

Highly Specialised Technologies Evaluation Committee Meeting

Minutes: Confirmed

Date and Time: Thursday 23 August 2018

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

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| Present: | 1. Dr Peter Jackson | Present for all notes |
| | 2. Sotiris Antoniou | Present for all notes |
| | 3. Paul Arundel | Present for all notes |
| | 4. Sarah Davis | Present for all notes |
| | 5. Carrie Gardner | Present for all notes |
| | 6. Jeremy Manual | Present for all notes |
| | 7. Dr Shehla Mohammed | Present for all notes |
| | 8. Francis Pang | Present for all notes |
| | 9. Linn Phipps | Present for all notes |
| | 10. Dr Mark Sheehan | Present for all notes |
| | 11. Professor Lesley Stewart | Present for all notes |

In attendance:

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| Helen Knight | Associate Director, National Institute for Health and Care Excellence | Present for all notes |
| Sheela Upadhyaya | Associate Director, National Institute for Health and Care Excellence | Present for all notes |
| Joanne Ekeledo | Project Manager, National Institute for Health and Care Excellence | Present for all notes |
| Thomas Paling | Technical Analyst, National Institute for Health and Care Excellence | Present for all notes |
| Mandy Tonkinson | Administrator, National Institute for Health and Clinical Excellence | Present for all notes |
| Ian Watson | Technical Adviser, | Present for all notes |

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| | National Institute for Health and Clinical Excellence | |
| Ellise Warren | Administrator, National Institute for Health and Clinical Excellence | Present for notes 1 to 13 |
| Mariana Bacelar | ERG Representative | Present for notes 1 to 13 |
| Sam Barton | ERG Representative | Present for notes 1 to 13 |
| Neil Jackson | Patient Expert | Present for notes 1 to 13 |
| Edmund Jessop | Commissioning Expert | Present for notes 1 to 13 |
| Gemma Marceniuk | ERG Representative | Present for notes 1 to 13 |
| Karen O'Hara | Patient Expert | Present for notes 1 to 13 |
| Professor David Parr | Clinical Expert | Present for notes 1 to 13 |
| Dr Alice Turner | Clinical Expert | Present for notes 1 to 13 |

Non-public observers:

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| Lucy Beggs | Technical Analyst, National Institute for Health and Clinical Excellence | Present for all notes |
| Rebecca Bouch | Administrator, National Institute for Health and Clinical Excellence | Present for all notes |
| Ann Greenwood | Editor, National Institute for Health and Clinical Excellence | Present for all notes |
| Lydia Shears | Public Involvement Adviser, National Institute for Health and Clinical Excellence | Present for notes 1 to 13 |

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 human alpha1-proteinase inhibitor for treating emphysema.

2. The Chair informed the Committee of the non-public observers at this meeting: Lucy Beggs, Rebecca Bouch, Ann Greenwood and Lydia Shears.
3. Apologies were received from Professor Ron Akehurst, Stuart Davies and Dr Glenda Sobey

Any other Business

4. None.

Evaluation of human alpha1-proteinase inhibitor for treating emphysema

Part 1 – Open session

5. The Chair welcomed the invited experts: Mariana Bacelar, Sam Barton, Neil Jackson, Edmund Jessop, Gemma Marceniuk, Karen O'Hara, Prof David Parr and Dr Alice Turner to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from CSL Behring UK Limited to the meeting.
7. The Chair asked all Committee members to declare any relevant interests
 - 7.1. Sotiris Antoniou, Paul Arundel, Sarah Davis, Carrie Gardner, Jeremy Manual, Dr Shehla Mohammed, Francis Pang, Linn Phipps, Dr Mark Sheehan and Professor Lesley Stewart 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 human alpha1-proteinase inhibitor for treating emphysema.
8. The Chair asked all NICE Staff to declare any relevant interests.
 - 8.1. Helen Knight, Joanne Ekeledo, Thomas Paling, Mandy Tonkinson, Ian Watson and Ellise Warren 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 human alpha1-proteinase inhibitor for treating emphysema.
 - 8.2. Sheela Upadhyaya declared a personal non-specific interest as she has worked with a Trustee of Alpha-1 Support Group on other HTA activities (patient engagement in HTA project and presenting on a panel at ISPOR and EURODIS meetings, all in 2017).
 - 8.2.1. It was agreed that this declaration would not prevent Sheela Upadhyaya from participating in this section of the meeting.
9. The Chair asked all other invited guests (assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
 - 9.1. Mariana Bacelar, Sam Barton, Neil Jackson, Edmund Jessop, Gemma Marceniuk and Karen O'Hara 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 human alpha1-proteinase inhibitor for treating emphysema.

- 9.2. Prof David Parr declared a personal specific financial interest as he has received honoraria from CSL Behring and Kamada for advisory services and as a speaker at conferences. He also declared a personal non-specific financial interest as he has co-authored published scientific abstracts and papers relating to Respreeza.
 - 9.2.1. It was agreed that this declaration would not prevent Prof David Parr from participating in this section of the meeting
- 9.3. Dr Alice Turner declared a personal specific financial interest as she has received personal fees for consultancy with CSL Behring.
 - 9.3.1. It was agreed that this declaration would not prevent Dr Alice Turner from participating in this section of the meeting
10. The Chair introduced the lead team, Sotiris Antoniou, Jeremy Manuel and Sarah Davis who gave presentations on the clinical effectiveness and cost effectiveness of human alpha1-proteinase inhibitor for treating emphysema
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 human alpha1-proteinase inhibitor for treating emphysema.
16. 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

17. Wednesday 19 September 2018 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.