**NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

Public Board Meeting
held on 13 December 2023 at 2 Redman Place, Stratford and via Zoom

These notes are a summary record of the main points discussed at the meeting and the decisions made. They are not intended to provide a verbatim record of the Board’s discussion. The agenda and the full documents considered are available in accordance with the NICE Publication Scheme.

## Board members present

Sharmila Nebhrajani Chairman

Mark Chakravarty Non-Executive Director

Jackie Fielding Non-Executive Director

Gary Ford Non-Executive Director

Alina Lourie Non-Executive Director

Bee Wee Non-Executive Director

Justin Whatling Non-Executive Director

Sam Roberts Chief Executive

Jonathan Benger Chief Medical Officer and Interim Director of the Centre for Guidelines

Helen Knight Director of Medicines Evaluation

Boryana Stambolova Interim Director, Finance

## Directors in **attendance**

Helen Brown Chief People Officer

Nick Crabb Interim Science, Evidence and Analytics Director

Clare Morgan Director of Implementation and Partnerships

Raghu Vydyanath Chief Information Officer

## In attendance

David Coombs Associate Director, Corporate Office (minutes)

Paul Chrisp Head of Products and Publishing

Naomi Lee Head of Organisational Transformation

Jeanette Kusel Director, NICE Advice

Danielle Mason Associate Director, Strategic Communications and Marketing

Chris Connell Associate Director, Field Team

Jacoline Bouvy Programme Director, Medicines Evaluation (item 7)

Sara Buckner Technical Adviser, Centre for Guidelines (item 7)

Lorna Dunning Senior Technical Adviser (item 7)

Rupert Franklin Senior Guidelines Commissioning Manager (item 7)

Bhash Naidoo Senior Health Economics Adviser (item 7)

Koonal Shah Associate Director, Science Policy and Research (item 7)

James Koh Scientific Adviser (item 8)

Helen Lovell Deputy Director, Medicine Regulation and Prescribing, Department of Health and Social Care

## Apologies for absence (item 1)

1. Apologies were received from Mark Chapman and Jane Gizbert who were represented by Jeanette Kusel and Danielle Mason respectively, and from Michael Borowitz.

## Declarations of interest (item 2)

1. The following new interests were noted:
	* Bee Wee: Appointment as a review board member for the National Medical Research Council of Singapore.
	* Justin Whatling: Appointment to techUK’s Health and Social Care Council, and appointment as a trustee of the Faculty of Clinical Informatics (FCI) and interim chair of the FCI’s Finance Audit and Risk Sub Committee.
	* Gary Ford: Attendance at a roundtable dinner hosted by Carnall Farrar, and hotel and accommodation provided for a meeting arranged by Novartis and NHS England on lipid management.
2. In addition, Justin Whatling noted that he is no longer a Visting Professor at University College London.
3. These changes, and the previously declared interests recorded in the register of interests were noted and it was confirmed there were no conflicts of interest relevant to the meeting.

## Minutes of the last meeting (item 3)

1. The minutes of the Board meeting held on 21 September 2023 were agreed as a correct record.

## Action log (item 4)

1. The Board noted the progress with the actions arising from the public Board meeting on 21 September 2023 and those open from preceding meetings as set out in the action log. The actions marked closed on the log were confirmed as complete.
2. Sharmila Nebhrajani reminded colleagues that Bee Wee has taken on the role of lead NED for workforce engagement and invited Bee to comment on her plans for the role. Bee noted that the role arose from a crowdsourcing suggestion and reflects the provisions in the corporate governance code. The role will seek to listen to and convey the voice of the workforce to the Board, and help the workforce understand the Board’s work. Bee highlighted the need for the role to support, and not cut across, existing mechanisms for staff communication and engagement.

## Update from the Department of Health and Social Care (item 5)

1. Helen Lovell provided an update from the Department of Health and Social Care (DHSC) and noted the appointment of a new Secretary of State and wider changes in the ministerial team. Helen highlighted Liz Woodeson’s imminent retirement from her role as the DHSC’s Director of Medicines and NICE’s senior departmental sponsor, with Liz’s replacement, Gila Sacks, now in post. Helen highlighted the recent publication of the heads of agreement for a new voluntary scheme for branded medicines pricing, access and growth (VPAG) following negotiations between the DHSC, Association of the British Pharmaceutical Industry (ABPI) and NHS England. The scheme’s objectives are to promote better patient outcomes and a healthier population; support UK economic growth; and contribute to a financially sustainable NHS, and it will run for 5 years from 1 January 2024. Helen noted NICE’s central role in supporting these objectives and highlighted that the scheme introduces a new investment facility to boost investment into technology assessment methods and processes used in the UK’s health technology assessment agencies. This will provide funding for NICE to invest in a new UK PharmaScan platform and the development of its methods and processes. The heads of agreement also renew the commitment to maintain NICE’s basic cost-effectiveness range.
2. Sharmila Nebhrajani thanked Helen for the update and on behalf of the Board, thanked Liz Woodeson for her support to NICE and wished her well in her retirement.

## Update on development, alignment and implementation of changes to NICE methods and processes (item 7)

1. Nick Crabb presented the paper that provided an update on how NICE is updating its methods and processes for guidance development, as part of transforming to become more relevant, timely, useable and impactful. The proposed interim methods and process statement for incorporating and integrating NICE technology appraisals (TAs) into guideline topic areas were presented for the Board’s approval to submit to public consultation, and the paper also provided an update on the pathways approach undertaken as part of the proportionate approach to technology appraisal (PATT), and the implementation of the 2022 manual for health technology evaluations.
2. Board members welcomed the work on integration and incorporation of TAs into guidelines and noted that combining existing multiple outputs into a single product would be highly beneficial for NICE users. It was queried whether the process would also be used to identify when a TA was no longer relevant and should be withdrawn, and whether it will consider the impact of generics coming to market. In response, it was confirmed that the integration process could consider whether a TA is no longer relevant and should be withdrawn, however such an outcome is expected to be rare. If a branded medicine subject to an optimised recommendation becomes available as a generic then it could be possible to look at whether the TA should be revisited to recommend wider access. The scenario whereby the comparator to a branded medicine becomes available as a generic, which could affect the existing positive TA recommendation for the branded medicine, requires further consideration. This is part of a wider piece of work looking at the impact of a number of medicines that are likely to be available as generics, and how NICE can best provide advice on these to the NHS.
3. Board members noted the proposed appeal process which would apply if integration leads to the complete withdrawal of a positive technology appraisal recommendation. It was noted that the appeals process is not currently proposed to apply to the sequencing of technologies, as the funding direction would still apply if the technology remains recommended for use at some point in the pathway. However, it is anticipated that this will be explored further in the consultation. Board members highlighted the importance of capturing feedback from a broad range of stakeholders on the proposals. In response, it was confirmed that this will be a full public consultation in which NICE will be keen to hear from a broad range of stakeholders.
4. Board members asked about the key learning from the committees’ first year of using the 2022 manual for health technology evaluations. Sam Roberts summarised the key findings and noted that the severity modifier has been applied in multiple topics, both cancer and non-cancer, with weightings of both 1.7 and 1.2 applied. However, wider use of the 1.2 severity weighting had been anticipated and this will be the subject of a review in 2024/25. The use of real-world evidence is progressing well, with committees accepting it as primary or supportive evidence in several topics. There is also evidence of a trend towards increasing use of real-world evidence in company submissions and acceptance by committees. The additional flexibilities available to the committees in the manual have also been used in multiple topics where there were significant challenges to evidence generation; where the technology addressed health inequalities; where there was high unmet need; or where the committee considered that there were significant benefits beyond those reflected in the health economic model.
5. In response to a question about the plan for future modular updates, it was noted that the next priorities may include the severity modifier (depending on the outcome of next year’s review), and health inequalities.
6. The Board:
	* Approved the Interim methods and process statement for incorporating and integrating NICE technology appraisals into guideline topic areas to proceed to public consultation and delegated authority to the NICE Guidance Executive to approve the final version following this consultation.
	* Noted the update on the other work on NICE’s methods and processes and supported the progress to date.

## Routine arrangements for antimicrobials following a public consultation (item 8)

1. Nick Crabb and James Koh presented the report that provided an update on NICE’s work with NHS England to establish routine arrangements for the evaluation of antimicrobials. It was noted that the feedback from the consultation on the proposals was positive, and the subscription model has been celebrated by stakeholders in the UK and internationally as the first pull incentive for antimicrobials that will be implemented anywhere in the world. In terms of next steps, NICE and NHS England will publish a thematic analysis of the consultation feedback in early 2024. NICE has appointed the chair of the new Antimicrobial Evaluation Panel, and the rest of the panel will be recruited over coming months. The new scheme will launch around spring 2024, when NHS England issues the first ‘invitation-to-tender’.
2. Helen Knight noted that the medicines evaluation team will be responsible for this work once it is launched and confirmed that the handover from colleagues in the science, evidence and analytics team is underway.
3. The Board noted the update and congratulated the staff involved. The pioneering nature of this work was highlighted, which it was noted could have significant global benefit if replicated and adopted more widely.

## Executive team update and integrated performance report (item 6)

1. Sam Roberts introduced the update from the executive team and the integrated performance report, and highlighted the achievements over the last year in improving the timeliness, relevance and usability of NICE’s guidance. These included reducing the time taken to publish technology appraisal (TA) recommendations; publishing guidance on topics that significantly benefit patients and can help reduce pressures on the NHS; and supporting the system to tackle health inequalities. Sam also highlighted the actions taken forward as part of NICE’s internal transformation following the crowdsourcing process and thanked staff for their ongoing commitment and expertise. Similarly, Sam thanked the committees, non-executive directors, and executive team for their contribution in 2023.
2. Jonathan Benger summarised progress with the business plan objectives that seek to ensure NICE is focusing on what matters most. Work on the new prioritisation framework continues, informed by the recent NICE Listens deliberative exercise, and the framework will be subject to consultation in early 2024. A single topic prioritisation team will be established in the clinical directorate to operationalise the integrated prioritisation board from April 2024, however, the integration of the topic selection oversight panel for health technology evaluations into the prioritisation board may take more time. Jonathan also highlighted the successful launch of the NICE Advice service to simplify and improve NICE’s early engagement with industry.
3. Board members queried why the guidelines programme has exceeded its 2023/24 year end target for new or updated guidelines. Jonathan Benger explained that the volume of outputs will in part depend on the mix of activity, and the implementation of the new prioritisation board should help provide better insight into future workload and output. Jonathan flagged that the upcoming reorganisation of the Centre for Guidelines, and the work on integrating and incorporating TAs into guidelines, will likely reduce the volume of outputs in 2024/25 and 2025/26.
4. Helen Knight summarised progress with the business plan objectives that seek to ensure NICE is providing useful and usable advice, and noted the earlier discussion about the incorporation of TAs into guidelines which is a key part of this ambition. In addition, the work known as late-stage assessments, in which NICE will provide advice on classes of HealthTech products already in use, will add significant value to the NHS. Helen noted that NICE is on track to deliver the volumes of TA and HealthTech guidance set out in the business plan, and there has been significant progress in improving the timelines in both programmes. In relation to TAs, the days between marketing authorisation and final guidance production for ‘optimal’ topics has reduced from 2022/23 and is below target, with more topics already considered through this route in 2023/24 than the whole of last year. A new timeline for HeathTech guidance is being piloted that will significantly reduce the time taken for these assessments. Helen acknowledged that the ambitious target to produce conditional recommendations for early value assessments within 6 months is unlikely to be met for the year, but there has been much progress and this will now transition from a pilot phase to business as usual.
5. Board members welcomed the progress with reducing the time taken to produce TA guidance for topics following the ‘optimal’ route, but noted that the majority of topics are ‘divergent’ and therefore it is important to understand the timeliness of these topics, given the data is affected by a small number of outliers. In response, it was noted that there is focused effort to complete the small number of topics that have been in progress for an extended period. It was agreed to provide timeliness data for the divergent topics excluding the outliers that have skewed the overall performance.

Action: Helen Knight

1. Paul Chrisp provided an update on the work to make NICE’s advice easier to access and stated that users should soon see improvements to the corporate website. In addition, there has been much activity on a product and channel strategy, including to identify and validate user needs. A key next step is to publish a prior information notice (PIN) in January to engage the market on how NICE can standardise, digitise and future-proof its guidance publication process.
2. Board members welcomed the proposed approach of issuing a PIN to work with suppliers to identify potential solutions to NICE’s needs, given the fast-moving nature of this technology. In the meantime, it was queried whether any action can be taken to improve the accessibility of NICE’s content. Paul Chrisp noted that the search facility on the website will be improved, and editorial changes can deliver some improvements through clearer recommendations and standardised language. Other changes, such as improved codability, and linkage of evidence to recommendations, are reliant on new technology.
3. Clare Morgan summarised progress with the business plan objective that seeks to ensure NICE is constantly learning from data and implementation. Data has now been analysed for 12 of the 14 quality standards and 7 groups of medicines, and the team are looking at what can be learnt from this. Clare noted the extensive work to adopt a prioritised approach to stakeholder engagement and stated that the target for 80% of prioritised stakeholders to have a named relationship lead is forecast to be met. Following a question from the Board, Clare confirmed that the learning from the work on using data to monitor the implementation of quality standards and prioritised medicines will be shared with the Board in March 2024.
4. Helen Brown summarised progress with the business plan objective that seeks to build a brilliant organisation, and noted the numerous achievements so far this year, including the talent management and succession planning initiatives; roll-out of well-being training for managers; and leadership and management development. In relation to the people KPIs, Helen noted the slight increase in sickness absence in October which will be kept under close review. Turnover is above target, but lower than last year. The targets on appraisal completion and the proportion of ethnic minority staff are forecast to be met by the end of the year.
5. Dani Mason summarised the performance against the communications and engagement indicators and highlighted the steady increase in engagement with NICE’s newsletters and website. The proportion of media coverage that is positive remains above target for the year to date, but the proportion of NICE generated news coverage that included at least one key message is below target.
6. Boryana Stambolova provided an update on the financial position and stated that the forecast outturn is now a £0.7m surplus compared to a £0.5m deficit that was reported to the September Board meeting. This reflects the impact of the mitigations discussed at the last Board meeting including review of vacancies and reallocation of the strategic reserve. Boryana stated that the forecast underspend creates an opportunity to invest in prioritised projects to conclude by the end of March 2024, including investment in the Digital, Information and Technology (DIT) directorate. In addition, DHSC have requested the return of any surplus funds to offset the pressures elsewhere in the system.
7. The improved financial position was welcomed and there was support for using the headroom to help mitigate the technical debt in the DIT directorate. Board members asked whether the movement in the financial position indicates forecasting could be improved. Boryana Stambolova noted that the size of the movement is relatively minor in the context of NICE’s overall budget, and explained that the requirement to avoid any year-end overspend does lead to a degree of conservatism. In addition, there is now greater clarity on the restructuring costs since the last meeting. Boryana Stambolova and Sam Roberts both noted the steps taken to improve forecasting around the TA income, with better visibility of changes in workload that drive income. There is also a more nuanced approach to forecasting elsewhere across NICE, with a range of scenarios now provided. Board members welcomed these actions but highlighted the need for ongoing focus on this issue to ensure a robust approach to forecasting.
8. NICE’s work on health inequalities was welcomed and a question was raised about how this compares internationally. Jonathan Benger stated that he would investigate any international comparison and report back to the Board.

Action: Jonathan Benger

1. Board members welcomed the wide range of achievements in the report and highlighted the importance of promoting these internally and externally, with a focus on the tangible impact for users of NICE’s guidance. While it was welcomed that many of the targets were rated ‘green’ there was encouragement to ensure a suitable level of ambition when setting targets for 2024/25, and also ensure the targets focus on outcomes. It was noted that the format for the performance report will be reviewed for 2024/25 to reduce the volume of text, focus on tangible achievements, and bring together the various work of each director to aid presentation at the Board meetings.
2. Subject to the above comments and actions, the Board noted the report.

## Audit and Risk Committee (item 9)

1. Alina Lourie presented the confirmed minutes of the Audit and Risk Committee meeting held on 18 September 2023 and the unconfirmed minutes of the meeting on 9 November 2023. Alina highlighted the committee’s work on the risk register, both in terms of the format to better distinguish between the controls and assurance, and to refine the risks themselves. The committee have also taken a close interest in the strengthening of internal controls which will be subject of an internal audit. Alina noted that the committee also received a briefing from the National Audit Office on cyber security, which will inform the committee’s review of this topic at its next meeting. Sharmila Nebhrajani asked the committee to consider NICE’s compliance with the cyber security essentials and cyber security essential plus standards as part of this.

Action: Raghu Vydyanath

1. Sharmila Nebhrajani thanked the committee for its work, in particular around internal controls, and noted that the 2022/23 annual accounts are almost finalised. The external auditors anticipate issuing a clean audit opinion, and it is hoped the annual report and accounts will be laid before parliament either before or shortly after Christmas recess.
2. Subject to the above action, the Board received the minutes.

## Risk management policy (item 10)

1. Boryana Stambolova presented the updated risk management policy for the Board’s approval and highlighted the key changes, notably to the risk appetite, in response to the recommendations in the recent board effectiveness review.
2. The Board approved the policy. It was noted that the next step will be to map the risk appetite to the 5x5 risk scoring matrix and use this to inform the target risk ratings in the strategic risk register.

## Standing orders and standing financial instructions (item 11)

1. Boryana Stambolova presented the outcome of the annual review of the standing orders and standing financial instructions, and highlighted the key changes, notably to clarify the circumstances when external approvals are required.
2. Sharmila Nebhrajani queried whether the level at which Board approval for expenditure outside of the approved budget was appropriate and suggested this is lowered. While the threshold has not been amended in the latest iteration, it was agreed to consider further the suitable level of delegation.
3. The Board approved the amended standing orders and standing financial instructions subject to reviewing the threshold for when Board approval is required for expenditure outside of the approved budget. It was agreed that confirmation of this threshold would be delegated to the Chairman, Audit and Risk Committee chair and Chief Executive.

Action: Boryana Stambolova

## Any other business (item 12)

1. There was no further business to discuss, and Sharmila Nebhrajani concluded the meeting by thanking staff, the Board, and committee members for their contribution to NICE in 2023.

## Next meeting

1. The next public meeting of the Board will be held on 20 March 2024 at 1:30pm.