

Technology Appraisal Committee Meeting (Committee B)

Minutes: Confirmed

Date and Time: Wednesday 12 August 2015, from 10am to 5pm

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

Present:	1. Dr Amanda Adler, Chair	Present for all notes
	2. Professor Ken Stein	Present for all notes
	3. Dr Ray Armstrong	Present for all notes
	4. Dr Jeff Aronson	Present for all notes
	5. Professor John Cairns	Present for all notes
	6. Mr Matthew Campbell-Hill	Present for all notes
	7. Mr David Chandler (present as Committee member for note 1 to 18 and notes 31 to 42, present as patient expert for notes 19 to 28)	Present for notes 1 to 28 and notes 32 to 43
	8. Mr Mark Chapman	Present for all notes
	9. Professor Imran Chaudry	Present for all notes
	10. Professor Daniel Hochhauser	Present for notes 1 to 19
	11. Dr Neil Iosson	Present for all notes
	12. Mrs Anne Joshua	Present for all notes
	13. Dr Sanjay Kinra	Present for all notes
	14. Dr Miriam McCarthy	Present for all notes
	15. Mr Christopher O'Regan	Present for notes 1 to 19 and notes 32 to 43
	16. Professor John Poundsford	Present for all notes
	17. Dr Danielle Preedy	Present for all notes
	18. Dr Marta Soares (present as Committee member for notes 1 to 30 and present as ERG representative for notes 31 to 39)	Present for notes 1 to 40
	19. Professor Matt Stevenson	Present for notes 32 to 43
	20. Dr Nicky Welton	Present for all notes

In attendance:

Meindert Boysen	Programme Director, National Institute for Health and Care Excellence	Present for all notes
Dr Elisabeth George	Associate Director, National Institute for Health and Care Excellence	Present for all notes
Dr Melinda Goodall	Associate Director	Present for all notes

	National Institute for Health and Care Excellence	
Jeremy Powell	Project Manager, National Institute for Health and Care Excellence	Present for all notes
Stuart Wood	Administrator, National Institute for Health and Care Excellence	Present for all notes
Sophie Laurenson	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 19
Helen Tucker	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 20 to 31
Raisa Sidhu	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 20 to 31
Martyn Burke	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 32 to 43
Phillip Lloyd Mayers	Clinical expert, Specialist Respiratory and ILD Pharmacist	Present for notes 6 to 16
Dr Toby Maher	Clinical expert, Chair Specialised Respiratory CRG, Consultant Respiratory Physician nominated by NHS England	Present for notes 6 to 16
Michael Bray	Patient expert, Chair of trustees for Action for Pulmonary Fibrosis Nominated by Action for Pulmonary Fibrosis	Present for notes 6 to 16
Peter Burns	Patient expert, Secretary of Papworth IPF patient support group nominated by Pulmonary Fibrosis Trust	Present for notes 6 to 16
Dr Keith Cooper	Senior Research Fellow, SHTAC	Present for notes 1 to 18
Neelam Kalita	Research Fellow, SHTAC	Present for notes 1 to 18

Dr Jo Picot	Senior Research Fellow, SHTAC	Present for notes 1 to 18
Dr Anthony Bewley	Clinical expert, Consultant Dermatologist	Present for notes 20 to 29
Professor Catherine Smith	Clinical expert, Professor of Dermatology and Therapeutics	Present for notes 20 to 29
David Chandler	Patient expert, Chief Executive of PAPAA	Present for notes 20 to 29
Dr Eldon Spackman,	Health Economist, Centre for Health Economics	Present for notes 20 to 29
Mark Simmonds	Research Fellow, Centre for Health Economics	Present for notes 20 to 29

Non-public observers:

Adam Storrow:	Resource Impact Lead, NICE	Present for all notes
Mohammed Gad	NICE International	Present for all notes
Micah Rose	SCHTAC	Present for all notes
Heidi Livingstone:	PIP, NICE	Present for all notes
Helen Barnett	Medical Editor , 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 nintedanib for treating idiopathic pulmonary fibrosis, apremilast for treating moderate to severe plaque psoriasis and vortioxetine for treating major depressive disorder.
2. The Chair informed the Committee that this was Professor Daniel Hochhauser's last Committee meeting and thanked him for his contribution to the Committee.
3. The Chair informed the Committee of the non-public observers at this meeting.
4. *Apologies were received from Professor Ruairidh Milne, Professor Stephen Palmer, Dr Sanjeev Patel and Mr Alun Roebuck.*

Any other Business

5. The Chair gave the Committee an update on the expected timelines for other appraisals.

Notes from the last meeting

6. The minutes of the meeting held on 9 July 2015 were approved.

Appraisal of nintedanib for treating idiopathic pulmonary fibrosis

Part 1 – Open session

7. The Chair welcomed the invited experts: Phillip Lloyd Mayers, Dr Toby Maher, Michael Bray, Peter Burns, Dr Keith Cooper, Neelam Kalita and Dr Jo Picot to the meeting and they introduced themselves to the Committee.
8. The Chair welcomed company representatives from Boehringer Ingelheim to the meeting.
9. The Chair asked all Committee members to declare any relevant interests
 - 9.1. Dr Amanda Adler, Professor Ken Stein, Dr Ray Armstrong, Dr Jeff Aronson, Professor John Cairns, Mr Matthew Campbell-Hill, Mr David Chandler, Mr Mark Chapman, Professor Imran Chaudry, Professor Daniel Hochhauser, Dr Neil Iosson, Mrs Anne Joshua, Dr Sanjay Kinra, Dr Miriam McCarthy, Mr Christopher O'Regan, Professor John Poundsford, Dr Danielle Preedy, Dr Marta Soares and Dr Nicky Welton all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 nintedanib for treating idiopathic pulmonary fibrosis.
10. The Chair asked all NICE Staff to declare any relevant interests.
 - 10.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 nintedanib for treating idiopathic pulmonary fibrosis.
11. The Chair asked all other invited guests assessment group/ERG and invited experts, (not including observers) to declare their relevant interests.
 - 11.1. Phillip Lloyd Mayers, Michael Bray, Peter Burns, Dr Keith Cooper, Neelam Kalita and Dr Jo Picot declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 nintedanib for treating idiopathic pulmonary fibrosis.
 - 11.2. Dr Toby Maher declared a personal non specific pecuniary interest as he has received payments for educational lectures and consultancy work from Boehringer and Roche.
 - 11.2.1. It was agreed that this declaration would not prevent Dr Maher from participating in this section of the meeting.
12. The Chair introduced the lead team, Dr John Poundsford, Professor Ken Stein and Mr Matthew Campbell-Hill who gave presentations on the clinical effectiveness and cost effectiveness of nintedanib for treating idiopathic pulmonary fibrosis.
13. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of nintedanib for treating idiopathic pulmonary fibrosis 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:

- 13.1. The clinical management of idiopathic pulmonary fibrosis and the place of nintedanib in the treatment pathway.
- 13.2. How clinicians assess lung function and the effect of acute exacerbations.
- 13.3. The clinical effectiveness of nintedanib, including the robustness of effectiveness estimates.
- 13.4. The cost-effectiveness evidence for nintedanib compared with pirfenidone and best supportive care.
- 13.5. External validity of the cost-effectiveness model.
- 13.6. Additional gains in health-related quality of life associated with nintedanib, not already included in the QALY calculations.

14. The Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
15. 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.
16. 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

17. The Committee continued to discuss the clinical and cost effectiveness of nintedanib for treating idiopathic pulmonary fibrosis.
18. The Chair then thanked the academic group for their attendance, participation and contribution to the appraisal and they left the meeting.
19. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

Appraisal of apremilast for treating moderate to severe plaque psoriasis

Part 1 – Open session

20. The Chair welcomed the invited experts: Dr Anthony Bewley, Professor Catherine Smith, Mr David Chandler and Dr Eldon Spackman to the meeting and they introduced themselves to the Committee.
21. The Chair welcomed company representatives from Celgene to the meeting.
22. The Chair asked all Committee members to declare any relevant interests
 - 22.1. Dr Amanda Adler, Professor Ken Stein, Dr Ray Armstrong, Dr Jeff Aronson, Professor John Cairns, Mr Matthew Campbell-Hill, Mr Mark Chapman, Professor Imran Chaudry, Dr Neil Iosson, Mrs Anne Joshua, Dr Sanjay Kinra, Dr Miriam McCarthy, Professor John Poundsford, Dr

Danielle Preedy, Dr Marta Soares and Dr Nicky Welton all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 apremilast for treating moderate to severe plaque psoriasis.

22.2. Chris O'Regan declared a non-personal specific pecuniary interest as his employer Merck, Sharp and Dohme UK Ltd is listed as a consultee on this appraisal

22.2.1. It was agreed that this declaration would prevent Chris O'Regan from participating in this part of the meeting.

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

23.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 apremilast for treating moderate to severe plaque psoriasis.

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

24.1. Mr David Chandler and Dr Eldon Spackman declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 apremilast for treating moderate to severe plaque psoriasis.

24.2. Professor Anthony Bewley declared a personal non specific pecuniary interest as he is a principal investigator on various studies within the UK and is involved in research on a range of biologics.

24.2.1. It was agreed that this declaration would not prevent Professor Anthony Bewley from participating in this section of the meeting.

24.3. Professor Catherine Smith declared a personal non specific pecuniary interest as she is the principal investigator in the ongoing secukinumab trial.

24.3.1. It was agreed that this declaration would not prevent Professor Catherine Smith from participating in this section of the meeting

25. 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.

26. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of apremilast for treating moderate to severe plaque psoriasis 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:

- The comments from consultees, commentators and from the website on the Appraisal Consultation Document
- The uncertainty in the company's economic analysis around amount of drug wastage, the costs associated with best supportive care and cost estimates for people whose disease does not respond to one systemic treatment and who then go on to get further systemic treatment
- The results of the company's revised cost effectiveness analysis for apremilast as a replacement for 1 of the biological therapies in a treatment sequence, in a population with PASI score of 10 or more
- The ERGs critique of the company's revised cost effectiveness analysis.

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

28. 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.

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

Part 2 – Closed session

30. The Committee continued to discuss the clinical and cost effectiveness of apremilast for treating moderate to severe plaque psoriasis.

31. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Appraisal of vortioxetine for treating major depressive disorder

Part 1 – Open session

32. The Chair welcomed the Evidence Review Group representatives: Mark Simmonds and Dr Marta Soares to the meeting and they introduced themselves to the Committee.

33. The Chair welcomed company representatives from Lundbeck to the meeting.

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

34.1. Dr Amanda Adler, Professor Ken Stein, Dr Ray Armstrong, Dr Jeff Aronson, Professor John Cairns, Mr Matthew Campbell-Hill, Mr David Chandler, Mr Mark Chapman, Professor Imran Chaudry, Professor Daniel Hochhauser, Dr Neil Iosson, Mrs Anne Joshua, Dr Sanjay Kinra, Dr Miriam McCarthy, Mr Christopher O'Regan, Professor John Poundsford, Dr Danielle Preedy, Dr Marta Soares, Professor Matt Stevenson and Dr Nicky Welton all declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-

specific pecuniary 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 vortioxetine for treating major depressive disorder.

35. The Chair asked all NICE Staff to declare any relevant interests.
 - 35.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 vortioxetine for treating major depressive disorder.
36. The Chair asked all other invited guests assessment group/ERG and invited experts, not including observers) to declare their relevant interests.
 - 36.1. All declared that they knew of no personal specific pecuniary interest, personal non-specific pecuniary interest, non-personal specific pecuniary interest, non-personal non-specific pecuniary 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 vortioxetine for treating major depressive disorder.

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.

37. The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of vortioxetine for treating major depressive disorder on the basis of the evidence before them. The discussions included:
 - 37.1. A recap of the clinical and cost effectiveness evidence presented in the company's original submission.
 - 37.2. A recap of the Committee's considerations leading to the preliminary recommendations in the ACD.
 - 37.3. The comments/responses provided during consultation by consultees, commentators and via the web site.
 - 37.4. The additional analyses and clarifications provided by the company in response to the Committee's preliminary recommendations.
 - 37.5. The ERG's critique of the additional analyses and clarifications provided by the company in response to the Committee's preliminary recommendations.
 - 37.6. Key issues including the most appropriate position in treatment pathway for vortioxetine, the efficacy of vortioxetine relative to other antidepressants, whether the company's revised economic model structure adequately reflected clinical practice, and whether vortioxetine could be considered a cost effective use of NHS resources.
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 experts, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

41. The Committee continued to discuss the clinical and cost effectiveness of vortioxetine for treating major depressive disorder.
42. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

Date, time and venue of the next meeting

43. Wednesday 9 September 2015 at Prospero House, 241 Borough High Street, London, SE1 1GA.