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NICE POWERS MAY BE CLIPPED IN UK PHARMACEUTICAL PRICING OVERHAUL

The UK government will consult in the coming year on proposals to move the UK's National Health Service (NHS) towards a value-based system of pricing medicines from 2014. While official details are yet to be published, it is expected that doctors will be given powers to decide whether or not to make drugs available to patients. This would effectively remove the ability of the National Institute for Health and Clinical Excellence (NICE), the health technology appraisal body for England and Wales, to recommend which drugs can be reimbursed on the NHS. Rather, NICE is to take on an advisory role regarding the amount that the NHS would be prepared to pay.

BACKGROUND

NICE currently takes a relatively inflexible and formalistic approach to health technology assessment that is based on the concept of the cost per quality-adjusted life year (QALY). In general, NICE will recommend a technology for reimbursement if the cost per QALY is less than £20,000, and may recommend reimbursement for a technology whose cost per QALY is up to £30,000. It is rare for NICE to give a positive recommendation for a technology whose cost per QALY exceeds the £30,000 threshold.

A simplistic view of NICE's QALY-based approach is that the Institute first produces a quality of life rating. This is typically between 0 and 1 (but can be negative), where 0 (or the negative value) indicates the worst possible health and 1 reflects the best possible health. Suppose NICE determines that a patient improves a health by 20% relative to the relevant baseline, which may be no or standard care, it would assess the quality of life rating as 0.2.

To convert this to a QALY, NICE must come to a view on the likely duration of the benefit. While it has significant discretion in this respect, it will often restrict itself to the duration of effect supported by the available clinical evidence. If the available data suggests that the improvement lasts for 3 years, NICE might conclude that new technology would result in 0.6 additional QALYs ((3 × 0.2 = 0.6 QALYs)), relative to baseline. Obviously, the longer the duration, the greater the number of QALYs.

If the cost of the new technology, including associated care, is £30,000 more than baseline over the relevant period, then the cost per QALY gained would be approximately £50,000 (*i.e.*, £30,000 ÷ 0.6). NICE assesses technologies on a case-by-case basis, but maintains that, in general, a technology costing more than £20,000-£30,000 per QALY would not be considered cost effective.

This somewhat rigid QALY-based system was devised and implemented in the 1990s, when the innovative industry was focused on drugs for large patient populations that were therefore more commoditized. Changes in the nature of products that NICE typically assesses means that its rigid focus on QALY thresholds appears more and more dated. In particular, many would argue that the Institute has struggled to perform a meaningful cost-effectiveness assessment for

life-extending products, such as oncology drugs,[1] and many orphan and ultra-orphan products.[2] The Institute has acknowledged that rigid adherence to these thresholds means that it is unlikely to recommend reimbursement of many new technologies, although NICE has taken steps to increase its discretion with regards to life-extending products[3] and it has issued draft guidance on how it might appraise ultra-orphan drugs.[4] The UK government also announced in October 2010 that it will make £200 million a year in funding available for cancer drugs from April 2011 to the end of 2013.[5]

VALUE-BASED PRICING

NICE nevertheless still considers itself to be constrained by rigid QALY thresholds and the UK is falling behind many other member states in Europe with regards to the availability of new medicines.[6] The government's value-based pricing plans are intended to close this gap. Value-based pricing was proposed by the UK's Office of Fair Trading in 2007 as a means of making effective treatments affordable to the NHS.[7] Under a value-based pricing system, the maximum reimbursement price of a drug will be set according to the net health benefit it brings, taking into account the cost of the drug, its clinical benefit and the savings made from the drugs or health services that it displaces.

It is thought that a new value-based process will use NICE's appraisal of a drug to determine a fair price for the NHS to pay, with the appraisal made available to the NHS and the public to help inform local decisions on its clinical use. It remains to be seen, however, whether NICE will be involved in negotiating the NHS reimbursement prices for medicines or if that role will be carried out centrally by the Department of Health or some other body. However, the UK Health Secretary Andrew Lansley said that NICE's role with respect to pricing would "inevitably evolve." He also suggested that pharmaceutical companies should focus on developing medicines for a "significant unmet need." Mr. Lansley said:

> "The NHS must use every penny wisely and reforming the way we pay for new medicines is a key part of this. We need a system that encourages the development of innovative drugs **addressing areas of significant unmet need**. And we need a much closer link between the price the NHS pays and the value that a new medicine delivers,. **sending a powerful signal about the areas that the pharmaceutical industry should target for development**.

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[1] Exceptional Progress? Assessing the progress made in improving access to treatment for people with rarer cancers, Rarer Cancer Forum, March 2010. See

[2] Strengthening National Commissioning Consultation, Summary of Responses to the Consultation on Proposals For Strengthening National Commissioning, Department of Health, 18 March 2010. See http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_114297.pdf, last accessed 10 November 2010.

[3] Appraising life-extending, end-of-life treatments, NICE Supplementary Advice, July 2009. See http://www.nice.org.uk/media/E4A/79/SupplementaryAdviceTACEoL.pdf, last accessed 10 November 2010.

[4] Appraising Orphan Drugs, Draft v3 (2006), National Institute for Health and Clinical Excellence, See http://www.nice.org.uk/niceMedia/pdf/smt/120705item4.pdf, last accessed 10 November 2010.

[5] The government had already made available £50 million for cancer drugs between 1 October 2010 and 31 March 2011. The precise operation of the cancer fund is currently under consultation but it is expected that the few cancer drugs recommended as clinically and cost effective by NICE will continue to be funded by the NHS. For those cancer drugs rejected by NICE or yet to be approved by NICE, accessing the cancer fund is a possibility and funding decisions are expected to be based on clinical need rather than health economics.

[6] The Influence of the Pharmaceutical Industry, Volume 1, Fourth Report of Session 2004–05, House of Commons Health Committee, March 2005. See http://www.publications.parliament.uk/pa/cm200405/cmselect/cmhealth/42/42.pdf, last accessed 10 November 2010.

[7] The Pharmaceutical Price Regulation Scheme -An OFT market Study, February 2007. See http://www.oft.gov.uk/OFTwork/markets-work/completed/pprs, last accessed 10 November 2010.

> "Over the next three years we will be working towards a new system of pricing for medicines, where the price of a drug will be linked to its assessed value. Value-based pricing will ensure licensed and effective drugs are available to NHS clinicians and patients at a price to the NHS that reflects the value they bring.
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> "I am determined that not only will we have a reimbursement price for medicines which reflects their benefit to patients, but also one which incentivises innovation, and supports those new medicines which respond to unmet healthcare need and those which provide wider benefits to society." (Emphasis added.)

NICE RESPONSE

How exactly the system of value-based pricing and other initiatives, such as the cancer drug fund, will work remains unclear. However, NICE's chief executive, Sir Andrew Dillan, has stated: "We are confident that the government will want to take advantage of NICE's expertise and experience as it develops value-based pricing. The UK led the world in the appraisal of new health technologies, when it set up NICE in 1999. It can do the same in 2014 with a new approach to managing the entry of effective new treatments into the NHS, in a way which meets the needs and expectations of patients and which uses the health service's resources effectively."

NHS REFORM

The proposals follow the publication of the UK government's ambitious plans to reform the NHS. In July, the government's White Paper, *Equity and Excellence: Liberating the NHS*, outlined plans to give GP practices full responsibility for commissioning care and services for local communities from 2013, with many GP practices beginning to take over commissioning from local health authorities as early as 2011. The report suggested NICE's remit would be expanded to developing quality standards to help inform commissioning decisions and "create a comprehensive library of standards for all the main pathways of care".

COMMENTS

Some commentators have expressed concern that shifting to doctors responsibility for deciding who is treated with which drug, particularly in relation to the cancer fund, could lead to the "post code lotteries" that NICE was intended to end. Others have suggested that companies will need to consider entering into local risk-share schemes or significantly discount their products to provide value-for-money at a local level.

What is clear is that the pricing and reimbursement landscape in the UK is changing rapidly and pharmaceutical companies need to keep abreast of these developments to ensure that their pricing strategies are aligned with the new UK pricing system.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

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