NICE and access to *medicines*

The National Institute for Health and Clinical Excellence (NICE) has been in existence for seven years. In that time, it has done much to promote the concept of evidence-based medicine and has produced guidance on the use of more than 100 individual health interventions, guidelines for the management of 40-plus conditions, advice on the safety and efficacy of more than 160 interventional procedures, and latterly has moved into delivering guidance on public health interventions and programmes.

However, patient access to modern medicines remains an issue. The UK remains one of the slowest countries in Europe to adopt innovative medicines, and 'postcode prescribing' still exists. Optimising the contribution that NICE can make to improving patient care is important, as health outcomes in the UK are still generally poorer than in comparable countries.

The pharmaceutical industry believes that patients will benefit more from NICE guidance if:

- All aspects of NICE guidance are fully funded and implemented.
- Selection of topics for NICE guidance is faster, more efficient and more transparent.
- The NICE appraisal process is quicker and more efficient, recognising the need for a pragmatic and flexible approach to assessment of a wide range of health interventions and the need for stakeholder consultation.
- The NICE appraisal process adopts a more interactive and collaborative approach to assessment.
- Immediate action is taken to minimise or eliminate NICE 'blight'.
- Mandatory funding remains for positive reviews of NICE technology appraisals.

THE AIMS OF NICE

The UK-based pharmaceutical industry supports the stated aims of NICE, which are to:

- Encourage faster uptake of clinically and cost effective new treatments.
- Promote more equitable access to treatments.
- Promote better use of NHS resources.
- Promote the longer-term interest of the NHS in the development of innovative treatments for the future.

However, there are aspects of the ways that NICE operates and the NHS implements its guidance that hinder achievement of these aims. The pharmaceutical industry wants to work with NICE and its stakeholders to minimise the barriers to patient access to medicines.

IMPLEMENTATION OF NICE GUIDANCE

In spite of considerable efforts by NICE to dedicate resource to working with the NHS and other stakeholders to improve implementation of its guidance, implementation remains slow and patchy, denying patients access to medicines that have been found to be clinically and cost effective.

According to *Standards for Better Health* (July 2004), implementation of technology appraisal guidance is a core NHS standard and implementation of clinical guidelines a developmental standard. The Healthcare Commission is inspecting against these standards and giving its performance assessments accordingly. However, there is a long way to go before NICE guidance is firmly embedded into care for patients.

Implementation is complex and multi-factorial, involving different organisations and individuals within them. The ABPI believes that:

- The Healthcare Commission should put in place measurement and inspection systems that give a clear picture of the quality and extent of implementation. Current systems focus primarily on process and it is unclear how quantitative measures are used to assess implementation.
- NHS organisations should improve financial planning and adopt the recommendations in

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the Audit Commission Report, *Managing the Financial Implications of NICE Guidance* (September 2005). This report found that, while many organisations believed they could not afford NICE guidance, a significant proportion did not have the financial systems in place to assess its impact.

- NICE should work with the industry to use its expertise, skills and resources to support promotion and implementation of NICE guidance.

SELECTION OF TOPICS FOR GUIDANCE

The ABPI welcomes plans to improve the speed, transparency and efficiency of the topic selection system. The aim of the selection process should be to ensure that NICE produces guidance that is timely and promotes improvements in the quality of NHS patient care. Each month that is taken to select topics potentially delays patients' access to modern medicines, with the 'old' process taking about 18 months.

The new process needs to be shorter, more efficient and much more transparent, so that all stakeholders know which topics are under consideration, where they are in the process, and why they were selected.

FASTER TECHNOLOGY APPRAISALS

The appraisal process, used by NICE since its inception, takes some 15-18 months. Topic selection, scheduling into the NICE work programme and appraisal can therefore take years, with guidance being issued to the NHS months or years after the launch of a new medicine or indication.

In recognition of the needs of the NHS and patients for NICE guidance to be provided as closely as possible to the time of launch, NICE has introduced a 'Single Technology Appraisal' (STA) process for new, 'single products with single indications'.

The STA process will be shorter, with the aim to issue guidance within four months of launch. It will rely upon assessment by Evidence Review Groups (ERGs) of evidence submitted by the manufacturer/sponsor. This is a sensible approach and avoids much unnecessary duplication of work.

However, NICE and its ERGs will need to recognise that there are likely to be limitations in the evidence base at the time of launch, as clinical and cost effectiveness evidence generally only reaches maturity after years of use in a normal clinical setting. NICE will need to adopt a pragmatic approach to evidence assessment and decision-making – a one-size-fits-all, 'purist' approach, with, for example, a rigid adherence to cost per QALY thresholds, will not be appropriate. The ABPI advises the ERGs, NICE staff and appraisal committees to maintain a close and constructive dialogue with manufacturers/sponsors during STA review.

NICE has set an example in ensuring that its guidance is developed in close consultation with expert stakeholder organisations (patient, professional). As NICE seeks to speed up its appraisal process, it must ensure that stakeholder engagement is taken into account in its consultation processes and not sacrificed. Failure to consult may reduce the quality of appraisals and run the risk of generating unnecessary appeals.

A MORE INTERACTIVE AND COLLABORATIVE APPROACH TO ASSESSMENT

Review Groups selected by NICE have generally created their own economic models or adapted an existing model – sometimes inappropriately – in order to challenge the conclusions of cost-effectiveness models developed by manufacturers/sponsors in their evidence submissions. While a degree of challenge is of course legitimate, this approach can be duplicative, often increases the length of the appraisal process, and runs the risk of introducing bias, unnecessary rework and arguments over methods and quality of work, resulting in appeals and further delays.

The ABPI would prefer a more collaborative approach whereby a constructive dialogue between the Review Group, the NICE Executive and the company could take place throughout the assessment, allowing discussion and debate on methods, data quality and sources used. It would also address unnecessary misunderstandings, speed up the process, and reduce the number of appeals.

NICE 'BLIGHT'

The policy of the Department of Health, as expressed in EL99/176, is that patients should not automatically be denied funding for medicines that are awaiting NICE guidance. NHS organisations should use local arrangements for the managed introduction of new technologies which are not referred to NICE or where NICE guidance is not yet available.

In spite of this, NHS organisations routinely delay funding decisions until guidance is available. This means that patients are often denied access to modern medicines for months or years.

The ABPI believes that the Department of Health should re-issue and clearly communicate its policy to all stakeholders with immediate effect.

REVIEWS OF TECHNOLOGY APPRAISALS

It is mandatory for NHS organisations to fund NICE technology appraisal guidance – an essential pre-requisite for successful implementation. However, in 2005 companies were informed that mandatory funding will be lost when NICE decides to conduct the review of a technology appraisal as part of a clinical guideline. Reviews are generally conducted three years after publication of the original guidance and NICE has argued that the NHS should have fully implemented the guidance by then. It is well known, however, that implementation is slow and patchy and that the UK is one of the slowest adopters of modern medicines.

The ABPI believes that funding should remain mandatory for positive reviews of technology appraisals that are conducted as part of a guideline, and that the decision-making process on how a review is handled should be made transparent.

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