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Providing guidance to the NHS: The Scottish Medicines Consortium and the National Institute for Clinical Excellence compared

John Cairns

London School of Hygiene and Tropical Medicine, London WCIE 7HT, UK

Abstract

There is wide acceptance that cost-effectiveness is a relevant consideration when deciding which treatments to make available in publicly funded health services. An unresolved issue concerns the timing and the extent of such evaluations. The United Kingdom provides examples of two distinct approaches. The Scottish Medicines Consortium (SMC) provides guidance to the NHS in Scotland based on a rapid early review of the evidence. The National Institute for Health and Clinical Excellence (NICE) provides guidance to the NHS in England and Wales based on a later, more extensive review of the evidence. This paper explores how the difference in approach affects the role of the pharmaceutical industry, clinical experts and other stakeholders. It compares the guidance produced when both bodies have evaluated the same medicines. It addresses the general question of when to assess the cost-effectiveness of medicines. It concludes that there are important differences between the approaches of SMC and NICE, relating primarily to the timing of the review of evidence on clinical and cost-effectiveness. The difference in timing means that the activities of the two bodies are to a large extent complementary.

Keywords: Health technology appraisal; Cost-effectiveness advice

1. Introduction

There is wide acceptance that cost-effectiveness is a relevant consideration when deciding which treatments to make available in publicly funded health services. Consideration of economic evidence is now a formal requirement in several countries [1]. An unresolved issue concerns the timing and the extent of such evaluations. The United Kingdom provides examples of two distinct approaches. The Scottish Medicines Consortium (SMC) provides guidance to the NHS in Scotland based on a rapid, early review of the evidence. The National Institute for Health and Clinical Excellence (NICE) provides guidance to the NHS in England and Wales based on a later, more extensive review of the evidence. The approach followed by NICE is fairly distinctive internationally with its emphasis on detailed independent external assessment of evidence. Whereas the approach followed by SMC is closer to that used elsewhere in Europe.

The purpose of this paper is to compare these two approaches. The remits of the two bodies and the nature

E-mail address: John.Cairns@lshtm.ac.uk.

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of their guidance are described in the next section. The significance of the difference in approach for the roles of the different players is examined. This is followed by a comparison of SMC and NICE guidance where both bodies have assessed the same medicines. Finally some aspects NICE and SMC's provision of guidance are appraised.

2. NICE and SMC

NICE was established as a Special Health Authority in 1999. The SMC, a consortium representing all 15 Health Boards and their Area Drug and Therapeutic Committees (ADTCs), was established in 2001. NICE completed their first appraisal in April 2000 and have completed nearly 90 to date. SMC published their first recommendation in April 2002 and have now issued guidance on about 170 medicines. The SMC (with a membership of about 30) is larger than the two (formerly three) NICE technology appraisal committees (each with about 21 members). A broad mix of clinical, managerial and academic expertise, and lay representation is common to both committees. However, NICE appraisal committees contain a higher proportion of health economists and statisticians, and SMC has a higher representation from NHS management and finance.

The products to be assessed by SMC are essentially determined by the medicines' licensing authorities and the pharmaceutical companies, in that they comprise all medicines licensed since January 2002 which are to be marketed in Scotland. Whereas, the Department of Health and the Welsh Assembly Government are responsible for selecting topics for NICE's work programme. Although there is a web-based system for individual clinicians, patients and organisations to propose topics, and also National Clinical Directors are to advise on priorities, the selection remains the responsibility of DH and WAG.

The remit of the SMC is to provide advice to NHS Boards and their Area Drug and Therapeutics Committees across Scotland about the status of: all newly licensed medicines; all new formulations of existing medicines; and any major new indications for established products. The advice being the need for, and effectiveness, and likely cost of these medicines. The advice is to be made available as soon as possible after the launch of the product. SMC and its emphasis on rapid, early review results from a desire to avoid the inefficiency and potential inconsistency of adoption decisions being taken independently and in parallel across several ADTCs.

NICE produces guidance on: the use of new and existing medicines and treatments within the NHS in England and Wales (technology appraisals) [2]; the appropriate treatment and care of people with specific diseases and conditions within the NHS in England and Wales (clinical guidelines) and whether interventional procedures used for diagnosis or treatment are safe enough and work well enough for routine use in England, Wales and Scotland. In reaching its judgement the institute is required to have regard to: broad clinical priorities; the degree of clinical need; the broad balance of benefits and costs; any guidance on the resources likely to be available and the effective use of available resources. Thus, although NICE has a much wider remit than SMC, in the specific area of medicines they are engaged in a common activity of providing guidance to the NHS, and, although the phrasing differs, both bodies are required to consider cost-effectiveness.

The SMC has three categories of guidance: accepted for use; accepted for restricted use and not recommended. Note that this last decision can be made in the absence of a company submitting their product for review although this has only happened once. The motivation being to ensure that one company cannot obtain an advantage over another by non-submission. NHS Boards must meet any additional costs arising as a result of implementing SMC recommendations from within their general revenue allocations. The Minister for Health & Community Care has publicly stated that "NHSScotland should take account of the advice and evidence from the SMC and ensure that recommended medicines are made available to meet *clinical need*". However, the ADTCs do not as a consequence of SMC guidance have to add a new medicine to their formularies. The only exception concerns "unique" drugs which (if approved by SMC) are to be introduced into NHSScotland to an agreed national programme and made available uniformly across Scotland [3]. The definition of unique is unclear but appears to be close to "no alternative treatment available" for patients with a particular clinical indication. Uniformly, as with unique, remains undefined.