ENFORCEABILITY OF NICE GUIDANCE AND GUIDELINES

PAUL RANSON
Consultant, Pinsent Masons

CHRISTIAN HILL
Director, MAP BioPharma

Introduction

An aging population, rapid increases in medical technology innovation and the trend for increasingly expensive drugs becoming available have meant that the NHS has long sought to determine which medical products and technologies do and do not represent value for money.

Previously, medical technology appraisals were carried out by a variety of professional and academic bodies, at both the national and local levels. Work was duplicated, standards were variable and the status of findings was frequently unclear. Variations in determinations of NHS clinicians as to which new products and technologies were the most effective led to local variations in commissioning practices. This in turn led to a situation where patients’ addresses determined whether they were able to obtain particular treatments – the problem of ‘postcode prescribing’. The government had previously attempted to address this problem, introducing the selected list scheme, which listed obsolete or ineffective treatments, in 1986.

It was intended that the National Institute for Clinical Excellence, NICE, would replace the old arrangements with a central, consistent and authoritative system of appraisal, and this role was detailed in the 1998 paper, ‘A First Class Service – Quality in the New NHS’. NICE was established and began work in April 1999.

Now called the National Institute for Health and Care Excellence, NICE is a non-departmental public body charged with providing national guidance and advice to improve health and social care. The way NICE was established in legislation means that its guidance is officially ‘England only’, but NICE has agreements to provide certain products and services to Wales, Scotland and Northern Ireland. Decisions on how NICE guidance applies in these countries are made by the devolved administrations, who are often either directly involved, or at least consulted with, in the development of NICE guidance and guidelines.

Currently, NICE recommendations are issued in the form of Guidelines (clinical, public health, social care, safe staffing, medicines practice), Quality Standards, Technology Appraisals, Interventional Procedures, Medical Technologies, Diagnostics and Highly Specialised Technology. In this article we focus on Technology Appraisals and Clinical Guidelines. Technology Appraisals are based on a review of evidence of clinical and cost effectiveness for a particular technology or group of technologies, and give recommendations about whether and in what circumstances the technology should be used in the NHS. Historically, the majority of technologies assessed by NICE were pharmaceutical, but this is changing to include more innovations such as surgical procedures, medical devices and diagnostic technologies.

Legislation for Enforcement

The National Institute for Health and Care Excellence (Constitution and Functions) and the Health and Social Care Information Centre (Functions) Regulations 2013 (‘the Regulations’) set out three forms of NICE recommendation – a general power to give general advice, guidance or recommendations under regulation 5, technology appraisals under regulation 7 and specialised technology appraisal(s) under regulation 8. It has long been established (except where the recommendation relates to an unlicensed medicine) that in relation to both forms of technology appraisals, recommendations constitute NHS Directions under section 6 of the National Health Service Act 2006 and as a consequence, funding must be provided within three months of the date the recommendation is published by NICE unless an extension has been authorised by the Secretary of Health.
State. This obligation is now specifically set out in the Regulations. It was generally considered there is no such specific obligation in relation to general advice, guidelines or recommendations under regulation 5. However the recent decision of R (Rose) v Thanet CCG challenges this assumption and this is discussed below.

**Enforcement of Technology Appraisals**

NICE technology appraisal guidance, referred to in regulations 7 and 8 of the Regulations, looks at one or more treatments for a particular clinical condition. In relation to such guidance, since 2002 there have been provisions in force from the Secretary of State for Health to health authorities, PCTs/CCGs and NHS trusts in England requiring compliance. The Regulations themselves now confirm the binding form of such guidance in law. The only exception relates to off-label use. It is stated that ‘Unless the Department of Health specifically indicates otherwise, NICE will not publish guidance on the use of a technology for … unlicensed or “off-label” use outside the terms of the technology’s marketing authorisation’. Where NICE is given a remit by the Department of Health there is no requirement on CCGs to provide funding in relation to such off-label use, although NICE does state that evidence summaries for unlicensed or off-label medicines provide information for clinicians and patients to ‘inform their decision-making and support the construction and updating of local formularies’.

Given the legal requirement in relation to HTAs, it is evident that positive appraisal from NICE is likely to trigger increased usage of a treatment. While there is no evidence to suggest that denial of this patient right is widespread, it does happen locally and there are examples of positive HTAs having only a partial effect on local clinical practice. Clinicians or NHS budget holders appear to resist some new treatments, or to implement them partially, or to continue to use alternatives that they prefer. There is clearly a problem translating mandatory guidance to the clinical level. The possible reasons may include: attachment to local clinical practice and/or ‘second-guessing’ of NICE guidance; systemic weaknesses in some NHS organisations that prevent or delay implementation; failure to audit, review and change practice at the clinical level where providers and their clinicians often have a perception that funding has not been agreed; or that funding only covers the treatment, not related costs such as follow-up. The NHS publishes the Innovation Scorecard, which monitors NHS compliance with HTAs and is intended to assist the NHS in the identification and management of variations in such compliance.

These regulations are reflected in the March 2013 NHS Constitution, which establishes the principles and values of the NHS in England. It sets out rights to which patients, public and staff are entitled, and pledges which the NHS is committed to achieve under which nationally approved treatments, drugs and programmes. This states that ‘You have the right to drugs and treatments that have been recommended by NICE for use in the NHS, if your doctor says they are clinically appropriate for you’ and echoes the Regulations in providing that ‘the relevant health body is obliged to fund specified NICE recommendations from a date no longer than three months from the publication of the recommendation unless, in certain limited circumstances, a longer period is specified’.

**Enforcement of General NICE Guidance**

The more general clinical guidelines referred to in regulation 5 are described as ‘recommendations by NICE on the appropriate treatment and care of people with specific diseases and conditions within the NHS. They are based on the best available evidence. While clinical guidelines help health professionals in their work, they do not replace their knowledge and skills’. Unlike the technology appraisals that are the subject of regulations 7 and 8, they were not specifically stated to be of binding force. The NHS Commissioning Board policy states that such general guidance is non-binding and intended to assist the NHS in the exercise of its statutory duties. It provides that ‘NHS bodies are entitled to take decisions which do not follow Guidance (other than NICE’s Technology Appraisals) if they have a good reason to do so. The availability of resources and competing priorities can be a good reason.’

However, the case of R (Rose) v Thanet CCG adds a new dimension. The case concerned Elizabeth Rose, a 25-year-old woman with Crohn’s disease about to undergo bone marrow transplantation and chemotherapy likely to lead to infertility.
and the early onset of the menopause. The claimant wished to secure the best chance of having her own genetic children, and sought NHS funding for egg freezing before beginning the treatment. In the clinical guidelines in question, GC 156 on fertility, NICE made a strong recommendation that egg freezing should be funded. Thanet CCG’s policy, however, was not to grant funding for this unless the applicant has exceptional clinical circumstances, and the group saw no exceptional circumstances in this case.

The Court’s Decision

The Administrative Court decided that, even without a statutory obligation laid down in regulation 5 itself, general principles of public law required the CCG to follow a regulation 5 recommendation unless the CCG could provide clear reasons for not following it. An earlier case, R v North Derbyshire Health Authority, ex parte Fisher (1997), was referred to. This case established that a decision not to follow national policy in the form of guidance from the Secretary of State was only lawful if there was some ‘special factor’ that ‘exceptionally justified departure’. Disagreement with the policy was not enough. As Rose leaves matters, the only difference between regulation 7 and regulation 8 recommendations and a regulation 5 recommendation seems to be that the latter permits special factors that exceptionally justify non-compliance.

Legislative Intent?

Significantly, regulation 9 of the Regulations provides for appeals against regulation 7 and regulation 8 recommendations but not against regulation 5 recommendations. This strongly suggests that the court’s decision might not be what the Secretary of State intended: the fact that there was no specific compliance obligation and that there seems to be no right of appeal suggests that it was not envisaged that regulation 5 guidance would carry such weight. As the Regulations did not seem to envisage binding force, then consequentially regulation 5 provides no fixed timescale for implementation and would seem to allow for differences in the different ways services are delivered in very different organisations. However, at the very least, such a recommendation would need to be in place within a reasonable time and the current three-month period for technology appraisals could well inform what is considered reasonable.

What Rose means

The recent court judgment indicates that if organisations refuse to put NICE clinical guidelines in place because they disagree with them, this could leave them open to challenge. We do not know yet whether there will be an appeal of the decision to the Court of Appeal. If the decision stands as is, only a special factor would justify a recommendation not being followed.

Even were the decision on applying Fisher to be successfully appealed or if it were distinguishable, it seems that CCGs will need to give good and detailed clinical grounds for not following regulation 5 guidance on scientific medical grounds. Unfortunately for the Thanet CCG, its rationale for not following the guidance and questioning its efficacy was insufficient, and was thereby considered to render its decision to depart from the guidance irrational. The court considered that the CCG was under an implied obligation to give reasons for any general policy not to fund a particular intervention, including a reasoned explanation of why a NICE recommendation made under regulation 5 is not being followed.

For the time being, as the law stands, special and exceptional circumstances will need to be identified by CCGs taking a contrary decision to a NICE regulation 5 clinical guideline.