# Technology Appraisal Committee Meeting (Committee [A])

**Minutes:** [Confirmed]

**Date and Time:** Wednesday 11 January 2017, 10am

**Venue:** National Institute for Health and Care Excellence  
10 Spring Gardens, SW1A 2BU

### Present:

1. Chair, Jane Adam Present for all notes  
2. Professor Iain Squire Present for all notes  
3. Dr Graham Ash Present for all notes  
4. Dr Jeremy Braybrooke Present for all notes  
5. Dr Justin Daniels Present for all notes  
6. Mr Andrew England Present for all notes  
7. Mr Adrian Griffin Present for all notes  
8. Dr Rachel Hobson Present for all notes  
10. Professor John McMurray Present for all notes  
11. Dr Ian Bernstein Present for all notes  
12. Ms Pamela Rees Present for all notes  
13. Dr Paul Robinson Present for all notes  
14. Ms Ellen Rule Present for all notes 1 to 42  
15. Dr Brian Shine Present for notes 1 to 17  
16. Professor Olivia Wu Present for notes all notes  
17. Dr Nerys Woolacott Present for notes all notes  
18. Dr Rita Faria Present for notes all notes

### In attendance:

- **Meindert Boysen**  
  Programme Director, National Institute for Health and Care Excellence  
  Present for all notes 18 to 53

- **Janet Robertson**  
  Associate Director, National Institute for Health and Care Excellence  
  Present for all notes

- **Liv Gualda**  
  Project Manager, National Institute for Health and Care Excellence  
  Present for all notes

- **Marcia Miller**  
  Technology Appraisal Administrator, National Institute for Health and Care Excellence  
  Present for all notes

- **Thomas Strong**  
  Technical Analyst, National Institute for Health and Care  
  Present for notes 1 to 17
<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Present for notes</th>
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<tbody>
<tr>
<td>Joanna Richardson</td>
<td>Technical Adviser, National Institute for Health and Care Excellence</td>
<td>1 to 17 and 43 to 53</td>
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<tr>
<td>Eleanor Donegan</td>
<td>Technical Adviser, National Institute for Health and Care Excellence</td>
<td>18 to 26</td>
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<tr>
<td>Irina Voicechovskaja</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>18 to 26</td>
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<tr>
<td>Zoe Charles</td>
<td>Technical Adviser, National Institute for Health and Care Excellence</td>
<td>30 to 42</td>
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<tr>
<td>Abintha Senthinathan</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>30 to 42</td>
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<tr>
<td>Sana Khan</td>
<td>Technical Analyst, National Institute for Health and Care Excellence</td>
<td>43 to 53</td>
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<td></td>
<td><strong>Evidence Review Group</strong></td>
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<tr>
<td>Bram Raemakers</td>
<td>Health Economist, Kleijnen Systematic Reviews (KSR)</td>
<td>18 to 26</td>
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<tr>
<td>Rob Riemsama</td>
<td>Health Economist, Kleijnen Systematic Reviews (KSR)</td>
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<tr>
<td>Maiwenn Al</td>
<td>Health Economist, Kleijnen Systematic Reviews, (KSR)</td>
<td>18 – 26</td>
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<td><strong>Experts</strong></td>
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<tr>
<td>Dr Alistair Ring</td>
<td>Consultant Medical Oncology nominated RCP</td>
<td>1 to 13</td>
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<td>Dr Nicholas Turner</td>
<td>Consultant Medical Oncologist nominated by Pfizer</td>
<td>1 to 13</td>
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<tr>
<td>Dr Gideon Hirschfield</td>
<td>Consultant Hepatologist nominated by British Society of Gastroentrology</td>
<td>17 to 25</td>
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<tr>
<td>Dr George Mells</td>
<td>Research Fellow and Honorary Consultant Hepatologist</td>
<td>17 to 25</td>
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<tr>
<td>Name</td>
<td>Title and Nominating Organization</td>
<td>Notes Presented</td>
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<tr>
<td>Professor David Halpin</td>
<td>Consultant Physician nominated by AstraZeneca</td>
<td>30 to 40</td>
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<tr>
<td>Dr Shuaib Nasser</td>
<td>Consultant Physician nominated by RCP</td>
<td>43 to 50</td>
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<tr>
<td>Dr Andrew Wardlaw</td>
<td>Professor of Allergy and Respiratory Medicine nominated by British Society for Allergy and Clinical Immunology</td>
<td>43 to 50</td>
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<tr>
<td>Tamara Sandoul</td>
<td>Patient expert by nominated Breast Cancer Now</td>
<td>17 to 25</td>
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<tr>
<td>Robert Mitchell Thain</td>
<td>Patient expert nominated by The PBC Foundation</td>
<td>17 to 25</td>
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<tr>
<td>Mrs Mhari Robertson</td>
<td>Patient expert nominated by The PBC Foundation</td>
<td>17 to 25</td>
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<tr>
<td>Miss Nichola Duane</td>
<td>Patient experts nominated by Asthma UK</td>
<td>17 to 25</td>
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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 Single Technology Appraisal of Palbociclib in combination with an aromatase inhibitor for previously untreated metastatic, hormone receptor-positive, HER2-negative breast cancer.

2. The Chair informed the Committee of the non-public observers at this meeting: Sanjeev Patel, Joshua South, Chloe Kastoryano and Orsoyla Balogh.

3. Apologies were received from Mr Andrew England, Dr Mohit Misra, Dr Mohit Sharma, Mrs Sarah Parry and Mr Stephen Sharp

Notes from the last meeting

4. The minutes of the last meeting were held.

Appraisal of palbociclib in combination with an aromatase inhibitor for previously untreated metastatic, hormone receptor-positive, HER2-negative breast cancer.

Part 1 – Open session

5. The Chair welcomed the invited experts: Nigel Fleeman, Dr Alistair Ring, Dr Nicholas Turner, Tamara Sandoul, and Angela Stainthorpe to the meeting and they introduced themselves to the Committee.

6. The Chair welcomed company representatives from Pfizer to the meeting.

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

7.1. Chair, Jane Adam, Professor Iain Squire, Dr Graham Ash, Dr Justin Daniels, Mr Adrian Griffin, Dr Rachel Hobson, Dr Anne McCune, Professor John McMurray, Dr Ian Bernstein, Ms Pamela Rees, Dr Paul Robinson, Ms Ellen Rule, Dr Brian Shine, Dr John Watkins, Professor Olivia Wu, Dr Nerys Woolacott and Dr Rita Faria all declared that they knew of no personal specific financial interest, personal non-specific financial interest, non-personal specific financial interest, 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 palbociclib in combination with an aromatase inhibitor for previously untreated metastatic, hormone receptor-positive, HER2-negative breast cancer.

7.2. Dr Jeremy Braybrooke declared a non-personal specific financial interest as he was investigator on clinical trial with palbociclib in early breast care

9.2.1 It was agreed that this declaration would not prevent Dr Jeremy Braybrooke from participating in this section of the meeting.
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 appraisal of Palbociclib in combination with an aromatase inhibitor for previously untreated metastatic, hormone receptor-positive, HER2-negative breast cancer.

9. The Chair asked all other invited guests to declare their relevant interests.

9.1. Nigel Fleeman, Tamara Sandoul, Angela Stainthrope 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 palbociclib in combination with an aromatase inhibitor for previously untreated metastatic, hormone receptor-positive, HER2-negative breast cancer.

9.2. Dr Alistair Ring declared a personal non-specific financial interest as he is a UK Chief Investigator of the adjuvant palbociclib study “PALLAS” and also UK Chief Investigator of a study using another CDK 4/6 inhibitor (COMPLEEMENT study using: ribociclib). I am also a co-investigator in other studies using palbociclib and abemaciclib. None of these roles involves any personal or non-personal financial interests

9.2.1. It was agreed that this declaration would not prevent Dr Alistair Ring from participating in this section of the meeting

9.3. Dr Nicholas Turner declared a personal specific financial interest as he has received honoraria from Pfizer for advisory boards

9.3.1. It was agreed that this declaration would not prevent Dr Nicholas Turner from participating in this section of the meeting

10. The Chair introduced the lead team, Dr Brain Shine, Dr Olivia Wu and Ms Pamela Rees who gave presentations on the clinical effectiveness and cost effectiveness of Palbociclib in combination with an aromatase inhibitor for previously untreated metastatic, hormone receptor-positive, HER2-negative breast cancer.

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 appraisal 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 palbociclib in combination with an aromatase inhibitor for previously untreated metastatic, hormone receptor-positive, HER2-negative breast cancer.

16. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.
Part 1 – Open session

17. The Chair welcomed the invited experts: Maiwenn Al, Sabine Grimme, Professor Gideon Hirschfield, Professor George Mells, Mrs Mhari Robertson, Mr Robert Mitchell-Thain, Rob Riemsma and Bram Raemakers to the meeting and they introduced themselves to the Committee.

18. The Chair welcomed company representatives from Intercept to the meeting.

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

19.1. Chair Jane Adam, Professor Iain Squire, Dr Graham Ash, Dr Justin Daniels, Mr Andrew England, Mr Adrian Griffin, Dr Rachel Hobson, Professor John McMurray, Dr Ian Bernstein, Ms Pamela Rees, Dr Paul Robinson, Ms Ellen Rule, Dr Brian Shine, Dr John Watkins, Professor Olivia Wu, Dr Nerys Woolacott and Dr Rita Faria 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 obeticholic acid for treating primary biliary cirrhosis.

19.2. Dr Anne McCune declared personal specific financial interest as she has been involved with trials: Intercept 301 (POISE) – patients are still enrolled in the long term extension study (POISE is main study for the appraisal) Intercept 302 (COBALT) – Obeticholic acid in PBC, Intercept 303 (REGENERATE) – Obeticholic acid in NASH. It was agreed that this declaration would prohibit Dr Anne McCune from participating in the appraisal and she remained absent.

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 appraisal of obeticholic acid for treating primary biliary cirrhosis.

21. The Chair asked all other invited guests to declare their relevant interests.

21.1. Maiwenn Al, Rob Riemsma and Bram Raemakers and Mrs Mhari Robertson 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 Obeticholic acid for treating primary biliary cirrhosis.

21.2. Professor Gideon Hirschfield declared a personal non-specific financial interest as he has advised Intercept Pharma on the conduct of the COBALT OLA clinical trials.

21.2.1. It was agreed that this declaration would not prevent Professor Gideon Hirschfield from participating in this section of the meeting.
21.3. Dr George Mells declared a personal non-specific financial interest as he was involved in a research programme and previously received a £50K research grant from Intercept Pharmaceuticals to facilitate development of the UK-PBC Research Cohort. He has also participated in Intercept’s PBC Advisory Board in the UK.

21.3.1. It was agreed that this declaration would not prevent Dr George Mells from participating in this section of the meeting.

21.4. Mr Robert Mitchell-Thain declared a personal non-specific financial interest as PBC Foundation has been funded for core costs and specific projects by Intercept to a level of approximate 6% of income annual.

21.4.1. It was agreed that this declaration would not prevent Mr Robert Mitchell-Thain from participating in this section of the meeting.

22. The Chair introduced the lead team, Dr Ian Bernstein, Ms Pamela Rees who gave presentations on the clinical effectiveness and cost effectiveness of Obeticholic acid for treating primary biliary cirrhosis.

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.

25. 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

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

27. *The Committee continued to discuss the clinical and cost effectiveness of Obeticholic acid for treating primary biliary cirrhosis*

28. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.
29. The Chair welcomed the invited experts: Professor David Halpin and Rob Riemsmma to the meeting and they introduced themselves to the Committee.

30. The Chair welcomed company representatives AstraZeneca to the meeting.

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

31.1. Chair, Jane Adam, Dr Graham Ash, Dr Justin Daniels, Mr Andrew England, Mr Adrian Griffin, Dr Rachel Hobson, Dr Ian Bernstein, Ms Pamela Rees, Dr Paul Robinson, Ms Ellen Rule, Dr Brian Shine, Dr John Watkins, Professor Olivia Wu, Dr Nerys Woolacott and Dr Rita Faria 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 Obeticholic acid for treating primary biliary cirrhosis.

31.2. Professor John McMurray declared a non-personal specific financial interest as his employer I was paid by AstraZeneca for his participation in a planning committee for a clinical trial in heart failure with an unrelated drug.

9.3.1 It was agreed that this declaration would prevent Professor John McMurray from participating in this section of the meeting.

31.3. Professor Iain Squire declared a non-personal specific financial interest as he has received honoraria funding from Novartis (comparator) for research in cardiovascular disease.

9.3.1 It was agreed that this declaration would prevent Professor Iain Squire from participating in this section of the meeting.

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

32.1. 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 Obeticholic acid for treating primary biliary cirrhosis.

33. The Chair asked all other invited guests to declare their relevant interests.

33.1. 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 Obeticholic acid for treating primary biliary cirrhosis.

1.1.1. Professor David Halpin declared personal, non-specific financial interest for fees and non-financial support from AstraZeneca, personal fees and non-financial support from Boehringer Ingelheim, personal fees from GlaxoSmithKline, personal fees and non-financial support from Novartis, personal fees from Pfizer, personal fees from Chiesi,
1.1.2. It was agreed that this declaration would not prevent Professor David Halpin from participating in this section of the meeting.

36. The Chair introduced the lead team, Professor John McMurray, Dr Rita Faria and Ms Pamela Rees who gave presentations on the clinical effectiveness and cost effectiveness of Roflumilast for treating chronic obstructive pulmonary disease (review of technology appraisal guidance 244).

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

38. 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.

39. 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

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

41. The Committee continued to discuss the clinical and cost effectiveness of Obeticholic acid for treating primary biliary cirrhosis

42. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.
Appraisal of reslizumab for treating eosinophilic asthma after inhaled corticosteroids

Part 1 – Open session

43. The Chair welcomed the invited experts: Miss Nichola Duane, Dr Shuaib Nasser, Dr Andrew Wardlaw, to the meeting and they introduced themselves to the Committee.

44. The Chair welcomed company representatives Teva to the meeting.

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

45.1. Chair, Jane Adam, Dr Graham Ash, Dr Justin Daniels, Mr Andrew England, Mr Adrian Griffin, Dr Rachel Hobson, Dr Ian Bernstein, Ms Pamela Rees, Dr Paul Robinson, Ms Ellen Rule, Dr Brian Shine, Dr John Watkins, Professor Olivia Wu, Dr Nerys Woolacott and Dr Rita Faria 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 Reslizumab for treating eosinophilic asthma after inhaled corticosteroids.

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

1.1. 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 Reslizumab for treating eosinophilic asthma after inhaled corticosteroids.

47. The Chair asked all other invited guests to declare their relevant interests.

47.1. Miss Nichola Duane 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 Reslizumab for treating eosinophilic asthma after inhaled corticosteroids.

47.2. Dr Shuaib Nasser declared a personal non-specific financial interest as he has been involved in clinical trials for GSK, AstraZeneca, Novartis. He has sat on advisory board for GSK, Novartis, Teva and given lectures for NAPP.

47.2.1. It was agreed that this declaration would not prevent Dr Shuaib Nasser from participating in this section of the meeting.

47.3. Dr Andrew Wardlaw declared a personal non-specific financial interest as he has been involved in data safety monitoring boards for Teva and advisory boards for GSK and Boehringer research grants, GSK and Pfizer.

47.3.1. It was agreed that this declaration would not prevent Dr Andrew Wardlaw from participating in this section of the meeting.

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

49. 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.

50. 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

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

52. The Committee continued to discuss the clinical and cost effectiveness of Obeticholic acid for treating primary biliary cirrhosis

53. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) in line with their decisions.

Date, time and venue of the next meeting

Wednesday 8 February 2017 at 10am National Institute of Care Excellence, 10 Spring Garden SW1A 2BU