

Highly Specialised Technologies Evaluation Committee Meeting

Minutes: Confirmed

Date and Time: Thursday 23 November 2017

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

Present:	1. Chair, Dr Peter Jackson 2. Professor Ron Akehurst 3. Ayesha Ali 4. Sarah Davis 5. Carrie Gardner 6. Jeremy Manuel 7. Dr Shehla Mohammed 8. Francis Pang 9. Linn Phipps 10. Dr Mark Sheehan 11. Dr Glenda Sobey 12. Professor Lesley Stewart	Present for all notes Present for all notes
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In attendance:

Meindert Boysen	Programme Director, National Institute for Health and Care Excellence	Present for notes 17 to 29
Joanne Ekeledo	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Mary Hughes	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 17 to 29
Raisa Sidhu	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 17 to 29
Thomas Strong	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 5 to 16

Mandy Tonkinson	Administrator, National Institute for Health and Care Excellence	Present for all notes
Ian Watson	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 5 to 16
Sheela Upadhyaya	Associate Director, National Institute for Health and Care Excellence	Present for all notes
Antony Fearn	Patient Expert, nominated by The British Porphyria Association (BPA)	Present for notes 17 to 16
Jo Lord	ERG representative, Southampton Health Technology Assessments Centre	Present for notes 17 to 16
Fiona Marley	NHS England	Present for notes 5 to 13 and 17 to 26
Professor Lesley Rhodes	Clinical Expert, nominated by Clinuvel and British Association of Dermatologists (BAD)	Present for notes 17 to 16
Dr Robert Sarkany	Clinical Expert, nominated by British Association of Dermatologists (BAD)	Present for notes 17 to 16
Jonathan Shepherd	ERG representative, Southampton Health Technology Assessments Centre	Present for notes 17 to 16
Dr Geoff Sloan	Patient Expert, nominated by The British Porphyria Association (BPA)	Present for notes 17 to 16

Non-public observers:

Helen Barnett	Editor, National Institute for Health and Care Excellence	Present for all notes
Nicola Bodey	Senior Business Analyst, National Institute for	Present for all notes

	Health and Care Excellence	
Heidi Livingstone	Public Involvement Programme, National Institute for Health and Care Excellence	Present for notes 17 to 26
Elaine Repton	Governance Manager National Institute for Health and Care Excellence	Present for all notes
Micah Rose	Technical Adviser, National Institute for Health and Care Excellence	Present for all notes
Karen Samuels	All Wales Therapeutics and Toxicology Centre	Present for all notes
Aminata Thiam	Technical Analyst, National Institute for Health and Care Excellence	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 evaluations of strimvelis for treating severe combined immunodeficiency caused by adenosine deaminase deficiency and afamelanotide for treating erythropoietic protoporphyrina.
2. The Chair informed the Committee of the non-public observers at this meeting: Helen Barnett, Nicola Bodey, Heidi Livingstone, Elaine Repton, Micah Rose, Karen Samuels, and Aminata Thiam.
3. Apologies were received from Sotiris Antoniou and Stuart Davies.

Any other Business

4. None.

Evaluation of Strimvelis for treating severe combined immunodeficiency caused by adenosine deaminase deficiency [ID926]

Part 1 – Open session

5. The Chair welcomed the invited experts: Fiona Marley to the meeting and she introduced herself to the Committee.

6. The Chair welcomed company representatives from GlaxoSmithKline to the meeting.
7. The Chair asked all Committee members to declare any relevant interests
 - 7.1. 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 evaluation of strimvelis for treating severe combined immunodeficiency caused by adenosine deaminase deficiency.
8. The Chair asked all NICE Staff to declare any relevant interests.
 - 8.1. 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 evaluation of strimvelis for treating severe combined immunodeficiency caused by adenosine deaminase deficiency.
9. The Chair asked all other invited guests to declare their 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 evaluation of strimvelis for treating severe combined immunodeficiency caused by adenosine deaminase deficiency.
10. The Chair introduced the key themes arising from the consultation responses to the Evaluation Consultation Document (ECD) received from consultees, commentators and through the NICE website.
11. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
12. 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.
13. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the evaluation and they left the meeting.

Part 2 – Closed session

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

15. The Committee continued to discuss the clinical and cost effectiveness of strimvelis for treating severe combined immunodeficiency caused by adenosine deaminase deficiency.
16. The Committee instructed the technical team to prepare the Evaluation Consultation Document (ECD) or Final Evaluation Determination (FED) in line with their decisions.

Evaluation of afamelanotide for treating erythropoietic protoporphyria

Part 1 – Open session

17. The Chair welcomed the invited experts: Antony Fearn, Professor Lesley Rhodes, Jo Lord, Fiona Marley, Dr Robert Sarkany, Jonathan Shepherd, Dr Geoff Sloan to the meeting and they introduced themselves to the Committee.
18. The Chair welcomed company representatives from Clinuvel Pharmaceuticals to the meeting.
19. The Chair asked all Committee members to declare any relevant interests
 - 19.1. 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 evaluation of afamelanotide for treating erythropoietic protoporphyria.
20. The Chair asked all NICE Staff to declare any relevant interests.
 - 20.1. 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 evaluation of afamelanotide for treating erythropoietic protoporphyria.
21. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
 - 21.1. Antony Fearn, Jo Lord, Fiona Marley, Dr Robert Sarkany, Jonathan Shepherd and Dr Geoff Sloan 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 evaluation of afamelanotide for treating erythropoietic protoporphyria.
 - 21.2. Prof Lesley Rhodes declared a non-personal financial interest as she directs a research programme on sunlight effects on health with funding from numerous organisations.
 - 21.2.1. It was agreed that this declaration would not prevent Prof Lesley Rhodes from participating in this section of the meeting

22. The Chair introduced the lead team, Dr Glenda Sobey, Jeremy Manuel and Francis Pang who gave presentations on the clinical effectiveness, patient perspective and cost effectiveness of afamelanotide for treating erythropoietic protoporphyria.
23. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
24. 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.

Part 2a – Closed session

25. Discussion on confidential information continued. This information was supplied by the company
26. The Chair then thanked the experts and company representatives for their attendance, participation and contribution to the evaluation and they left the meeting.

Part 2b – 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 afamelanotide for treating erythropoietic protoporphyria.
29. The Committee instructed the technical team to prepare the Evaluation Consultation Document (ECD) or Final Evaluation Determination (FED) in line with their decisions.

Date, time and venue of the next meeting

30. Wednesday 17 January 2018 from 10am to 5pm at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.