NICE-wide topic prioritisation and the strategic principles for public health, social care and rare diseases: response to stakeholder consultation feedback

1 Introduction

To support NICE's strategic objective to focus on what matters most we are implementing an organisation-wide approach to prioritisation and topic selection. This will be overseen by a single prioritisation board that will guide the selection and coordination of our guidance development.

The process for how new guidance topics and updates to existing NICE guidance are identified, prioritised and routed at NICE, and the decision-making framework that will be used by the NICE prioritisation board, is set out in the new NICE-wide topic prioritisation manual. This manual will replace the NICE health technology evaluation topic selection: the manual (PMG37).

To complement and assist the prioritisation of topics related to public health, social care and rare diseases, the prioritisation board will also utilise NICE's strategic principles for the prioritisation of public health, social care and rare diseases. These principles will guide the application of the prioritisation framework to ensure that decisions made balance the needs of the system and give clearer direction as to NICEs' role in those areas.

This paper provides an overview of the public consultation on the approach to prioritisation and the prioritisation principles for Public Health, Social Care and rare diseases. It summarises, by theme, the comments received during the consultation, along with the planned response to those comments, including any planned changes to the proposals. The themes and responses contained in this paper will be published on the NICE website alongside the final topic prioritisation manual and strategic principles.

2 Engagement and consultation overview

A public consultation on the proposed approach to topic prioritisation and the strategic principles for public health, social care and rare diseases was held between 5th March and 4 April 2024.

A series of internal and external stakeholder events and meetings were held ahead of the consultation, to inform the development of the approach and the associated consultation document. The external stakeholders engaged in pre-consultation activities included: representatives from the voluntary and community sector; patient advocacy groups; professional membership organisations; topic-specific advisory groups, boards and forums; local, regional and national government bodies; public health, health and social care partners; academia; other arms-length bodies.

The consultation comprised two elements:

- NICE's integrated topic prioritisation manual (prioritisation approach), and
- NICE's strategic principles for the prioritisation of public health, social care and rare diseases (strategic principles).

Respondents were given the opportunity to provide detailed comments on all sections of the consultation document and the supporting documentation. 55 respondents provided comments, 51 of which were provided on behalf of an organisation (see table 1).

Table 1 Consultation responses by organisation type

Respondent	Number of organisations (or individuals)	Percentage (of 769 comments)
Industry	25	54% (413)
Voluntary and community sector organisations	14	17% (130)
NHSE & DHSE	2	15% (112)
Royal colleges, academic & professional societies	6	9% (69)
Individuals (external to NICE)	4	3% (26)
Arms-length bodies, NHS trusts, ICB/ICS & NHS Wales	4	2% (17)

Overall, the proposed new approach to the prioritisation of topics and the strategic principles was welcomed by respondents, with comments primarily focused on seeking further detail. Key themes that emerged from the consultation were:

- Details on specifics of the strategic principles
- Application of the prioritisation framework
- Relationship between the framework and the strategic principles
- Identifying system priorities
- Interpretation of proposals in relation to the voluntary scheme for branded medicines pricing, access and growth (VPAG)
- Highly Specialised Technologies (HST) criteria and routing
- Communicating prioritisation board decisions
- Clarification process and timings
- Prioritisation board governance
- Terminology
- Key methods work for NICE

It should be noted that there were concurrent NICE consultations during the period of this consultation, the outcomes of which (where relevant) will be considered in the final approach to NICE-wide topic prioritisation. The other consultations were:

- [Methods and processes for including NICE technology appraisal recommendations in guidelines](#),
- [Interim methods and processes for Late Stage Assessment (LSA) in HealthTech](#), and
- [Working alongside people and communities at NICE: a strategy](#)

Furthermore, NHS England and NICE have been commissioned to develop an integrated, rules-based approach to the assessment and commissioning of new medical technologies including devices, diagnostics and digital. NICE and NHS England will shortly launch a joint consultation on proposals to develop this new pathway.

To deliver this new medical technologies pathway a tripartite joint prioritisation process involving NICE, DHSC and NHS England will select technologies for the pathway against a set of agreed criteria. This will include an assessment of budget impact, overall affordability as well selecting a limited number of technologies per annum. Further work will confirm how this will operate in practice, but all parties are clear that the process will be aligned with and integrated into the prioritisation process, as set out in the NICE-wide topic prioritisation and strategic principles consultation.

3 Findings from the topic prioritisation and strategic principles consultation, implications for proposals and next steps

3.1 Details on specifics of the strategic principles

3.1.1 Summary of comments received for public health

The majority of comments from respondents on the public health principles were related to the definition of Public Health. Comments were focused on the lack of breadth in the definition, specifically:

- That public health also includes ageing well, mental health and wellbeing, and preventing deterioration (through healthcare public health interventions), and early intervention.

- A lack of focus on population health
- Lack of a mention of inequalities (in the definition of public health and within the principles themselves).

The majority of comments on the public health principles themselves, requested increased specificity or clarity of wording.

3.1.2   Our response and any changes to proposals for public health

We are in the process of reviewing and updating the definition of public health used by NICE and published in our glossary definition; the feedback on the definition of public health received during this consultation will be incorporated into an updated definition. The principles for public health will also be reviewed and updated based on consultation feedback.

3.1.3   Summary of comments received for social care

Respondents reiterated the usefulness of NICE guidance as a valued reference point within social care. They were pleased to see an acknowledgement of the distinct considerations and specific challenges involved in producing social care guidance.

The emphasis on integration of health and social care guidance (including thinking beyond implementation in traditional healthcare settings) was welcomed. However, some questioned how this would work in practice. Stakeholders requested clarity on how terms such as 'significant' or 'sufficient' evidence' and 'clear routes to implementation' would be defined and interpreted. Respondents also emphasised the need for flexible treatment of evidence, acknowledging the different nature of evidence within social care in comparison to clinical practice.

Given the above, some respondents stressed the need for standalone social care guidance in certain instances. On a more general level, respondents queried how these principles would be integrated effectively into the overarching prioritisation process and highlighted the need for social care expertise on the prioritisation board. This is covered under the section 3.3: The relationship between the framework and the strategic principles.

3.1.4 Our response and proposed changes to proposals for social care

As part of a broader review of the membership, and in response to consultation feedback, the prioritisation board has been expanded to include NICE's Social Care Advisor. This will offer a social care perspective and support the interpretation of the social care strategic principles, particularly regarding what 'sufficient' or 'significant new' evidence might look like in relation to social care. The use of the term 'clear route to implementation' alludes to there being a clear audience that is positioned to progress key recommendations, and ideally the presence of system levers to incentivise action. Social care representation will assist in clarifying where this is the case.

NICE recognises the distinction between social care and social work. For simplicity the term 'social care' has been used in the broadest sense in relation to these principles. As part of this work our [glossary definition](#) has been revised with input from our Social Care Advisor.

While we aim to integrate social care recommendations within the NICE portfolio, we recognise there will be situations where this is not useful or usable. In cases where there is a compelling reason to do so, the prioritisation board will retain the authority to consider standalone social care guidance as an option.

3.1.5 Summary of comments received for rare diseases

Respondents were pleased to see that NICE acknowledges the need for a defined approach to rare diseases. They agreed with the definitions stated, although it was noted that these do not wholly align with previous documentation, and alignment with the rare disease framework was proposed.

There were some concerns regarding the principle of commonality to produce guidelines for rare diseases and some responders felt that some rare diseases may be disadvantaged by this approach. Consultation responses also highlighted a tension between the principle of increased engagement and the principle of common products.

Clarity was sought on how NICE will create an attractive environment for innovation in rare diseases and how collaboration will lead to an increased evidence base. Stakeholders also requested a review of the HST criteria and the use of modifiers.

3.1.6   Our response and any changes to proposals for rare diseases

We are pleased to see a positive response to the definitions provided and acknowledge that these are an update from previous documentation; corresponding documents will be reviewed and updated to align with this work in due course. We will continue to align with the rare disease framework and NICE staff will continue to sit on the steering group to ensure this happens.

Resource constraints mean NICE cannot commit to writing guidelines for all individual rare disease topic areas and may not always be best placed to do so. Our system intelligence team will continue to engage with stakeholders to understand the impact of our work in this area. We will work closely with stakeholders to understand where a commonalities approach is feasible and appropriate to ensure equity and impact.

We hope that engagement will also allow stakeholders to understand NICE methods and processes within technology appraisal, Highly Specialised Technologies and guideline creation. We believe better understanding of NICE processes will help organisations to produce their own useful and usable guidelines and relieve some of the tensions highlighted during consultation. Ensuring stakeholders have a better understanding of technology appraisals will also unite stakeholders and research groups to combine registries and avoid silo research in these areas.

NICE will continue to appraise all new medicines for rare diseases that come to market. Highly Specialised Technology Appraisals (HST) will continue to provide an attractive environment for innovation in ultra rare, severe diseases. More detail on NICE's response to the need to review HST criteria can be found in the section 3.6: Highly Specialised Technologies (HST) criteria and routing and comments regarding the use of modifiers will feed into any future methodological work being undertaken in this area.

3.2 Application of the Prioritisation framework

3.2.1 Summary of comments received

The majority of responses did not raise concerns over the proposed criteria within the prioritisation framework. Additionally, there was support for the appropriateness of the criteria at a high level and no strong cases were made for alternative criteria or removal of any criteria from the draft framework.

Respondents commented that there is a lack of detail on how the proposed criteria in the prioritisation framework will be operationalised by the prioritisation board. For example, what is the prioritisation board's decision-making process, which sources are used to retrieve data or intelligence to assess the proposed criteria, how are the rare diseases principles incorporated into the prioritisation framework (see section 3.1 about details on specifics of the strategic principles), and how will the criteria be weighted?

Respondents also requested more information on the proposed possible outcomes for new topics or updates of existing guidance that are not considered a priority; for example, more clarification on methods and processes for using guidance produced by external organisations and the criteria for standing down content.

There was particular concern from respondents (particularly from Industry and patient groups) about the application of the framework to rare diseases with challenge around the population impact and evidence criteria, and a concern that rare conditions would be disadvantaged. However, this is the main reason that we developed, and also consulted on, strategic principles relating to the prioritisation of rare diseases, and these principles will be applied to support and supplement the application of the framework.

3.2.2 Our response and any changes to proposals

In response, more detail on how the proposed criteria will be operationalised has been added. This includes explaining that individual criterion will have different levels of impact based on the topic area of interest, and that a fixed scoring and weighting approach will not be applied. For example, there should not be a fixed numerical score or weighting for population impact as a proposed criterion when

assessing the priority of high prevalence but self-limiting upper respiratory tract infections, in comparison to low prevalence but debilitating conditions such as motor neurone disease. The manual has been updated to emphasise that the decision-making approach is a combination of the framework and prioritisation board (PB) members' deliberations and trade-offs among the different criteria specific to the topic area of interest, with a final formal voting process.

The topic intelligence and monitoring team is working closely with the NICE impact and partnerships directorate and data and analytics team to ensure appropriate sources are used to retrieve data and intelligence to assess the proposed criteria. Also, more information has been added to the population impact criterion to ensure the rare disease principles are considered and deliberated by PB members where appropriate.

To ensure robustness and transparency, more NICE-wide methods and process work is required on how and when to use guidance/recommendations produced by external organisations (see section 3.11 on key methods work for NICE). This has been included in the relevant Directorate business plans for the coming (24/25) year.

3.3 Relationship between the framework and the strategic principles

3.3.1 Summary of comments received

Respondents requested clarity on how the strategic principles will be integrated into the broader prioritisation framework, with concern that the principles for public health, social care and rare diseases seemed subsidiary and potentially, in some instances, contradictory to the new approach to the prioritisation of topics.

3.3.2 Our response and any changes to proposals

The intention is that the overarching framework will be used for all topics considered by the prioritisation board. The principles are designed to work alongside the prioritisation framework. Specifically, the principles offer additional nuance and context to interpretation and application of the framework criteria to certain topic areas (for example social care). These principles recognise that certain criteria (for example 'evidence quality') may look different for these topic areas and therefore

additional consideration is required to ensure these areas are not marginalised by the new prioritisation process. The manual will be updated to add clarity on this and to clearly link the two components.

3.4 Identifying system priorities

3.4.1 Summary of comments received

Respondents welcomed the general approach of prioritising guidance based on priorities for the health and care system. However, there was an acknowledgement that the process for establishing the priorities needs to be clear and transparent. It was queried if stakeholders such as companies and patient, voluntary and community sector organisations will be involved in any part of the process and how they would be communicated with. Feedback highlighted a challenge in defining priorities and the variety of perspectives that could be taken and who could be engaged.

Various respondents queried whether they would be able to notify NICE about new topics, including companies, patient groups, voluntary and community sector organisations, charities and other public bodies. It was noted that detail is lacking with regards to the alerting process for topics not prioritised against the pre-stage 1 criteria, specifically with regards to the process and the responsibility for alerting.

Concerns were also raised about prioritisation and system intelligence with regards to updates of existing guidance. There was an acknowledgement that there are robust monitoring mechanisms as part of NICE's existing processes. However, it was queried whether and how stakeholders external to NICE can proactively notify NICE when they consider that an update is necessary. Members of the healthcare system also noted that it is unclear if unpublished system intelligence can be used to notify NICE.

3.4.2 Our response and any changes to proposals

Strategically, NICE is aiming to build the foundations of a national learning healthcare system. Internal transformation activity will support a focus on what matters most – through this activity and strategic engagement mechanisms we aim to be able to identify system priorities to play into the prioritisation board

deliberations and the membership of the board covers the breadth of the organisation accordingly.

The proposal is to have an accessible approach to the suggestion of suitable topics for prioritisation board consideration. All suggestions will be considered in a consistent manner. We recognise the role the system plays in supporting NICE to ensure that our guidance reflects service needs in addition to evidence changes. Bringing the surveillance and topic intellligence functions to work alongside the prioritisation function will allow NICE information flows and intelligence to be acted on consistently and more effectively.

3.5   Interpretation of proposals in relation to the voluntary scheme for branded medicines pricing, access and growth (VPAG)

3.5.1   Summary of comments received

A number of responses raised queries with regards to how the prioritisation of medicines would relate to the Voluntary Scheme for Pricing, Access and Growth (VPAG). Respondents expressed concern that the current wording in the manual is ambiguous in that it suggests that new medicines and significant extensions falling under VPAG could be routed to stage 2 criteria for further consideration by the prioritisation board.

It was also noted that more clarity should be added regarding the case when medicines falling under VPAG would not be prioritised, for example when they are covered by an existing policy (such as NHSE's policy on commissioning medicines for children in specialised services) or when a new policy can be developed (for example, when not enough people are eligible to receive the technology for NICE guidance to be developed).

Respondents from industry also noted that the example provided in [section 2.4 of the consultation document](#) (which discusses using several medicines with distinct mechanisms of action to form a combination regimen) could create confusion, given that combination therapies are considered under the VPAG agreement. This

example could imply that combination therapies are subject to separate arrangements.

3.5.2   Our response and any changes to proposals

The prioritisation board will work in coordination with the VPAG arrangements, and will not alter these. The prioritisation board will only consider new medicines and line extensions where there is uncertainty over the substance meeting the VPAG commitment. In such cases, those medicines will be considered using the Stage 2 prioritisation framework.

The previous CHTE topic selection manual highlighted an interpretation of "clear rationale not to do so" which remains relevant and appropriate, and will be clarified within the updated NICE-wide topic prioritisation manual. In response to concerns about combination topics we have adjusted the text accordingly.

3.6   Highly Specialised Technologies (HST) criteria and routing

3.6.1   Summary of comments received

Respondents noted that clarification is needed as to whether all medicines identified by companies as potentially appropriate for Highly Specialised Technologies (HST) guidance will have the option to be considered by the NICE prioritisation board for HST routing, noting concerns that the Single Technology Appraisal (STA) process will be the default. Respondents welcomed the suggestion that HST routing decisions will be taken by the prioritisation board but expressed objection to medicines potentially appropriate for HST guidance being considered within the context of the stage 2 prioritisation framework and not the HST criteria. Respondents noted that those should rather be automatically eligible for a NICE technology appraisal as per the VPAG commitment (see section 3.5 on interpretation of proposals in relation to VPAG). Respondents thus felt that the circumstances under which new medicines need further ratification by the prioritisation board before being routed to HST, as described in section 6.3.3 of the consultation document on eligibility criteria for new medicine topics, required clarification.

Respondents from industry requested a review and consultation on a revision to the current HST criteria, also noting that this is linked to an action outlined in the 2024

England Rare Diseases Action Plan. Some respondents expressed dissatisfaction with the current HST criteria and an example was given regarding subpopulations with a specific genetic mutation not being eligible for HST because the overall population does not fit the edibility criteria.

Respondents from the public sector noted that clarification is needed as to whether health technologies specifically could be eligible for HST guidance.

3.6.2   Our response and any changes to proposals

We understand the concerns raised in relation to the application of the approach to HST and will clarify the position clearly since, on reflection, it was unclear in the consultation. Medicines that are to be considered for HST routing will be assessed by the prioritisation board against the existing HST criteria and not against the stage 2 framework.

A review of the HST criteria is planned for this business year and comments received around the criteria will feed into that work.

3.7   Communicating prioritisation board decisions

3.7.1   Summary of comments received

NICE's commitment to transparency was welcomed by respondents but they requested further clarity around how decisions will be communicated, and the method of communication that will be used by the prioritisation board.

Respondents queried how decisions will be communicated about new topics, updates or when topics are retired or stood down. Further information has also been requested about how NICE will engage externally to communicate with stakeholder organisations about upcoming updates or future priority areas.

Responses also included questions about how the prioritisation board will communicate with companies when there are factual inaccuracies or when more information is required, and whether a list of proposals that have not been prioritised will also be published. Further clarification was requested by stakeholders on what information would be needed to allow reconsideration of a topic area.

The prioritisation board has been asked how the Welsh context will be considered during topic prioritisation and how guidance will be applied to healthcare delivery in Wales, and also why it only plans to share pre-publication decisions with DHSC and NHSE, and not with Welsh counterparts.

3.7.2   Our response and any changes to proposals

All prioritisation board decisions will be published on the NICE website. For each topic under consideration the outcome and a concise and clear rationale will be published routinely. This will include decisions to stand down guidance/recommendations or cross refer to the content of other reputable guidance-producing organisations.

We understand the apprehension expressed by some respondents around the information considered by prioritisation board. It is anticipated that a robust approach to developing briefing papers and suitable external engagement in the preparation of topics will mitigate the risk raised by stakeholders.

We will arrange to share pre-board information with the Welsh government for comment ahead of each meeting, alongside the DHSC and NHS England. Consideration will also be given to communication with Scotland and Northern Ireland administrations where relevant.

3.8   Clarification process and timings

3.8.1   Summary of comments received

Two main areas of concern were highlighted by respondents in relation to the clarification process: firstly the proposed new clarification process may not be appropriate for Highly Specialised Technologies (HST) routing as there is no opportunity to appeal, and secondly the timeframe for organisations to seek clarification is insufficient given the complexity of the subject matter.

To allow a comprehensive review of the decisions made by the prioritisation board, a formal appeals process with clear criteria, pre-decision engagement with stakeholders and transparency of rationale for a decision was suggested by some respondents.

Comments highlighted that the NICE-wide topic prioritisation manual suggests that companies will need to wait 6 months before they can apply for the topic to be reconsidered by the prioritisation board. Although there is recognition that this will provide companies an opportunity to gather evidence, NICE is requested to consider a shorter window of 3 months.

3.8.2   Our response and any changes to proposals

NICE has proposed the new clarification process with the intention of providing consistency and clarity about our rationale for decision-making, and doing so in a way that uses NICE resources efficiently. It will use existing structures for governance within NICE, and still allows the opportunity for challenge from stakeholders. Using a digitally available proforma on our website, stakeholders will be given an opportunity to submit questions about areas on which they require further clarity, and if dissatisfied with NICE's initial response, the approach allows further opportunity to seek clarity (second stage). At this second stage, the request for further clarification will be escalated to the chair of the prioritisation board, and discussed at NICE's guidance executive before a final clarification will be provided.

The response to a clarification request will be communicated directly to the stakeholder and will also be published on the website to ensure transparency.

Having considered the points made by our stakeholders, NICE will now extend the period for seeking clarification after the publication of its prioritisation decision to 20 working days, and this will be updated within the manual.

NICE will not revisit topics that have not been selected in less than six months if no new evidence is available. Equally, it will not be possible to immediately review a topic as soon as a stakeholder submits new evidence due to the scheduling of other topics in the pipeline for discussion at the prioritisation board. Therefore, a six-month period is considered a pragmatic way forward. However, there will be consideration of an earlier review, if a slot becomes available.

In response to concerns about the suitability of the clarification process for HST, we feel that the proposed approach is proportionate. We understand that there have previously been concerns about the application of the HST criteria and concerns with

the criteria themselves. The application of the criteria will be included in the proposed clarification process and plans are in place to review and consult on the HST criteria in the coming business year.

3.9   Prioritisation board governance

3.9.1   Summary of comments received

Respondents highlighted some concerns and suggestions regarding the membership of the prioritisation board. A key concern highlighted through consultation was related to the limited patient and public voice and asscoiated input into the decision-making process to prioritise topics, which currently includes two lay members. Another concern was the absence of DHSC and NHSE within the board membership and input from the wider stakeholder community.

Respondents also queried how the following roles and expertise are contributing to the prioritisation board – namely social care professionals, public health experts, pharmacists, patient safety experts and more generally the diversity of clinical voices (i.e., doctors, nurses and other health care professionals).

A suggestion was noted that the associate director of NICE advice, a member of the prioritisation board, should have a right to vote on topics that are prioritised by the board to support innovation.

Respondents expressed a broad range of queries regarding the terms of reference of the prioritisation board. The main queries were related to how decisions regarding 'standing down or retiring topics' would be communicated (see section 3.7 on communicating prioritisation board decisions) and NICEs' mandated duties, particularly with regards to medicines (see section 3.5 on interpretation of proposals in relation to VPAG).

There were also questions requesting further clarity about the processes to select topics outside board meetings and the capacity for scheduling new topics.

3.9.2   Our response and any changes to proposals

NICE is committed to ensuring that it considers the voice of patients and public, as well as input from the wider stakeholder community. In addition to the inclusion of

two lay members on the prioritisation board, a broader view of the voluntary and community sector will be considered through engagement with our people and communities involvement team. Similarly, the views of the wider stakeholder community will be fed into the prioritisation board's decision-making through the work of the implementation and insight function that sits in NICE's implementation and partnerships directorate.

NICE is committed to making independent decisions, and although DHSC and NHSE are not members of the prioritisation board, we will continue to work closely with our sponsor teams at DHSC and NHSE, with a clear channel of communication pre and post prioritisation board meetings, and a process for considering any referrals (with no changes to current regulation).

NICE will also reassure stakeholders that the prioritisation board includes public health experts with expertise in health inequalities. Similarly, there are two pharmacists and a strong clinical voice on the board through the involvement of our consultant clinical advisers and the clinical expertise of the programme director in the medical directorate. The board is chaired by NICE's chief medical officer, a practising emergency medicine consultant.

It was agreed that the associate director for NICE advice would not be a voting member of the prioritisation board to avoid any conflicts of interest as a result of the support they provide to our industry partners.

Our recently appointed social care advisor will now be a member of the prioritisation board and this will be reflected within our updated membership.

The chair of the prioritisation board is NICE's Caldicott guardian with responsibility for clinical and patient safety and also sits on NICE's internal patient safety oversight group. A specific consideration of patient safety is included in the preparation of all topics for stage two consideration. Therefore, there is a clear mechanism to consider patient safety within our decision-making.

Please note: NICE plans to revisit the term "lay member" in June 2024, following the publication of the responses to the consultation on [working alongside people and communities at NICE: a strategy](#).

The terms of reference for the prioritisation board will be updated to be clear that at least one lay member must be present to reach quorum. The lay member representation on the board has been carefully considered following consultation with the public involvement programme at NICE and the members have been provided with bespoke training around the decision-making process using the prioritisation framework.

3.10   Terminology

3.10.1   Summary of comments received

Respondents highlighted terminology that lacked consistency, or a precise definition, and had therefore caused confusion. For example, the use of the term 'integrated' topic prioritisation caused confusion among stakeholders with the currently proposed interim process for integration of technology appraisals. Also, there were some inconsistencies in terminology used in this manual and VPAG 2024. Some NICE-specific terms such as guidance/guideline were identified for further definition to improve clarity.

3.10.2   Our response and any changes to proposals

In response, the title of the manual has been changed to NICE-wide topic prioritisation to avoid confusion with the proposed interim process for integration of technology appraisals. Terminology used in this manual has also been cross checked and aligned with VPAG 2024, with the addition of a glossary to provide definitions for specific terms.

3.11   Key methods work for NICE

3.11.1   Summary of comments received

The consultation highlighted some themes that are methodological challenges for NICE to consider organisationally rather than being specific to the approach proposed for the prioritisation of topics. Two key areas were identified: biosimilars and branded generics and the use of/curation of other content and associated withdrawing/standing down of NICE content.

Respondents commented that currently there is a lack of clarity regarding NICE's position on biosimilars and branded generics especially when there is a cost saving opportunity to the health and care system. Comments highlighted uncertainty in the criteria, methods and process for incorporation of biosimilars and branded generics into guideline recommendations.

The lack of information on methods and process for using guidance produced by external organisations and criteria for standing down content (also see theme 1) was also raised in consultation. An anticipated consequence of a NICE wide approach to topic prioritisation is increased opportunity for integration of content; it is therefore important that the position on standing down content is revisited and agreed across NICE.

3.11.2   Our response and any changes to proposals

In response, NICE will explore more cross-Institute harmonisation work on the methods and processes for standing down or withdrawing content, incorporating biosimilars and branded generics in NICE recommendations, and contextualising and curating external guideline recommendations. This work is underway.

May 2024