NICE Proportionate Approach to Technology Appraisals

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Background

In 2022, NICE introduced the concept of taking a proportionate approach to technology appraisals (PATT) and has been working to test and implement changes to its process for health technology evaluation. The idea behind the work programme is for NICE to apply a faster, lighter-touch approach to evaluations considered to be low risk, supporting more efficient ways of working and quicker patient access. With limited internal and committee resources, improved process efficiencies are needed for NICE to be able to deliver its technology appraisal work programme and offer tailored support to more complex evaluations.

The first phase of the PATT work programme has now concluded following a period of process simplification/reconfiguration, piloting and recent consultation on a modular update to the health technology evaluation (HTE) manual. NICE has reported successful outcomes, with medicines being recommended through the proportionate approach up to 20 weeks (45%) more quickly than the standard process and the approach contributing to a 17% increase in NICE's capacity.[i]

Information about NICE's PATT work programme is available on the NICE website.

Association of the British Pharmaceutical Industry (ABPI) perspective

The ABPI is broadly supportive of NICE's PATT work programme and finding more efficient ways of working to support the delivery of the technology appraisal work programme. NICE has committed to publishing timely guidance on all new medicines and significant indications, which is needed to enable patient access, and this new approach is helping NICE to achieve this. The first phase of the work programme has shown there are process and resource efficiencies that can be realised and ABPI member feedback has been largely positive, particularly on the streamlined approach, which reduces the process steps and time needed for NICE to make a recommendation.

Following NICE's consultation on incorporating the first wave of proportionate approaches into the HTE manual, there remain some outstanding questions – particularly on the cost comparison approach. It is not yet fully clear how NICE will determine whether a medicine is suitable for cost comparison and there will need to be sufficient dialogue with the company to determine this. Ensuring medicines selected for the cost comparison route do not have to be re-routed into the single technology appraisal process will be key to providing predictability and confidence to companies that decisions will not be delayed if cost comparison is being considered as an option. Close monitoring of how this is working in practice will be needed.

To be successful, the approach requires all stakeholders involved in the evaluation to be more pragmatic, appropriately balancing the need for sufficient rigour and expert input with removing and/or reconfiguring process steps. It is critical that NICE retains sufficient patient and clinical expert input during the process.

The ABPI is working closely with its members to provide ongoing feedback and input to NICE and is grateful for the regular engagement opportunities between the organisations. It is essential that industry remains fully engaged as the first phase of the work programme is implemented and the second phase considers further approaches that could be developed.

PATT 2.0

NICE has confirmed the second phase of the work programme will look at developing new ways of working across four work strands: pathways approach, high-value steps, products with many indications and rapid entry into managed access (REMA).[ii]

Of these work strands, the ABPI's priority is developing an approach for medicines that are identified early on as suitable for managed access to enter into these agreements without needing a full upfront evaluation (REMA). Using managed access to allow patient access while additional evidence is generated currently involves doing two full evaluations, a few years apart, which is heavily time- and resource-consuming for everyone involved. To move away from this situation, the ABPI considers there will need to be a departure from existing requirements to demonstrate plausible cost-effectiveness when the evidence is not yet available to do so with any degree of confidence. This sort of approach has been successful in other countries and there are ways to mitigate any risk to the NHS regarding the price paid during the period of managed access, for example by doing a 'true-up' at the time of the full evaluation and routine commissioning decision.

Following the publication of the MHRA's new International Recognition Procedure, there is an increased need to develop quick and efficient NICE decision-making processes for some priority medicines if the UK is to provide a joined-up regulatory and access pathway that enables patients to be treated when high-priority medicines are granted a licence.

Some medicines are effective in treating patients with different diseases or subsets of disease and at multiple points in a care pathway. These medicines, such as immuno-oncology therapies, can put pressure on NICE's work programme because NICE does an individual evaluation for each medicine in each indication. It is likely that the existing proportionate approaches will be able to be used in some but not all cases. The ABPI is keen to explore alternative approaches for these medicines through the second phase of the PATT work programme as soon as possible.

NICE is currently doing two pilots for pathway appraisals: one in renal cell carcinoma and one in non-small-cell lung cancer. While the idea behind building a pathway model that can support multiple NICE evaluations is interesting, it is also incredibly complex and challenging to do. Companies invest significant money and resources into developing economic models that meet the needs of NICE to inform decision-making at a single point in a care pathway. Moving away from this approach and towards a NICE-developed, single-pathway model may not be feasible or desirable in practice. The ABPI's members have raised some concerns about the ongoing pilots, including that they may not meet NICE's justification for a more efficient approach when decisions are considered 'low risk' and that they could create inequity in the way medicines in different disease areas are evaluated. It will be important to continue reviewing the pilots at key milestones to determine whether the approach can successfully support NICE's aims, including supporting timely patient access to new medicines.

Key principles for new approaches

The ABPI considers some key principles should be adhered to when developing new approaches to evaluating medicines:

1. Adaptations to the NICE evaluation process must not inadvertently advantage or disadvantage some companies.
2. If using live topics to pilot new approaches, this should be done in full agreement with the submitting company and any potential delays to decision-making assessed.
3. Proposed adaptations to the appraisal process should be made clear to the company and set out in writing ahead of the appraisal starting. Any scope creep during the appraisal should be discussed, documented and agreed with the company.
4. NICE's committees should be made aware of any process changes implemented for the topic at the start of the committee discussion.
5. NICE's approach of making recommendations for individual medicines, based on the evidence submitted for the appraisal, should be retained.
6. Pilots should be fully and transparently reviewed, with feedback sought from the company, clinical and patient experts, the NICE technical team, the Evidence Assessment Group and the committee. Learnings should be distilled and used to make continual improvements.
7. Stakeholder consultation is required to move from the development/piloting phase to a modular update of the HTE manual.
8. If proportionate approaches are established as routine practice via a modular update to the HTE manual, the resource/process efficiencies should be reviewed and incorporated into the fee for appraisal.
9. Companies should retain the right to decide which NICE evaluation route is most suitable for their medicine and its evidence base.

Next steps

The ABPI understands work has progressed on REMA and that NICE will be piloting a new approach in the coming months. The ABPI seeks urgent involvement to help NICE and the NHSE shape the new approach; co-development of an approach, akin to the re-design of the Cancer Drugs Fund, will help ensure the REMA process is successful and workable for companies. The ABPI is also keen to contribute to the thinking for more proportionate ways to evaluate medicines with many indications.

The pathways appraisal work programme is highly complex, piloting significantly different ways of working. A full review of the pilots, which engages all stakeholders – including industry – is needed before the approach is progressed any further.

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i NICE, 'Taking a proportionate approach to technology appraisals', (accessed August 2023), available at https://www.nice.org.uk/about/what-we-do/proportionate-approach-to-technology-appraisals

ii GOV.UK, 'International Recognition Procedure', (accessed August 2023), available at https://www.gov.uk/government/publications/international-recognition-procedure/international-recognition-procedure

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