**National Institute for Health and Care Excellence**

Senior Management Team

# Minutes of the meeting held on 16 April 2019

**Present**

Andrew Dillon Chief Executive

Ben Bennett Director – Business Planning and Resources

Meindert Boysen Director – Centre for Health Technology Evaluation

Paul Chrisp Director – Centre for Guidelines

Jane Gizbert Director – Communications

Gill Leng Director – Health and Social Care

Alexia Tonnel Director – Evidence Resources

**In attendance**

David Coombs Associate Director – Corporate Office (minutes)

Nick Crabb Programme Director – Science Advice and Research

Helen Knight Programme Director – Centre for Health Technology Evaluation (item 7.3)

Mirella Marlow Programme Director – Centre for Health Technology Evaluation (item 7.2)

Eric Power Programme Director – Health and Social Care (item 7.1)

Shaun Rowark Senior Analyst – Health and Social Care (item 7.1)

Jenniffer Prescott Associate Director – Planning and Operations, Centre for Health Technology Evaluation (item 7.3)

## Apologies (item 1)

1. None.

## Freedom of Information and publication scheme (item 2)

1. The final minutes will be made available on the NICE website subject to the redaction of any exempt material.

## Declarations of interest (item 3)

1. The previously declared interests were noted. There were no conflicts of interest relevant to the meeting.

## Notes of the previous meeting (item 4)

1. The minutes of the meeting held on 9 April 2019 were approved.

## Matters arising (item 5)

1. The actions from the meeting held on 9 April 2019 were noted as complete or in hand.
2. Andrew Dillon stated that he and David Haslam have drafted a foreword for the 2018/19 annual report, which he would circulate to SMT for comment.

ACTION: AD

## April Board Strategy meeting (item 6)

1. The agenda, papers and arrangements for the Board Strategy meeting on 17 April were noted.
2. It was agreed that the EU exit risk register should remain a standing item on the Board’s agenda.

## NICE impact: stroke (item 7.1)

1. Eric Power and Shaun Rowark presented the latest impact report, which is focused on stroke. In response to the Board’s feedback, this report includes information on variation across England.
2. SMT reviewed the report and welcomed the information on variation and the local examples of how NICE’s guidance has been used to improve services. SMT discussed the information in the report on the increased use of direct oral anticoagulants (DOACs) and agreed the text was appropriately balanced and reflected NICE’s guidance. Paul Chrisp noted the upcoming work to update the guideline on rehabilitation and suggested this is referenced in the report. Subject to this and other minor amendments, the report was agreed for submission to the May Board meeting.

ACTION: EP/SR

## Digital health technologies evaluation pilot (item 7.2)

1. Mirella Marlow presented the proposal to establish a pilot to evaluate four digital health technologies (DHTs) in 2019/20, using a project team embedded within the Medical Technologies Evaluation Programme (MTEP), and committee input from the Medical Technologies Advisory Committee (MTAC).
2. Mirella explained that the evaluation pilot process will be based on the process for developing medical technologies guidance, but with a significant amendment tailored to the need for data collection to be carried out flexibly and nimbly on these products. Topics will first go through a pre-evaluation assurance process, and as part of the streamlined process, a product will not be taken to the committee if the evidence is insufficient. Instead, the product would be subject to time limited data collection, funded by the company but with advice on data collection design from the External Assessment Centre (EAC).
3. SMT discussed the criteria for selecting topics, in particular that the technologies must be cost saving. It was agreed that it could be challenging to provide evidence of cost saving in the required time frame and it would instead be appropriate to require the technology to enable a more effective use of resources.
4. SMT discussed the approach of utilising the MTAC for the pilot. Mirella Marlow highlighted that the proposal reflects that an increasing number of technologies considered by the MTAC comprise a digital element, and DHTs will increasingly be part of NICE’s core business. SMT agreed with the proposal to utilise the MTAC for the pilot but asked that the requirement for any additional expertise amongst the committee on digital health technologies is considered. It was agreed that in the long-term, it would be important to consider whether to also route DHTs to the technology appraisal committees or Diagnostic Advisory Committee depending on the value proposition, in line with the CHTE 2020 vision.

ACTION: MM

1. SMT discussed the role of the EACs in providing advice on data collection. Mirella Marlow confirmed that NHS England have agreed to fund the EAC’s work during the pilot. Gill Leng stated that in the longer-term, it would be preferable to utilise the internal capacity of NICE’s own data analytics team. SMT asked for clarification over NICE’s liability for the EACs’ advice to companies on data collection.

ACTION: MM

1. SMT discussed the proposed guidance output and welcomed the proposal to use similar wording to the medical technologies guidance (MTG), which refers to the extent the case for adoption has been made. It was noted that the technical team will undertake a pre-publication check of any linkages to existing NICE guidance, and the pilot will provide the opportunity to review the level of work this entails. For products with insufficient evidence, it was agreed that it would be helpful to publish a briefing to explain the next steps in terms of the time limited data collection. SMT noted the rapidly evolving nature of DHTs and agreed on the need to clarify the arrangements for updating any published guidance.

ACTION: MM

1. Subject to the above points, SMT approved the pilot. It was agreed that in addition to the individual pieces of guidance, it would be helpful to produce a report that sets out the outcome of the pilot and any issues that need to be considered in any longer-term programme to evaluate DHTs, including any questions to address through formal research.

ACTION: MM

## Routing decision for sapropterin (item 7.3)

1. Meindert Boysen presented the outcome of the reconsideration of the most appropriate NICE programme to appraise sapropterin for treating phenylketonuria (PKU). Meindert reminded SMT of the background to this matter, and the potential judicial review.
2. Meindert stated that that the topic selection decision-making group met on 15 February 2019 and reconsider the drug. Having reviewed this afresh, the group agreed the topic should continue to be routed to the technology appraisal (TA) programme, as three of the criteria for routing a topic to the highly specialised technologies (HST) programme were not met.
3. Meindert highlighted that the Department for Health and Social Care (DHSC) has advised that the decision on which programme to appraise a drug through is a matter for NICE not the Secretary of State, noting that the topic selection decision making group has the relevant expertise. Legal advice provided to NICE supports this view, and therefore it is necessary to confirm the arrangements within NICE for making such decision.
4. SMT discussed the governance of the topic selection process in light of the feedback from DHSC and the legal advice. It was agreed that the decision making group should continue in its current form. Where the group requests its advice, or where a decision of the group is challenged, the SMT would then consider whether the group had properly discharged its responsibilities, in line with its remit. In so doing, SMT would undertake analogous role to the Guidance Executive in relation to the outputs from the independent advisory committees.
5. On this basis, SMT reviewed the outcome of the topic selection group on 15 February and supported the decision to route sapropterin for treating phenylketonuria to the TA committee.

## Cyber security draft audit report (item 7.4)

1. Ben Bennett presented the draft internal audit report and the proposed management response.
2. SMT welcomed the report and the substantial assurance audit opinion. The report and management response were agreed for submission to the Audit and Risk Committee.

## EU exit (item 8)

1. Andrew Dillon stated that he has asked the DHSC about the purdah rules should the UK participate in the EU elections and was advised these are likely to be similar to those for the upcoming local elections. It was agreed that the Cabinet Office pre-election guidance for the local elections should be added to next week’s SMT agenda.

ACTION: DC

1. Meindert Boysen stated that in light of guidance from the DHSC, he has stood down the internal weekly EU exit planning meetings, and will likely restart these in September in line with the national operational response planning. In the meantime, he will continue to work through the implications for the TA programme of any changes to the medicines regulatory process in both a ‘no deal’ and ‘with deal’ EU exit.

## NICE Connect project (item 9)

1. Gill Leng stated that the list of issues to cover in the report to the September Board meeting is being prepared, for consideration by the NICE Connect steering group. Andrew Dillon proposed that the public Board meeting in September receives an update on the outcome of the pilot, with the October Board Strategy away-day considering the next steps in further detail.

## Weekly staff SMT updates (item 10)

1. SMT agreed the staff updates.

ACTION: DC

## Any other business (item 11)

1. Alexia Tonnel highlighted interest from Quebec University in translating the recently published evidence standards framework for digital technologies, and proposed the standard arrangements for utilising NICE’s intellectual property should apply. SMT welcomed the interest and supported this approach.
2. Andrew Dillon highlighted interest from the World Health Organisation’s (WHO) essential medicines committee in utilising NICE’s guidance on antimicrobial prescribing. He has asked the WHO to provide further information, so NICE can consider its response.
3. Andrew Dillon stated that the advert for the new chair is due to publish later today. The current timetable culminates with the proposed appointee attending a pre-appointment hearing with the Health Select Committee in July.