

# The Kennedy report: appraising the value of innovative medicines

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**Steve Chaplin outlines the recommendations made by Professor Sir Ian Kennedy in his recent report on the appraisal of innovative new medicines.**

**Figure 1.** The report recommends raising the usual cost-effectiveness threshold for innovative medicines for three to five years

The relationship between the NHS and the pharmaceutical industry, and in particular the perception that cost-cutting obstructs the uptake of innovative medicines, has been getting a lot of attention. In 2007, the Office of Fair Trading highlighted a drawback of the Pharmaceutical Price Regulation Scheme (PPRS), saying 'It is clearly right that the NHS should seek to constrain what it spends on drugs, but we believe regulating profits [of the pharmaceutical industry] is a very indirect means of doing so, and one that is ill-suited to an innovative sector such as pharmaceuticals'.<sup>1</sup>

In 2009, the new PPRS included for the first time a provision specifically to promote the use of innov-

ative medicines, with both the Department of Health and the industry 'committed to increasing uptake and patient access for new clinically and cost-effective medicines in the NHS in a sustainable manner'.<sup>2</sup>

A Working Party of the Royal College of Physicians concluded that NHS-industry relationships were so damaged that major changes were needed to enable the NHS to deliver innovation for patients effectively.<sup>3</sup>

The Cookys report called for an 'independent review of the way in which NICE (the National Institute for Health and Clinical Excellence) values medicines so that the current economic evaluation is comple-

mented by clinician, patient and research inputs on the value of the innovation from their perspectives'.<sup>4</sup>

That review was published in July 2009.<sup>5</sup> Commissioned by NICE but carried out independently by Professor Sir Ian Kennedy, former head of the Healthcare Commission, it acknowledged that NICE and the pharmaceutical industry appear to be at war and suggested how they could work more closely and more productively.

The report asks whether medicines offer benefits that NICE does not take into account but should, and whether innovation is properly valued as a benefit.

The proposed answers are prefaced by three points. First, the price

of a medicine is a fundamental determinant of NICE's estimates of cost effectiveness. It is determined by the industry for a global market, bearing in mind that the UK price influences what other markets are prepared to pay, but it is unclear how a company spreads its development costs between different markets.

Second, the potential benefit of financial incentives to the industry (such as tax breaks) has not been sufficiently acknowledged.

Finally, both NICE and the industry need to change: NICE should be more sensitive to the views of the industry and patients, and the industry must accept NICE's statutory role in ensuring fair allocation of the NHS's fixed budget.

### Defining benefits

Kennedy describes the use of the QALY and the incremental cost effectiveness ratio (ICER) as 'quite simply the best tool available to do the job which NICE has been set' – but it is not perfect. Critics say these measures do not include all the relevant benefits of treatment. NICE says its guidance to appraisal committees ensures they do, but Kennedy believes the NICE process is not sufficiently transparent. The benefits should be explicitly identified, with an explanation of how they will be incorporated into the analysis or why they will be excluded.

Benefits could include improvements in how individuals view their health, including oral rather than parenteral administration, fewer daily doses and treatment at home rather than in hospital, and how society values patient groups (the status of individuals affected by illness and people at the end of life). NICE should now consult on which benefits to include and how best to quantify them.

NICE is currently barred from assessing the social benefits of medicines, *eg* return to work, reduced

- the price of a medicine is a fundamental determinant of NICE's estimates of cost effectiveness
- NICE should be more sensitive to the views of the industry and patients, and the industry must accept NICE's statutory role in ensuring fair allocation of the NHS's fixed budget
- the QALY is 'quite simply the best tool available to do the job that NICE has been set' but it is not perfect
- NICE should not assess the social benefits of medicines, pending further research
- there should be greater industry involvement in the NICE process
- NICE should define what is an 'innovative medicine'
- the NHS should periodically specify its priorities for treatments so that industry knows how to direct its research to produce innovation where it is needed
- the threshold for cost effectiveness of an innovative product should be higher than for other drugs for 3-5 years
- postmarketing surveillance should monitor efficacy as well as safety

**Table 1.** Main points of the Kennedy report

carer burden. Kennedy concluded that this should continue to be the case for now, but research is needed to consider the issue and how the benefits could be measured.

There should also be greater industry involvement in the NICE process. This should start with considering its claims for innovation at the scoping meetings that recommend topics to the Department of Health, and continue with industry attendance at appraisal committees, providing video of meetings conducted in secret (after decisions have been published), and closer working between NICE and industry before a product is marketed.

NICE needs to improve its understanding of the impact of its recommendations. To that end, it should learn more about PCT spending behaviour and work with the NHS on disinvesting from drugs that do not offer value for money.

### Rewarding innovation

The purpose of claiming that a product is innovative is that it should receive special treatment. It has been argued that NICE's threshold for cost effectiveness should be increased for innovative medicines

– that is, the manufacturer should be allowed a higher price. To date, this approach has been rejected and Kennedy accepted that cost effectiveness should not be determined by 'the characteristics of the patient, technology or disease under consideration in any specific appraisal'. However, he agreed that this approach does not adequately reward innovation.

Conversely, recognising and rewarding innovation could undermine the primacy of the QALY and ICER. His proposals would have to be implemented with 'extreme rigour', Kennedy noted.

First, NICE should establish a definition that identifies truly innovative medicines. The NHS should periodically specify its priorities for treatments so that industry knows how to direct its research to produce innovation where it is needed. When an innovative product emerges, NICE should work closely with the industry to produce the evidence needed for appraisal.

The normal cost effectiveness threshold could be raised temporarily, allowing a higher price for three to five years. After this period, the usual NICE appraisal process

would be completed and the product would be required to meet the normal criteria for cost effectiveness.

The higher cost should be met not by the NHS but centrally and may need to be offset by lower prices on a manufacturer's other products. A new mechanism would be needed to recover costs if a product fails to live up to its early promise. The Government should support the development of innovative products through research and funding, but the industry should not be protected from the risks of product failure. Postmarketing surveillance should monitor efficacy as well as safety, the costs being shared between government and industry.

Some of these concepts are being piloted in the 'innovation pass', a joint initiative between the government and NICE in which innovative medicines will bypass the usual assessment procedure and be available to the NHS for a limited time.<sup>6</sup> Funding for 2010/11 is £25 million, which Kennedy describes as 'rather too modest a sum to have any real impact'.

Kennedy closes with an acknowledgement that the appraisal of technologies other than drugs – devices and psychological therapies – requires special consideration. NICE should work with others to develop research and a systematic approach to acquiring evidence.

### Summary

The Kennedy report joins others in calling for a closer relationship between NICE and the pharmaceutical industry. NICE is generally doing its job well but it should be more transparent and inclusive. Industry must accept that the NHS budget is finite. Kennedy calls for a system that identifies innovative products and provides rapid access to the NHS for a limited period. Manufacturers should be rewarded with an initially higher price, but their product should be monitored and undergo the usual appraisal process when the privileged term ends.

### References

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