Assessment Group (PenTAG)	Present for notes 06 to 14 and notes 18 to 28
Keith Pennington	Patient Expert, nominated by Kidney Patient Association	Present for notes 06 to 14
Keith Rigg	NHS Commissioning Expert, nominated by NHS England	Present for notes 06 to 14
Tristan Snowsill	Assessment Group Representative, Peninsula Technology Assessment Group (PenTAG)	Present for notes 06 to 14 and notes 18 to 28
Mr Christopher Watson	Clinical Expert, nominated by Bristol-Myers Squibb (BMS)	Present for notes 06 to 14
Mr Colin Wilson	Clinical Expert, nominated by Cochrane Renal Group	Present for notes 06 to 14
Professor Nicholas Webb	Clinical Expert, nominated by Astellas Pharma	Present for notes 18 to 28
Sophie Whyte	Evidence Review Group Representative, School of Health Related Research (SchARR)	Present for notes 32 to 42

Non-public observers:

Ann Greenwood	Medical Editor, National Institute for Health and Clinical Excellence	Present for notes 06 to 31
Laura Norburn	Public Involvement Programme, National Institute for Health and Clinical Excellence	Present for notes 06 to 31
Jay Stone	Medical Relations, National Institute for Health and Clinical	Present for notes 18 to 31

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 immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85), immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99) and degarelix for treating advanced hormone-dependent prostate cancer.
2. The Chair informed the Committee of the non-public observers at this meeting.
3. Apologies were received from Dr Ian Campbell, Professor Carol Haigh, Mr Malcolm Oswald, Professor Oluwafemi Oyeboode and Dr Paula Parvulescu.

Any other Business

4. The Chair announced that Dr Warren Linley had stepped down from his role on the committee.

Notes from the last meeting

5. Agreement of the meeting minutes from the last committee discussion on 6 October 2015.

Appraisal of immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85).

Part 1 – Open session

6. The Chair welcomed the invited experts: Rob Anderson, Marcela Haasova, Tracey Jones-Hughes, Ruben Mujica-Mota, Keith Pennington, Keith Rigg, Tristan Snowsill, Mr Christopher Watson and Mr Colin Wilson to the meeting and they introduced themselves to the Committee.
7. The Chair welcomed company representatives from Astellas, Bristol-Myers Squibb, Sandoz, Sanofi, Teva and Novartis to the meeting.
8. The Chair asked all Committee members to declare any relevant interests
 - 8.1. Professor Gary McVeigh, Dr Lindsay Smith, Dr Aomesh Bhatt, Dr Andrew Black, Professor David Bowen, Dr Matthew Bradley, Dr Ian Davidson, Mrs Susan Dutton, Dr Alexander Dyker, Mrs Gillian Ells, Professor Paula Ghaneh, Dr Susan Griffin, Dr Tim Kinnaird, Dr Mohit Sharma and Dr Murray Smith 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 Immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85).

- 8.2. Ms Tracey Cole declared a non-personal non-specific financial interest as Neurological Commissioning Support (NCS) whom she worked for on secondment between October 2012 and May 2013 received grants from some of the companies participating in this appraisal although Ms Cole did not receive payment personally.

8.2.1 It was agreed that this declaration would not prevent Ms Cole from participating in this section of the meeting.

- 8.3. Professor Simon Dixon declared a non-personal non-specific financial interest as he is the Director of a Health Economics Unit that has undertaken research for BMS and Novartis but on unrelated topics. The University of Sheffield was paid for this work but Professor Dixon did not receive payment personally.

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

- 8.4. Professor Simon Dixon also declared a personal non-specific financial interest as he has undertaken work on an unrelated topic for Astellas within the last 12 months. Professor Dixon received personal payment for this work.

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

- 8.5. Professor John Henderson declared a non-personal non-specific financial interest as his organisation has received institutional funding from Pfizer for unrelated research. Professor Henderson did not receive personal payment for this work.

8.5.1 It was agreed that these declarations would not prevent Professor Henderson from participating in this section of the meeting.

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 immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85).

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

- 10.1. Rob Anderson, John Graham, Marcela Haasova, Tracey Jones-Hughes, Ruben Mujica-Mota, Keith Pennington, Tristan Snowsill, Mr Christopher Watson and Mr Colin Wilson 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 immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85).

- 10.2. Keith Rigg declared a personal non-specific financial interest as he has attended a European transplant meeting on the behalf of Astellas within the last 12 months. Mr Rigg received hospitality but was not paid for this work.
 - 10.2.1. It was agreed that this declaration would not prevent Mr Rigg from participating in this section of the meeting.
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 Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of Immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85) 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:
 - 12.1. Consideration of comments from consultees in response to the ACD:
 - 12.1.1. Restrictive recommendations
 - 12.1.2. Evidence base and subgroups
 - 12.1.3. Inconsistent use of drug acquisition costs
 - 12.1.4. Methodology used by the Assessment Group
 - 12.1.5. Scope of Technology Appraisal guidance
 - 12.2. Consideration of additional evidence submitted by Astellas and the Assessment Group's critique of that evidence
 - 12.3. Consideration of any potential equality issues
13. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
14. 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.
15. 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

16. Discussion on confidential information continued. This information was supplied by the company.
17. The Committee continued to discuss the clinical and cost effectiveness of Immunosuppressive therapy for kidney transplantation in adults (review of technology appraisal guidance 85).
18. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99)

Part 1 – Open session

19. The Chair welcomed the invited experts: Rob Anderson, Marcela Haasova, Sarah-Louise Harwood, Tracey Jones-Hughes, Dr David Milford, Ruben Mujica-Mota, Tristan Snowsill and Professor Nicholas Webb to the meeting and they introduced themselves to the Committee.
20. The Chair welcomed company representatives from Astellas, Novartis and Sanofi to the meeting.
21. The Chair asked all Committee members to declare any relevant interests
 - 21.1. Professor Gary McVeigh, Dr Lindsay Smith, Dr Aomesh Bhatt, Dr Andrew Black, Professor David Bowen, Dr Matthew Bradley, Dr Ian Davidson, Mrs Susan Dutton, Dr Alexander Dyker, Mrs Gillian Ells, Professor Paula Ghaneh, Dr Susan Griffin, Dr Tim Kinnaird, Mohit Sharma and Dr Murray Smith 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 immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99).
 - 21.2. Ms Tracey Cole declared a non-personal non-specific financial interest as Neurological Commissioning Support (NCS) whom she worked for on secondment between October 2012 and May 2013 received grants from some of the companies participating in this appraisal although Ms Cole did not receive payment personally.
 - 20.2.1 It was agreed that this declaration would not prevent Ms Cole from participating in this section of the meeting.
 - 21.3. Professor Simon Dixon declared a non-personal non-specific financial interest as he is the Director of a Health Economics Unit that has undertaken research for BMS and Novartis on unrelated topics. The University of Sheffield was paid for this work but Professor Dixon did not receive payment personally.
 - 20.3.1 It was agreed that this declaration would not prevent Professor Dixon from participating in this section of the meeting.
 - 21.4. Professor Dixon also declared a personal non-specific financial interest as he has undertaken work for, and been paid by Astellas, on an unrelated topic within the last 12 months.
 - 20.4.1 It was agreed that this declaration would not prevent Professor Dixon from participating in this section of the meeting.
 - 21.5. Professor John Henderson declared a non-personal non-specific financial interest as his organisation has received institutional funding from Pfizer for unrelated research. Professor Henderson did not receive personal payment for this work.
 - 20.5.1 It was agreed that these declarations would not prevent Professor Henderson from participating in this section of the meeting.

21. The 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 Immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99).
22. The Chair asked all other invited guests (ERG and invited experts, not including observers) to declare their relevant interests.
 - 22.1 Rob Anderson, Marcela Haasova, Sarah-Louise Harwood, Tracey Jones-Hughes, David Milford, Ruben Mujica-Mota and Tristan Snowsill 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 immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99).
 - 22.2 Professor Nicholas Webb declared a personal specific non-financial interest as he has served on Advisory Boards for Astellas and Novartis for a number of the technologies under appraisal.
 - 22.2.1 It was agreed that this declaration would not prevent Professor Webb from participating in this section of the meeting.
 - 22.3 Professor Nicholas Webb also declared a personal specific financial interest as he has acted as a Clinical Adviser for Astellas on this appraisal. Professor Webb received personal payment for this work.
 - 22.3.1 It was agreed that this declaration would not prevent Professor Webb from participating in this section of the meeting.
24. 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.
25. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of Immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99) 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:
 - 25.1 Consideration of comments from consultees in response to the ACD:
 - 25.1.1 Restrictive recommendations
 - 25.1.2 Evidence base and subgroups
 - 25.1.3 Scope of Technology Appraisal guidance
 - 25.1.4 Consideration of any potential equality issues

26. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
27. 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.
28. 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

29. Discussion on confidential information continued. This information was supplied by the company.
30. The Committee continued to discuss the clinical and cost effectiveness of Immunosuppressive therapy for kidney transplantation in children and adolescents (review of technology appraisal guidance 99).
31. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of Degarelix for treating advanced hormone-dependent prostate cancer

Part 1 – Open session

32. The Chair welcomed the invited experts: Dr John Graham and Sophie Whyte to the meeting and they introduced themselves to the Committee.
33. The Chair welcomed company representatives from Ferring Pharmaceuticals to the meeting.
34. The Chair asked all Committee members to declare any relevant interests
 - 34.1. Professor Gary McVeigh, Dr Aomesh Bhatt, Dr Andrew Black, Professor David Bowen, Dr Ian Davidson, Professor Simon Dixon, Mrs Susan Dutton, Dr Alexander Dyker, Mrs Gillian Ells, Professor Paula Ghaneh, Dr Susan Griffin, Dr Tim Kinnaird and Dr Mohit Sharma 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 Degarelix for treating advanced hormone-dependent prostate cancer.
 - 34.2. Dr Matthew Bradley was absent due to a conflict of interest. Dr Bradley declared that he holds shares in AstraZeneca who are a comparator in this appraisal. It was decided that Dr Bradley would withdraw from this section of the meeting.
 - 34.3. Dr Lindsay Smith was absent due to a conflict of interest. It was decided that Dr Smith would withdraw from 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 Degarelix for treating advanced hormone-dependent prostate cancer.
36. The Chair asked the Guidance Development Group representative to declare any relevant interests.
- 36.1. 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 Degarelix for treating advanced hormone-dependent prostate cancer.
37. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
- 37.1. 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 Degarelix for treating advanced hormone-dependent prostate cancer.
38. 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.
39. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of Degarelix for treating advanced hormone-dependent prostate cancer on the basis of the evidence before them, and potential equality issues raised in this appraisal.
- 39.1. The discussions included:
- 39.1.1. Whether the new evidence presented by the company clearly defined a subgroup of patients in whom degarelix would be cost effective
- 39.1.2. Appropriateness of company's model assumptions including: the rate of spinal cord compression, the proportion of patients suitable for treatment, life expectancy in the subgroup proposed, hospital stay while awaiting treatment with anti-androgens, and health-related quality of life values.
- 39.1.3. Degarelix list price and Commercial Medicines Unit contracts
- 39.1.4. Equalities issues
40. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
41. 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.

42. 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

43. Discussion on confidential information continued. This information was supplied by the company.
44. The Committee continued to discuss the clinical and cost effectiveness of Degarelix for treating advanced hormone-dependent prostate cancer.
45. The Committee agreed to defer a decision on the content of the guidance section of the Final Appraisal Determination (FAD) until further economic analysis has been undertaken.

Date, time and venue of the next meeting

46. Wednesday 27 January 2016 at the National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.