

## Technology Appraisal Committee Meeting (Committee D)

**Minutes:** Confirmed

**Date and Time:** Thursday 3 September 2015, 10:16-14:40

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

<b>Present:</b>	1. Professor Gary McVeigh, Chair	Present for all notes
	2. Dr Lindsay Smith, Vice Chair	Present for all notes
	3. Dr Ian Davidson	Present for all notes
	4. Professor Simon Dixon	Present for all notes
	5. Mrs Susan Dutton	Present for all notes
	6. Mrs Gillian Ells	Present for all notes
	7. Professor Paula Ghaneh	Present for all notes
	8. Professor Carol Haigh	Present for all notes
	9. Dr Tim Kinnaird	Present for all notes
	10. Dr Malcolm Oswald	Present for all notes
	11. Dr Mohit Sharma	Present for all notes
	12. Dr Murray Smith	Present for all notes

**In attendance:**

Carol Longson	Centre 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 17 to 29
Anwar Jilani	Technical Analyst, National Institute for Health and Clinical Excellence	Present for notes 01 to 16 and 30 to 40
Nwamaka Umeweni	Technical Adviser, National Institute for Health and Clinical Excellence	Present for all notes
Alexis Llewelyn	Research Fellow, Centre for Reviews and	Present for notes 01 to 14

	Dissemination and centre for Health Economics - York	
Paul Tappenden	Senior Research Fellow, School of Health and Related Research (SchARR)	Present for notes 17 to 26
Praveen Thokala	School of Health and Related Research (SchARR)	Present for notes 17 to 26
Beth Woods	Research Fellow, Centre for Reviews and Dissemination and centre for Health Economics - York	Present for notes 01 to 14

**Non-public observers:**

Toni Gasse	Project coordinator, NICE	Present for notes 01 to 16
Jasdeep Hayre	Technical Analyst, NICE	Present for all notes
Chloe Kastoryano	Public Involvement Programme, NICE	Present for all notes
Paula Parvulescu	Public Health Physician	Present for notes 01 to 16

**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 Daclatasvir for treating chronic hepatitis C, Ledipasvir-sofosbuvir for treating chronic hepatitis C and Ombitasvir/paritaprevir/ritonavir with or without dasabuvir for treating chronic hepatitis C.
2. The Chair informed the Committee of the non-public observers at this meeting: Toni Gasse, Jasdeep Hayre, Chloe Kastoryano and Paula Parvulescu.
3. Apologies were received from Dr Aomesh Bhatt, Dr Andrew Black, Dr David Bowen, Dr Matthew Bradley, Dr Ian Campbell, Ms Tracey Cole, Dr Alexander Dyker, Dr Susan Griffin, Professor John Henderson, Dr Warren Linley and Professor Oluwafemi Oyeboode.

**Any other Business**

4. None

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

## Part 1 – Open session

5. The Chair welcomed the invited experts: Beth Woods and Alexis Llewellyn to the meeting and they introduced themselves to the Committee.
6. The Chair welcomed company representatives from Bristol-Myers Squibb Pharmaceuticals to the meeting.
7. The Chair asked all Committee members to declare any relevant interests
  - 7.1. Professor Gary McVeigh, Dr Lindsay Smith, Dr Ian Davidson, Professor Simon Dixon, Mrs Susan Dutton, Mrs Gillian Ells, Professor Paula Ghaneh, Professor Carol Haigh, Dr Tim Kinnaird, Mr Malcolm Oswald, Dr Mohit Sharma 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.
  - 7.2. Professor Simon Dixon declared a non-personal specific pecuniary interest as his Health Economics Unit has undertaken work for BMS, although he was not directly involved. The University of Sheffield received payment for the work and he was not paid personally.
    - 9.2.1 It was agreed that this declaration would not prevent Professor Dixon 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 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.
9. The Chair asked all other invited guests (ERG), not including observers, to declare their relevant interests.
  - 9.1. 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.
10. 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.
11. 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:
  - 11.1. A recap of the Committee's preliminary recommendations
  - 11.2. The comments received from consultees and commentators on the ACD
  - 11.3. The additional evidence and revised economic analyses submitted by the company and the ERG's critique

- 11.4. Key issues including variation in the marketing authorisation, the nationally available price reduction and whether any of the responses to consultation changed the preliminary recommendations
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 and company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

## **Part 2 – Closed session**

15. The Committee continued to discuss the clinical and cost effectiveness of Daclatasvir for treating chronic hepatitis C.
16. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

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

### **Part 1 – Open session**

17. The Chair welcomed the invited experts: Paul Tappenden and Praveen Thokala to the meeting and they introduced themselves to the Committee.
18. The Chair welcomed company representatives from Gilead Sciences to the meeting.
19. The Chair asked all Committee members to declare any relevant interests
  - 19.1. Professor Gary McVeigh, Dr Lindsay Smith, Dr Ian Davidson, Professor Simon Dixon, Mrs Susan Dutton, Mrs Gillian Ells, Professor Paula Ghaneh, Professor Carol Haigh, Dr Tim Kinnaird, Mr Malcolm Oswald, Dr Mohit Sharma 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.
  - 19.2. Professor Simon Dixon declared a non-personal non-specific pecuniary interest as his Health Economics Unit has undertaken work for BMS, although he was not directly involved. The University of Sheffield received payment for the work and he was not paid personally.
    - 9.2.1 It was agreed that this declaration would not prevent Professor Dixon from participating in this section of the meeting.
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 Ledipasvir-sofosbuvir for treating chronic hepatitis C.

21. The Chair asked all other invited guests (ERG), 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 Ledipasvir-sofosbuvir for treating chronic hepatitis C.
  - 21.2. Paul Tappenden declared a non-personal, non-specific, pecuniary interest as his organisation has undertaken work for BMS on an unrelated technology. He did not receive personal payment for this work.
    - 21.2.1. It was agreed that this declaration would not prevent Paul Tappenden from participating in this section of the meeting.
  - 21.3. Praveen Thokala declared a non-personal, non-specific, pecuniary interest as his organisation has undertaken work for BMS on an unrelated technology. He did not receive personal payment for this work.
    - 21.3.1. It was agreed that this declaration would not prevent Praveen Thokala from participating in this section of the meeting.
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 proceeded to discuss the clinical effectiveness and cost effectiveness of Ledipasvir-sofosbuvir for treating chronic hepatitis C on the basis of the evidence before them. The discussions included:
  - 23.1.1. A recap of the Committee's preliminary recommendations in the second ACD.
  - 23.1.2. The comments received from consultee and commentators on the second ACD.
  - 23.1.3. Key issues including whether any of the responses to consultation changed the preliminary recommendations and whether the wording of section 1.2 should be revised.
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 and company representatives 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 continued to discuss the clinical and cost effectiveness of Ledipasvir-sofosbuvir for treating chronic hepatitis C.
29. The Committee instructed the technical team to prepare the Final Appraisal Determination (FAD) in line with their decisions.

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

#### **Part 1 – Open session**

30. The Vice Chair welcomed company representatives from AbbVie to the meeting.
31. The Vice Chair asked all Committee members to declare any relevant interests
  - 31.1. Professor Gary McVeigh, Dr Lindsay Smith, Dr Ian Davidson, Professor Simon Dixon, Mrs Susan Dutton, Mrs Gillian Ells, Professor Paula Ghaneh, Professor Carol Haigh, Dr Tim Kinnaird, Mr Malcolm Oswald, Dr Mohit Sharma 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.
  - 31.2. Professor Simon Dixon declared a non-personal non-specific pecuniary interest as his Health Economics Unit has undertaken work for BMS, although he had not been directly involved. The University of Sheffield received payment for the work and he was not paid personally.
    - 9.2.1 It was agreed that this declaration would not prevent Professor Dixon from participating in this section of the meeting.
32. The Vice Chair asked all NICE Staff to declare any relevant interests.
  - 32.1. 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.
33. The Vice 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.
34. 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:
  - 34.1. A recap of the Committee's preliminary recommendations
  - 34.2. The comments received from consultee and commentators on the ACD
  - 34.3. The revised economic analyses submitted by the company and the ERG's critique
  - 34.4. Key issues including the nationally available price reduction and whether any of the responses to consultation changed the preliminary recommendations

35. The Vice Chair asked the company representatives whether they wished to comment on any matters of factual accuracy.
36. The Vice 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.
37. The Vice Chair then thanked the company representatives for their attendance, participation and contribution to the appraisal and they left the meeting.

## **Part 2 – Closed session**

38. Discussion on confidential information continued. This information was supplied by the company.
39. The Committee continued to discuss the clinical and cost effectiveness of Ombitasvir/paritaprevir/ritonavir with or without dasabuvir for treating chronic hepatitis C.
40. 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**

41. Tuesday 6 October 2015 at National Institute for Health and Care Excellence, Level 1A, City Tower, Piccadilly Plaza, Manchester M1 4BT.