Technology Appraisal Committee Meeting (Committee A)

Minutes: Confirmed

Date and Time: Thursday 28th May 2015, 10.00am – 5.00pm

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

Present:	Dr Jane Adam	Present for all notes
	Dr Jeremy Braybrooke	Present for all notes
	Dr Gerardine Bryant	Present for all notes
	Dr Mohit Misra	Present for all notes
	Dr John Watkins	Present for all notes
	Dr Eldon Spackman	Present for all notes
	Dr Nerys Woolacott	Present for all notes
	Dr Brian Shine	Present for all notes
	Mr David Thomson	Present for all notes
	Mrs Pamela Rees	Present for all notes
	Mr Stephen Sharp	Present for all notes
	Ms Sarah Parry	Present for all notes
	Dr Andrew England	Present for all notes
	Professor John McMurray	Present for notes 17 to 29
	Dr Paul Robinson	Present for notes 1 to 16

In attendance:

Meindert Boysen	Programme Director, National Institute for Health and Care Excellence	Present for all notes
Janet Robertson	Associate Director, National Institute for Health and Care Excellence	Present for all notes
Bijal Joshi	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
Carl Prescott	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 1 to 16
Joanna Richardson	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 1 to 16
Linda Landells	Technical Analyst, National Institute for Health and Care Excellence	Present for notes 17 to 29

Zoe Charles	Technical Adviser, National Institute for Health and Clinical Excellence	Present for notes 17 to 29
Steve Edwards	Head of Clinical & Economic Evidence, BMJ-TAG	Present for notes 1 to 16
Fay Crawford	Senior HTA Analyst, BMJ-TAG	Present for notes 1 to 16
Mariana Bacelar	Senior Health Economist, BMJ-TAG	Present for notes 1 to 16
Rachid Rafia	Research Fellow, ScHARR - The University of Sheffield	Present for notes 17 to 29
Matt Stevenson	Professor of Health Technology Assessment, ScHARR - The University of Sheffield	Present for notes 17 to 29
Dr Luke Howard	Consultant Respiratory Physician	Present for notes 1 to 16
Dr Seamus J Murphy	Consultant Gastroenterologist	Present for notes 17 to 29
Dr Jeremy Sanderson	Consultant Gastroenterologist	Present for notes 17 to 29
Professor Beverley Hunt	Medical Director	Present for notes 1 to 16
Ms Paula L Battersby	Crohn's and Colitis UK	Present for notes 17 to 29
Diane Eaton	Project Development Manager - AntiCoagulation Europe	Present for notes 1 to 16

Non-public observers:

Laura Norburn	PIP, 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 edoxaban tosylate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism [ID662] and vedolizumab for treating moderately to severely active Crohn's disease after prior therapy [ID690].

2. Apologies were received from Dr Graham Ash, Ms Ellen Rule Professor Aileen Clarke, Mr Adrian Griffin, Dr Anne McCune, Professor Iain Squire, and Professor Olivia Wu.

Any other Business

3. None

Notes from the last meeting

4. The minutes were agreed.

Appraisal of edoxaban tosylate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism [ID662]

Part 1 – Open session

5. The Chair welcomed the ERG and invited experts: Steve Edwards, Fay Crawford, Mariana Bacelar, Dr Luke Howard, Professor Beverley Hunt, and Diane Eaton to the meeting and they introduced themselves to the Committee.

6. The Chair welcomed company representatives from Daiichi Sankyo to the meeting.

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

    7.1. Dr Jane Adam, Dr Jeremy Braybrooke, Dr Gerardine Bryant, Dr Mohit Misra, Dr Eldon Spackman, Dr Nerys Woolacott, Dr Brian Shine, Mr David Thomson, Mrs Pamela Rees, Mr Stephen Sharp, Ms Sarah Parry, Dr Paul Robinson, Dr John Watkins, and Dr Andrew England 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 edoxaban tosylate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism [ID662].

    7.2. Professor John McMurray was absent from the meeting, as he has worked with representatives of the company to prepare the edoxaban submission to the EMA.

    7.3. Mr Adrian Griffin was absent from the meeting as rivaroxaban is a Johnson n Johnson (the company he is employed by) product marketed in the USA.

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

    8.1. 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 edoxaban tosylate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism [ID662].

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

    9.1. Steve Edwards, Fay Crawford, Mariana Bacelar, Professor Beverley Hunt and Diane Eaton 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 edoxaban tosylate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism [ID662].

    9.2. Dr Luke Howard declared a personal pecuniary interest as he has received lecture fees and consultancy fees from Daiichi Sankyo, Bayer and Boehringer Ingelheim on the topic of Pulmonary Embolism (PE). Dr Luke Howard also declared a non-personal pecuniary interest as he has received research funding from Bayer for PE related research.

        9.2.1. It was agreed that these declarations would not prevent Dr Luke Howard from participating in this section of the meeting.

10. The Chair introduced the lead team, Dr Nerys Woolacott, Dr Andrew England, and David Thomson who gave presentations on the clinical effectiveness and cost effectiveness of

edoxaban tosylate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism [ID662].

11. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of edoxaban tosylate for the treatment and secondary prevention of deep vein thrombosis and/or pulmonary embolism [ID662] 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:

    11.1. The patient experience of people with VTE
    11.2. The current treatment pathway for VTE
    11.3. The design and the results of the pivotal trial, Hokusa-VTE
    11.4. The generalisibility of Hokusai-VTE to people in the NHS with VTE
    11.5. The design and the results of the network meta-analysis comparing edoxaban with warfarin, rivaroxaban, dabigatran and apixaban
    11.6. The inputs of the health economic model that had been presented by the company
    11.7. The clinical plausibility of the health economic model
    11.8. The plausibility of the assumptions used for monitoring for warfarin, and the newer oral anticoagulants (edoxaban, rivaroxaban and dabigatran)

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, company representatives and academic group for their attendance, participation and contribution to the appraisal and they left the meeting.

Part 2 – Closed session

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

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

Appraisal of vedolizumab for treating moderately to severely active Crohn’s disease after prior therapy [ID690]

Part 1 – Open session

17. The Chair welcomed the ERG and invited experts: Rachid Rafia, Matt Stevenson, Dr Seamus J Murphy, Dr Jeremy Sanderson, and Paula L Battersby to the meeting and they introduced themselves to the Committee.

18. The Chair welcomed company representatives from Takeda UK to the meeting.

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

    19.1. Dr Jane Adam, Dr Jeremy Braybrooke, Dr Gerardine Bryant, Dr Mohit Misra, Dr Eldon Spackman, Dr Nerys Woolacott, Dr Brian Shine, Mr David Thomson, Mrs Pamela Rees, Mr Stephen Sharp, Ms Sarah Parry, Professor John McMurray, Dr John Watkins, and Dr Andrew England 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 vedolizumab for treating moderately to severely active Crohn's disease after prior therapy [ID690].

19.2. Dr Paul Robinson was absent from the meeting, as he is an employee of Merck, Sharpe and Dohme which markets one of the comparators, infliximab.

19.3. Mr Adrian Griffin was absent from the meeting as infliximab is a Johnson & Johnson (the company he is employed by) product marketed in the USA.

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

20.1. 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 vedolizumab for treating moderately to severely active Crohn's disease after prior therapy [ID690].

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

21.1. 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 vedolizumab for treating moderately to severely active Crohn's disease after prior therapy [ID690].

22. 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.

23. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of vedolizumab for treating moderately to severely active Crohn's disease after prior therapy [ID690] 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:

23.1. Identifying the key comparator treatments for vedolizumab in patients in whom TNF-alpha inhibitor has failed.
23.2. Determining the robustness of subgroup analyses used in the clinical- and cost-effectiveness analyses of vedolizumab compared with conventional non-biological therapy.
23.3. The acceptability of the changes made to the company's economic model, including each of the inputs that reduced the company's base-case ICER
23.4. The existing concerns about structure of the company's economic model and its parameterisation

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

25. 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.

26. 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

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

28. 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

29. Tuesday 30th June 2015 at Prospero House, 241 Borough High Street, London SE1 1GA