What next for NICE?

HJCL information - 01/2009

The threat that the National Institute for Health and Clinical Excellence (NICE) would become a body tasked with setting drug prices might well have receded recently, but if you thought that NICE's influence was on the wane, then think again.

Recent developments have served to expand the role and consolidate the power of NICE, not just in terms of the traditional areas – conducting health technology appraisals and developing national guidance and guidelines on the management of particular conditions – but more broadly. In the future, NICE could be directly influencing prescribing indicators and incentives for primary care, the information base for NHS decision-making and your R & D programme.

Quality and Outcomes Framework of the General Medical Services Contract

Under recently-published proposals from the Department of Health[1], NICE will be given the responsibility of developing and overseeing a new, independent process for developing QOF indicators from April 2009. As well as designing the process, NICE will asked to review the evidence of clinical and cost effectiveness appertaining to potential new indicators, before producing an annual "menu" of proposed QOF indicators for approval and negotiation by the BMA and NHS Employers.

The move is being trumpeted as an obvious extension to NICE's existing role, which is to evaluate the clinical and cost effectiveness of healthcare technologies and interventions based upon the best available evidence. And most healthcare clients would welcome a transparent process, independent of both primary care and government, which involves wider stakeholder consultation than has previously been the case. However, as always, the devil is in the detail and pharma clients will have plenty to think about (see box 1).

1 QOF and NICE - Things to think about

- For the first time, cost-effectiveness considerations and the Quality-Adjusted Life Year (QALY) will form an explicit part of the formal process by which appropriate QOF indicators are decided. Treatments and interventions will be deemed cost-effective where the 'net benefit' is greater than zero.
- Don't assume that the current indicators will remain. QOF's primary goal has been to incentivise GPs to change their prescribing behaviour - where practice is "embedded", the QOF incentive will be removed to make way for new therapeutic categories and targets that do require incentivisation. In this way, QOF becomes an overt political tool for directing resources at national healthcare priorities.

Pharmaceutical clients will need to consider the impact of a new QOF process across the whole business and product portfolio. With disease indicators being negotiated annually as part of a two-year rolling cycle, it will no longer be feasible to look at individual therapy areas or business franchises in isolation.

NHS Evidence

Not entirely coincidentally, April 2009 also sees the launch of NHS Evidence, a new service hosted by NICE for ensuring that NHS staff have access to quality assured information. Expanding on the service currently provided by the National Electronic Library for Health, NHS Evidence will pull together in a single web portal relevant information on primary research, clinical evidence, policy documents, commissioning and prescribing advice on drugs. A key component of the service will be a new quality assessment process to ensure that the 'best' information is clearly 'kite-marked'. The new 'kite mark' will become a "recognisable indicator of independently verified, high-quality evidence"[2] and will, presumably, be applied to all NICE guidance and guidelines!

[1] Developing the Quality and Outcomes Framework: Proposals for a new, independent process. Department of Health. October 2008.
[2] http://www.nice.org.uk/newsevents/infocus/NICEtohostNHSEvidence.jsp. Accessed 11th November 2008

Scientific Advice Service

NICE's first foray into the commercial sector - selling early scientific advice to manufacturers for drugs in development - has already attracted considerable interest, but pharmaceutical and biotech companies contemplating making use of this service need to consider a number of issues (box 2).

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Scientific Advice and NICE

- What are the risk and benefits of buying scientific advice from a Health Technology Appraisal (HTA) agency, which might be inconsistent with scientific advice given by the regulatory authorities?
- Are the goals of HTA and the regulatory process for securing a marketing authorisation mutually exclusive?
- Which products in your development portfolio are best suited to this type of service?
- Following the advice given does not guarantee a successful HTA outcome further down the line, but could have important ramifications for your global clinical trials and outcomes research programme. How will you act upon the advice received?

The Richards Review

Professor Mike Richards' review was originally intended to address the issue of NHS patients wishing to "top-up" their NHS by purchasing privately drugs that the NHS had refused to fund. It is no real surprise that the lion's share of the media coverage over the last week has focused on exactly that point. However, Richards' report, *Improving Access to Medicines for NHS Patients*[3], also made a number of recommendations relating to NICE's processes for appraising medicines, which may have gone unnoticed:

- ***Proposals to speed up the NICE appraisal process will be published for consultation in due course***
- ***The procedures at PCT level for reviewing cases for exceptional funding are to be formalised***
- ***Perhaps most significantly, NICE has been asked to urgently review the circumstances in which it might be appropriate to apply the current cost-effectiveness threshold more flexibly in order to approve more drugs. A consultation on these proposals runs until 10th December 2008***

The new flexible approach is expected to be suitable for life-extending treatments for rarer conditions where the patient has less than 24 months to live. In such circumstances, cost-effectiveness ratios of up to £80,000 per QALY could be allowed.

From a policy perspective, this development reinforces the point that the Department of Health just cannot keep its fingers out of the NICE pie – particularly when there is an immediate political crisis about the NHS to be averted. Methodologically speaking, the consultation around end-of-life treatments looks problematic. Until now, the QALY - however imperfect - has enabled fair comparisons to be made between different diseases and interventions all demanding a share of the NHS budget. At a stroke, the DH has pushed conditions which affect less than 7000 patients per annum to the top of the priority list on the basis of criteria which look, at best, to be lacking any sound, empirical basis and, at worst, completely arbitrary.

[3] *Improving Access to Medicines for NHS Patients. Department of Health. November 2008.*

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