**Technology Appraisal Committee Meeting (Committee D)**

**Minutes:** Confirmed

**Date and Time:** Tuesday 23 June 2015, 10:10 to 17:35

**Venue:** Floor 24, City Tower
Piccadilly Plaza
Manchester
M1 4BT

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| **Present:** | 1. Professor Gary McVeigh, Chair | Present for all notes |
| | 2. Dr Lindsay Smith, Vice Chair | Present for all notes |
| | 3. Dr Aomesh Bhatt | Present for all notes |
| | 4. Dr Andrew Black | Present for all notes |
| | 5. Professor David Bowen | Present for all notes |
| | 6. Dr Matthew Bradley | Present for notes 21 to 78 |
| | 7. Dr Ian Campbell | Present for notes 01 to 75 |
| | 8. Dr Ian Davidson | Present for all notes |
| | 9. Professor Simon Dixon | Present for all notes |
| | 10. Dr Alexander Dyker | Present for all notes |
| | 11. Dr Susan Griffin | Present for notes 5 to 20, 36 to 50 and 51 to 64 as a committee member and notes 21 to 32 and 65 to 75 as an ERG member |
| | 12. Professor John Henderson | Present for all notes |
| | 13. Mr Malcolm Oswald | Present for all notes |
| | 14. Professor Oluwafemi Oyebode | Present for all notes |
| | 15. Dr Mohit Sharma | Present for all notes |
| | 16. Dr Murray Smith | Present for all notes |

**In attendance:**

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| Meindert Boysen | Programme Director, National Institute for Health and Care Excellence | Present for all notes |
| Helen Knight | Associate Director, National Institute for Health and Care Excellence | Present for all notes |
| Kate Moore | Project Manager, National Institute for Health and Care Excellence | Present for all notes |
| Danielle Conroy | Administrator, National Institute for Health and Care Excellence | Present for all notes |
| Martyn Burke | Technical Analyst, National Institute for Health and Care Excellence | Present for notes 36 to 50 and 65 to 78 |

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| Ahmed Elsada | Technical Analyst, National Institute for Health and Care Excellence | Present for notes 21 to 35 |
| Anwar Jilani | Technical Analyst, National Institute for Health and Care Excellence | Present for notes 51 to 78 |
| Linda Landells | Technical Analyst, National Institute for Health and Clinical Excellence | Present for notes 01 to 20 |
| Raisa Sidhu | Technical Adviser, National Institute for Health and Clinical Excellence | Present for notes 21 to 35 and 65 to 78 |
| Nwamaka Umeweni | Technical Adviser, National Institute for Health and Clinical Excellence | Present for notes 21 to 78 |
| Beth Woods | Centre for Reviews and Dissemination and Centre for Health Economics - York | Present for notes 21 to 32 and 65 to 75 |
| Jeremy Jones | Southampton Health Technology Assessments Centre | Present for notes 51 to 61 and 65 to 75 |
| Karen Pickett | Southampton Health Technology Assessments Centre | Present for notes 51 to 61 and 65 to 75 |
| Richard Jeavons | NHS expert nominated by NHS England | Present for notes 65 to 75 |
| James Palmer | NHS expert nominated by NHS England | Present for notes 21 to 32, 36 to 47, 51 to 61 and 65 to 75 |
| Sarah Watson | NHS expert nominated by NHS England | Present for notes 01 to 16 |
| Malcolm Qualie | NHS expert nominated by NHS England | Present for all notes |
| Ian Bruce | Clinical expert nominated by the British Society for Rheumatology (BSR) | Present for notes 01 to 16 |
| Matthew Cramp | Clinical expert nominated | Present for notes 21 to 32, 36 |

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| | by Gilead Sciences | to 47, 51 to 61 and 65 to 75 |
| Geoffrey Dusheiko | Clinical expert nominated by BMS, Gilead and AbbVie | Present for notes 21 to 32, 36 to 47, 51 to 61 and 65 to 75 |
| Dr Ranjababu Kulasegaram | Clinical expert nominated by the British Association for Sexual Health and HIV, British HIV Association and British Society of Gastroenterology | Present for notes 21 to 32, 36 to 47, 51 to 61 and 65 to 75 |
| Charles Millson | Clinical expert nominated by the British Society of Gastroenterology | Present for notes 21 to 32, 36 to 47, 51 to 61 and 65 to 75 |
| Terrence Wong | Clinical expert nominated by the British Society of Gastroenterology | Present for notes 21 to 32, 36 to 47, 51 to 61 and 65 to 75 |
| Jane Dunnage | Patient expert nominated by Lupus UK. | Present for notes 01 to 16 |
| Richard Hall | Patient expert nominated by Liver 4 Life | Present for notes 21 to 32, 36 to 47, 51 to 61 and 65 to 75 |
| Raquel Peck | Patient expert nominated by the Hepatitis C Trust | Present for notes 21 to 32, 36 to 47, 51 to 61 and 65 to 75 |
| Helen Harris | Public Health representative nominated by Public Health England | Present for notes 21 to 32, 36 to 47, 51 to 61 and 65 to 75 |
| Matthew Hickman | Guideline Development Group representative nominated by the National Clinical Guideline Centre | Present for notes 21 to 32, 36 to 47, 51 to 61 and 65 to 75 |
| **Non-public observers:** | | |
| Christina McArthur | Implementation Consultant (North) | Present for notes all notes |
| Ann Greenwood | Senior Medical Editor, National Institute for Health and Clinical Excellence | Present for notes all notes |
| Dafydd Singleton | Web Editor, National Institute for Health and Clinical Excellence | Present for notes 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 Belimumab for the treatment of active autoantibody-positive systemic lupus erythematosus, Daclatasvir for treating chronic hepatitis C, Ledipasvir-sofosbuvir for treating chronic hepatitis C, Ombitasvir/paritaprevir/ritonavir with or without dasabuvir for treating chronic hepatitis C and the discussion of the Hepatitis C topics: Daclatasvir, Ledipasvir-sofosbuvir and Ombitasvir/paritaprevir/ritonavir with or without dasabuvir, in the context of the NHS England comments received on the consultation for the preliminary recommendations for Ledipasvir-sofosbuvir.

2. The Chair informed the Committee of the non-public observers at this meeting: Christina McArthur, Ann Greenwood and Dafydd Singleton.

3. Apologies were received from Mrs Tracey Cole, Mrs Susan Dutton, Mrs Gillian Ells, Professor Paula Ghaneh, Professor Carol Haigh, Dr Tim Kinnaird and Dr Warren Linley.

**Any other Business**

4. None

**Appraisal of Belimumab for the treatment of active autoantibody-positive systemic lupus erythematosus**

**Part 1 – Open session**

5. The Chair welcomed the invited experts: Ian Bruce, Jane Dunnage, Sarah Watson and Malcolm Qualie to the meeting and they introduced themselves 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

8. Dr Aomesh Bhatt, Dr Andrew Black, Professor David Bowen, Dr Ian Campbell, Dr Ian Davidson, Mrs Susan Dutton, Dr Alexander Dyker, Dr Susan Griffin, Professor Gary McVeigh (Chair), Mr Malcolm Oswald, Professor Oluwafemi Oyebode, Dr Mohit Sharma, Dr Lindsay Smith (Vice Chair) and Dr Murray Smith 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 Belimumab for the treatment of active autoantibody-positive systemic lupus erythematosus.

   8.1. Professor Simon Dixon declared a non-personal non-specific pecuniary interest as he is the Director of a Health Economics Unit that has undertaken work for a comparator company, although the work was for a different indication and he had not been directly involved. The University of Sheffield received payment for this work.
   8.1.1 It was agreed that this declaration would not prevent Professor Dixon from participating in this section of the meeting.

   8.2. Professor John Henderson declared a non-personal specific pecuniary interest as his institution receives funding from the company of this technology however he is not personally remunerated.
   8.2.1 It was agreed that this declaration would prevent Professor Henderson from participating in this section of the meeting.

   8.3. Dr Matthew Bradley was conflicted in this appraisal and so did not attend. He is employed by the company of this technology.

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

10. 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 Belimumab for the treatment of active autoantibody-positive systemic lupus erythematosus.

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

    11.1. 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 Belimumab for the treatment of active autoantibody-positive systemic lupus erythematosus.

12. 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.

13. The Committee then discussed the clinical effectiveness, patient perspective and cost effectiveness of Belimumab for the treatment of active autoantibody-positive systemic lupus erythematosus 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 general concept of a managed access agreement.

    13.2. The data that could be collected through a UK registry and the value of this when reviewing the technology appraisal guidance in the future.

    13.3. The potential sample size and duration of treatment that would be needed to provide meaningful registry data.

    13.4. The benefits of the registry data that were over and above those associated with ongoing clinical trials, and how these could address uncertainties in the evidence base.

    13.5. Whether there were any irrecoverable costs associated with establishing the registry.

    13.6. What would happen if belimumab were to be recommended with research but was later found to be not cost effective, and how the associated risk should be managed.

    13.7. Whether belimumab met the criteria for recommending a treatment with research according to ‘Guide to the methods of technology appraisal 2013’.

    13.8. Assessing if the potential value to the NHS of the recommended research was likely to represent good value in the context of limited research resources.

    13.9. The timing of a review of the technology appraisal guidance.

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

**Part 2 – Closed session**

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

18. The Committee continued to discuss the clinical and cost effectiveness Belimumab for the treatment of active autoantibody-positive systemic lupus erythematosus.

19. A vote was taken. The options were:

    Option 1: Recommend belimumab with research
    Option 2: Do not recommend belimumab with research

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

**Appraisal of Daclatasvir for treating chronic hepatitis C**

**Part 1 – Open session**

21. The Chair welcomed the invited experts: Matthew Cramp, Geoffrey Dusheiko, Richard Hall, Ranjababu Kulasegaram, Charles Millson, James Palmer, Malcolm Qualie and Terrence Wong to the meeting and they introduced themselves to the Committee.

22. The Chair welcomed company representatives from Bristol-Myers Squibb Pharmaceuticals to the meeting.

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

24. Dr Aomesh Bhatt, Dr Andrew Black, Professor David Bowen, Dr Matthew Bradley, Dr Ian Campbell, Dr Ian Davidson, Dr Alexander Dyker, Professor John Henderson, Professor Gary McVeigh (Chair), Mr Malcolm Oswald, Professor Oluwafemi Oyebode, Dr Mohit Sharma, Dr Lindsay Smith (Vice Chair) and Dr Murray Smith 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 Daclatasvir for treating chronic hepatitis C.

    24.1. Professor Simon Dixon declared a non-personal specific pecuniary interest as he is the Director of a Health Economics Unit that has undertaken work for the company of this technology, although he had not been directly involved nor was it for a particular drug or indication. The University of Sheffield received payment for this work.
    24.1.1 It was agreed that this declaration would not prevent Professor Dixon from participating in this section of the meeting.

    24.2. Dr Susan Griffin declared a personal specific non-pecuniary interest as she is a member of the Evidence Review Group for this appraisal.

24.3.1 It was agreed that Dr Griffin would not participate in this section of the meeting.

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

25.1. 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 Daclatasvir for treating chronic hepatitis C.

26. The Chair asked the Guidance Development Group and Public Health Guidelines representatives to declare any relevant interests.

26.1. 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 Daclatasvir for treating chronic hepatitis C.

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

27.1. Beth Woods, James Palmer, Malcolm Qualie, Matthew Cramp, Geoffrey Dusheiko, Ranjababu Kulasegaram, Charles Millson, Terrence Wong, Richard Hall, Raquel Peck, Helen Harris and Matthew Hickman 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 Daclatasvir for treating chronic hepatitis C.

27.2. Dr Susan Griffin declared a non-personal non-specific pecuniary interest as the Centre for Health Economics receives funding from the Department of Health through the Policy Research Programme. Dr Griffin was involved in a project commissioned through the Policy Research project on behalf of NHS England to look at the treatment of Hepatitis C in the UK. The University of York was paid for this work but Dr Griffin was not paid personally.
27.2.1 It was agreed that this declaration would not prevent Dr Griffin from participating in this section of the meeting.

28. 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.

29. The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of Daclatasvir for treating chronic hepatitis C on the basis of the evidence before them. The discussions included:

29.1. The ‘real-world’ evidence presented by the company.

29.2. The company’s additional cost-effectiveness analysis for people with genotype 3 HCV who are ineligible for, or cannot tolerate, interferon

29.3. The updated ERG results on the cost effectiveness of daclatasvir for genotype 3 HCV with significant fibrosis using the licensed treatment for this genotype

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

31. 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.

32. 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**

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

34. The Committee continued to discuss the clinical and cost effectiveness of Daclatasvir for treating chronic hepatitis C.

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

**Appraisal of Ledipasvir-sofosbuvir for treating chronic hepatitis C**

**Part 1 – Open session**

36. The Chair welcomed the invited experts: Matthew Cramp, Geoffrey Dusheiko, Richard Hall, Ranjababu Kulasegaram, Charles Millson, James Palmer, Malcolm Qualie and Terrence Wong to the meeting and they introduced themselves to the Committee.

37. The Chair welcomed company representatives from Gilead to the meeting.

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

39. Dr Aomesh Bhatt, Dr Andrew Black, Professor David Bowen, Dr Matthew Bradley, Dr Ian Campbell, Dr Ian Davidson, Dr Alexander Dyker, Professor John Henderson, Professor Gary McVeigh (Chair), Mr Malcolm Oswald, Professor Oluwafemi Oyebode, Dr Mohit Sharma, Dr Lindsay Smith (Vice Chair) and Dr Murray Smith 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 Ledipasvir-sofosbuvir for treating chronic hepatitis C.

    39.1. Professor Simon Dixon declared a non-personal specific pecuniary interest as he is the Director of a Health Economics Unit that has undertaken work for a non-listed comparator company, although he had not been directly involved nor was it for a particular drug or indication. The University of Sheffield received payment for this work.
    39.1.2 It was agreed that this declaration would not prevent Professor Dixon from participating in this section of the meeting.

    39.2. Dr Susan Griffin declared a non-personal non-specific pecuniary interest as the Centre for Health Economics receives funding from the Department of Health through the Policy Research Programme. Dr Griffin was involved in a project commissioned through the Policy Research project on behalf of NHS England to look at treatment of Hepatitis C in the UK. The University of York was paid for this work.

39.2.1. It was agreed that this declaration would not prevent Dr Griffin from participating in this section of the meeting.

39.3. Dr Susan Griffin also declared a personal specific non-pecuniary interest as she is a member of the Evidence Review Group for the appraisal of Daclatasvir for treating chronic hepatitis C.

39.3.1. It was agreed that this declaration would not prevent Dr Griffin from participating in this section of the meeting.

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

40.1. 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 Ledipasvir-sofosbuvir for treating chronic hepatitis C.

41. The Chair asked the Guidance Development Group and Public Health Guidelines representatives to declare any relevant interests.

41.1. 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 Ledipasvir-sofosbuvir for treating chronic hepatitis C.

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

42.1. 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 Ledipasvir-sofosbuvir for treating chronic hepatitis C.

43. 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.

44. The Committee then discussed the clinical effectiveness and cost effectiveness of ledipasvir-sofosbuvir for treating chronic hepatitis C on the basis of the evidence before them. They sought clarification and advice from the experts present. The discussions included:

44.1. The marketing authorisation.

44.2. A recap of the Committee's preliminary recommendations in the ACD.

44.3. The recommendations for ledipasvir-sofosbuvir in clinical guidelines.

44.4. The additional analyses provided by the company for previously treated people with HCV genotype 1 or 4 with cirrhosis.

44.5. Key issues including whether 12 weeks' ledipasvir-sofosbuvir could be recommended for previously treated people with HCV genotype 1 or 4 with

cirrhosis, and whether the Committee heard anything that would change the conclusion in the NICE position statement on the PPRS.

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

46. 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.

47. 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**

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

49. The Committee continued to discuss the clinical and cost effectiveness of Ledipasvir-sofosbuvir for treating chronic hepatitis C.

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

**Appraisal of Ombitasvir/paritaprevir/ritonavir with or without dasabuvir for treating chronic hepatitis C**

**Part 1 – Open session**

51. The Chair welcomed the invited experts: Matthew Cramp, Geoffrey Dusheiko, Richard Hall, Ranjababu Kulasegaram, Charles Millson, James Palmer, Malcolm Qualie and Terrence Wong to the meeting and they introduced themselves to the Committee.

52. The Chair welcomed company representatives from AbbVie to the meeting.

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

53.1. Dr Aomesh Bhatt, Dr Andrew Black, Professor David Bowen, Dr Matthew Bradley, Dr Ian Campbell, Dr Ian Davidson, Dr Alexander Dyker, Professor John Henderson, Professor Gary McVeigh (Chair), Mr Malcolm Oswald, Professor Oluwafemi Oyebode, Dr Mohit Sharma, Dr Lindsay Smith (Vice Chair) and Dr Murray Smith 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 Ombitasvir/paritaprevir/ritonavir with or without dasabuvir for treating chronic hepatitis C.

53.2. Professor Simon Dixon declared a non-personal specific pecuniary interest as he is the Director of a Health Economics Unit that has undertaken work for a comparator company, although he had not been directly involved nor was it for a particular drug or indication. The University of Sheffield received payment for this work.

54.2.1 It was agreed that this declaration would not prevent Professor Dixon from participating in this section of the meeting.

53.3. Dr Susan Griffin declared a non-personal non-specific pecuniary interest as the Centre for Health Economics receives funding from the Department of Health through the Policy Research Programme. Dr Griffin was involved in a project commissioned through the Policy Research project on behalf of NHS England to look at treatment of Hepatitis C in the UK. The University of York was paid for this work.

54.3.1 It was agreed that this declaration would not prevent Dr Griffin from participating in this section of the meeting.

53.4. Dr Susan Griffin also declared a personal specific non-pecuniary interest as she is a member of the Evidence Review Group for the appraisal of Daclatasvir for treating chronic hepatitis C.

54.4.1 It was agreed that this declaration would not prevent Dr Griffin from participating in this section of the meeting.

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

54.1. 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 Ombitasvir/paritaprevir/ritonavir with or without dasabuvir for treating chronic hepatitis C.

55. The Chair asked the Guidance Development Group and Public Health Guidelines representatives to declare any relevant interests.

55.1. 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 Ombitasvir/paritaprevir/ritonavir with or without dasabuvir for treating chronic hepatitis C.

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

56.1. 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 Ombitasvir/paritaprevir/ritonavir with or without dasabuvir for treating chronic hepatitis C.

57. 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.

58. The Committee proceeded to discuss the clinical effectiveness and cost effectiveness of Ombitasvir/paritaprevir/ritonavir with or without dasabuvir for treating chronic hepatitis C on the basis of the evidence before them. The discussions included:

58.1. A recap of the discussion at the previous Appraisal Committee meeting on 1st April 2015

58.2. The additional analyses provided by the company

58.3. ERG's critique of additional analyses

58.4. The Committee for Human Medicinal Product's (CHMP) clarification on licensed regimen for treating genotype 1a chronic hepatitis C with cirrhosis

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

60. 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.

61. 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**

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

63. The Committee continued to discuss the clinical and cost effectiveness of Ombitasvir/paritaprevir/ritonavir with or without dasabuvir for treating chronic hepatitis C.

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

**Discussion of the Hepatitis C topics: Daclatasvir, Ledipasvir-sofosbuvir and Ombitasvir/paritaprevir/ritonavir with or without dasabuvir, in the context of the NHS England comments received on the consultation for the preliminary recommendations for Ledipasvir-sofosbuvir.**

**Part 1 – Open session**

65. The Chair welcomed the invited experts: Matthew Cramp, Geoffrey Dusheiko, Richard Hall, Helen Harris, Matthew Hickman, Ranjababu Kulasegaram, Charles Millson, Raquel Peck and Terrence Wong to the meeting and they introduced themselves to the Committee.

The Chair also welcomed the experts from NHS England: Richard Jeavons, Malcolm Qualie and James Palmer to the meeting and they introduced themselves to the Committee.

66. The Chair welcomed company representatives from BMS, Gilead and AbbVie to the meeting.

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

67.1. Dr Aomesh Bhatt, Dr Andrew Black, Professor David Bowen, Dr Matthew Bradley, Dr Ian Campbell, Dr Ian Davidson, Dr Alexander Dyker, Professor John Henderson, Professor Gary McVeigh (Chair), Mr Malcolm Oswald, Professor Oluwafemi Oyebode, Dr Mohit Sharma, Dr Lindsay Smith (Vice Chair) and Dr Murray Smith 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 Hepatitis C appraisals.

67.2. Professor Simon Dixon declared a non-personal specific pecuniary interest as he is the Director of a Health Economics Unit that has undertaken work for a non-listed comparator company, although he had not been directly involved nor

was it for a particular drug or indication. The University of Sheffield received payment for this work.

68.2.1 It was agreed that this declaration would not prevent Professor Dixon from participating in this section of the meeting.

67.3. Dr Susan Griffin declared a non-personal non-specific pecuniary interest as the Centre for Health Economics receives funding from the Department of Health through the Policy Research Programme. Dr Griffin was involved in a project commissioned through the Policy Research project on behalf of NHS England to look at treatment of Hepatitis C in the UK. The University of York was paid for this work.

68.3.1 It was agreed that this declaration would not prevent Dr Griffin from participating in this section of the meeting.

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

68.1. 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 hepatitis C technologies to be considered.

69. The Chair asked the Guidance Development Group and Public Health Guidelines representatives to declare any relevant interests.

69.1. 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 hepatitis C technologies to be considered.

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

70.1. 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 hepatitis C technologies to be considered.

71. The Chair introduced the key themes arising from the NHS England consultation response to the Appraisal Consultation Document (ACD) for Ledipasvir-sofosbuvir.

72. The Committee proceeded to discuss the NHS England response to the NICE clarification questions and the associated consultation comments 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:

72.1 The implementation of 3 oral treatments for hepatitis C in the NHS (ledipasvir–sofosbuvir, daclatasvir and ombitasvir–paritaprevir–ritonavir).

72.2 NICE's general duties to have regard to the broad balance between benefits and costs of the provision of health services or of social care in England and the degree of need of persons for health services or social care in England.

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

74. 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.

75. 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**

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

77. The Committee continued to discuss the NHS England consultation responses and the associated consultation comments.

78. The Committee instructed the technical team to prepare the Appraisal Consultation Document (ACD) for the appraisals of Daclatasvir, Ledipasvir-sofosbuvir and Ombitasvir/paritaprevir/ritonavir with or without dasabuvir for treating chronic Hepatitis C in line with their decisions

**Date, time and venue of the next meeting**

79. Tuesday 7 July 2015, 10:00 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.