



CRA Insights: Life Sciences

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Value-based pricing in the UK – A discussion of the wider benefits from new medicines

Will the consideration of a wider range of benefits in assessing new pharmaceuticals create ripples elsewhere?

In this issue of *CRA Insights*, independent health economist Leela Barham (LB) and CRA's Tim Wilsdon (TW) discuss the potential impact that taking a wider perspective on the value of new pharmaceuticals may have in the UK as well as the broader implications for developing international models of health technology assessment (HTA).

Background

In 2007, the Office of Fair Trading (OFT) called for reform of the Pharmaceutical Price Regulation Scheme (PPRS). The PPRS is, at its heart, a profit control scheme focusing on a company's portfolio and not on individual products. The OFT's concern was that the scheme did not result in prices that were in line with the benefits of new drugs. Instead, they proposed a new value-based pricing (VBP) scheme to bring prices much closer to the benefits that new products provide. The report also noted that a system of value-based pricing would encourage investment in drugs for medical conditions where there is greatest need. Because the health services in many other countries base their prices on those in the UK, there could be additional benefits internationally.¹

VBP has been slow to evolve, but additional details are set out in the latest PPRS, published by the Department of Health and the Association of the British Pharmaceutical Industry in December 2013. This voluntary pricing agreement limits NHS spending on pharmaceuticals overall.² Commentators note that this approach is farther from the original vision of VBP.³ However, it does widen the scope of

¹ See 2007 OFT press release, <http://www.offt.gov.uk/news-and-updates/press/2007/29-07#.Usx5ovRDvrv>.

² The 2014 Pharmaceutical Price Regulation Scheme, Department of Health and Association of British Pharmaceutical Industry, https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/282523/Pharmaceutical_Price_Regulation.pdf

³ Leela Barham, "What Does the UK's 'New' PPRS Mean for Value-Based Pricing?", *PharmExec*, November 20, 2013, <http://www.pharmexec.com/pharmexec/Noteworthy/What-Does-the-UKs-New-PPRS-Mean-for-Value-Based-Pr/ArticleStandard/Article/detail/828958?contextCategoryId=48158>; Mike Birtwistle, "The new drug pricing scheme is a gamble," *Health Service Journal*, November 7, 2013, <http://www.hsj.co.uk/comment/the-new-drug-pricing-scheme-is-a-gamble/5065132.article>

what can be considered of value and is now termed value-based assessment (VBA). The National Institute for Health and Care Excellence (NICE) is responsible for delivering VBA in England.

How will NICE incorporate burden of illness and wider societal benefits as part of value-based pricing?

LB: More information has recently emerged on how NICE might deliver against the Terms of Reference set out by the Department of Health (DH).⁴ Though the proposals are not formally out for consultation, the NICE Board discussed working group proposals for delivering VBA in January 2014. NICE decided against the early approaches tested by the DH for wider societal benefits (WSBs). Instead, they will add the option for companies and patients to make a case for the burden of illness (BoI) and what they term wider societal impact (WSI). NICE wants WSI to be expressed in terms of the quality-adjusted life years (QALYs) that are lost from having a condition versus what people would expect to have in QALYs anyway. (See box below). This is potentially an important change to evaluating medicines and could have significant repercussions.

NICE proposals on burden of illness and wider societal impact instead of wider societal benefits

NICE proposes to define burden of illness as the total amount of future health (in QALYs) lost for people with the condition, which requires an understanding of what an individual's QALYs would have been without the condition. Options for this include absolute or proportional shortfall.

Absolute shortfall = total QALYs without the condition less the QALYs expected for people with the same age and gender distribution with the condition.

Proportionate shortfall = absolute shortfall divided by the total QALYs without the condition.

Wider societal impact uses the absolute shortfall in QALYs as a proxy for the impact of the condition on the person's ability to interact in and contribute to society. This would replace wider societal benefits, as originally developed by the Department of Health, which focused on net changes in production and consumption of those with a condition.

TW: Although value-based assessment has received considerable attention, it is important to remember the UK is not the first system to incorporate wider societal benefits in the assessment of medicines. The Dutch and Swedish systems established a willingness to consider wider societal benefits some years ago. Even in these two countries, the jury is still out on whether incorporating social benefits has been material in the assessment of new medicines. For example, it is not clear that the Netherlands or Sweden places more emphasis on the cost imposed on carers when assessing new Alzheimer's products or that this has meant greater access to medicine. Indeed, countries as diverse as Mexico and South Korea include some allowance for societal benefits.

⁴ National Institute for Health and Care Excellence, Terms of Reference, July 2013, http://www.nice.org.uk/media/9A4/92/DH_VBP_Terms_of_Reference.pdf

LB: You're right. And only time will tell if the changes here represent a sea change or just some tweaks at the edges. Don't forget that the NICE Appraisal Committees will still have discretion and NICE promotes these as "modifiers" and not formal weights on the basic cost per QALY calculation that NICE usually considers. But at least now, these factors can play a role in deliberations.

But will a consideration of wider societal benefits by NICE introduce unintended consequences?

TW: NICE already takes some time to come to a recommendation, with the result that patient access is delayed. Isn't it possible that assessing BoI and WSI could slow things down further or lead to appeals?

LB: It's true that the inclusion of these wider factors is already cause for concern. Recent media reports highlight that patients and industry aren't entirely happy, but we've always relied on deliberation and an ample helping of judgment from Appraisal Committees at NICE. I expect that doctors faced with real life patients already take into account wider factors: will their patient be able to get back to work? Will the patient be able to continue to care for family members? Perhaps it's better to bring it out in the open. Although I struggle to see how the formulas NICE is considering will relate to real patients and real clinical decisions.

TW: Exactly, the case for leaving judgment in the hands of the Appraisal Committee (and the potential for disputes) needs to be weighed against the advantages of a transparent system and the signals this provides about future value. Given the system has changed considerably over the last 10 years, I must admit to some skepticism on the impact on incentives.

So will the UK be a signpost or a distraction in the evolving debate over value-based pricing?

TW: To the extent that the new system encourages a wider assessment of value and balances the need for transparency, it will be a valuable model for other countries, providing it allows flexibility for idiosyncrasies between therapy areas and products. If nothing else, other countries will need to justify how they include BoI and WSB.

LB: Possibly, but the new system could do more harm than good if the potential for taking a wider look at value is lost in the deliberations or trumped by a more restrictive cost effectiveness threshold. It is particularly troubling that the Committees may be limited in how much weight to give these modifiers. A paper by the NICE Board suggested a limit of 2.5 times which equates to a rough cost per QALY threshold of £50,000. That could be the undoing of the opportunity of taking a wider perspective.

TW: We can agree the decision on how to implement WSB in the UK will have implications for access to medicines and incentives to innovate. More significant is the impact it may have on the wider debate in Europe and, ultimately, the use of HTA in emerging markets.

Leela Barham is an independent health economist who has been part of the discussions on WSBs. Tim Wilsdon is currently working on how international HTA models are evolving.

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