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The Common Drug Review: A NICE start for Canada?

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Abstract

Prescription drugs are one of the fastest growing cost components of modern health care systems. Efforts to control escalating costs while simultaneously maximizing population health outcomes have led many countries to implement restrictive criteria on the funding of certain drugs. While drugs are licensed for sale based on evidence of safety and efficacy versus a placebo, many funders now require evidence of clinical- and cost-effectiveness compared to existing drugs as part of their reimbursement criteria. In some countries, concerns about duplication of drug assessment and administrative effort across different jurisdictions have led to experimentation with various forms of centralized drug review processes. Centralized drug reviews strive to standardize, inform, and improve drug reimbursement decisions through critical assessments of comparative clinical- and cost-effectiveness. The ultimate objective is to inform formulary listing decisions that both maximize health outcomes and achieve good "value for money". This paper describes the Common Drug Review (CDR), a uniquely Canadian version of a centralized drug review process, and compares it with the much-studied National Institute for Health and Clinical Excellence (NICE) in the United Kingdom. Through this analysis, which draws on prior critiques and experiences of NICE, we highlight several critical issues for pharmaceutical priority setting that must be considered in the operation and appraisal of centralized drug review processes. These include the selection of drugs for review, centralized versus decentralized decision-making, receptor capacity at local decision making levels, and public participation.

Keywords: Pharmaceutical policy; Centralized drug assessment; Priority setting; Common Drug Review

1. Introduction

Drug benefit providers around the world are increasingly implementing restrictions on the coverage of pharmaceutical products in efforts to control soaring prescription drug costs. While drugs are licensed for sale based on evidence of safety and efficacy versus a placebo, many funders now require additional evidence of clinical- and cost-effectiveness compared to existing drugs as part of their reimbursement criteria. Such information is not usually generated in drug licensing processes. Funders must therefore collect and critically assess evidence of comparative clinical- and cost-effectiveness after a product is licensed for sale.

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In some countries, concerns about duplication of drug assessment and administrative effort across different jurisdictions have led to experimentation with various forms of centralized drug review processes. The ultimate objective is to inform formulary listing decisions that both maximize health outcomes and achieve good "value for money".

This paper describes the Common Drug Review (CDR), a uniquely Canadian version of a centralized drug review process. We first review the origins of the CDR, describe its relationship with provincial formulary decision-making processes, and present evidence on the uptake of its early recommendations. We then compare the CDR with the much-studied National Institute for Health and Clinical Excellence (NICE) (formerly known as the National Institute for Clinical Excellence) in the United Kingdom, a system comparable to the CDR with centralized recommendations combined with decentralized funding. Using a comparative framework that draws on prior critiques and experiences of NICE, we highlight several critical issues for pharmaceutical priority setting that must be considered in the operation and appraisal of centralized drug review processes. These lessons, while important for Canadian decision makers, generalize beyond the CDR experience.

2. Pharmaceutical policy in Canada

Pharmaceuticals have accounted for the second largest share of Canadian health expenditures since 1997 [1]. Yet pharmaceuticals consumed outside hospital settings are not included under the Canada Health Act, the federal–provincial cost-sharing agreement that ensures national standards for universal public health insurance. As a result, there are currently 13 provincial and territorial drug plans, as well as several federal drug programs, in operation across Canada. Each has independently defined its own eligibility requirements, levels of coverage, and reimbursement criteria [2].

The patchwork nature of pharmacare policy in Canada has resulted in administrative duplication and policy variation. This has been particularly true of the assessment of drugs for potential inclusion on drug plan formularies, creating inter-provincial disparities in access to medicines [3–5]. Set against this backdrop, the management of pharmaceutical coverage has been identified as a top priority for health care policy in Canada [6,7]. A major initiative to emerge out of this is the CDR.

3. The Common Drug Review

The CDR was established in 2003 as a model of centralized review for new drugs on behalf of participating drug plans. All federal, provincial and territorial drug benefit plans are participating in the CDR process, except for the province of Québec [7]. The CDR is funded by the provinces and managed by and housed at the Canadian Coordinating Office for Health Technology Assessment (CCOHTA), an organization at arms length from the government specializing in health technology assessment.

The objectives of the CDR are to reduce the duplication of effort by participating drug plans, provide a consistent and rigorous approach to drug reviews, and to maximize the use of limited resources and expertise. The CDR also provides an evidence-based listing recommendation, which is based on a systematic review of the best available clinical evidence and a critique of pharmacoeconomic evidence submitted by the manufacturer [8]. The CDR only considers drugs after they have received Health Canada's 'Notice of Compliance', which indicates that, compared to a placebo, basic safety, efficacy and product quality requirements have been met. Because such data are not required by Health Canada for product licensing, the CDR focuses on providing evidence about effectiveness, efficacy and costs compared to existing treatments.

Despite centralization of the review process, provincial and territorial drug plans are not bound by the recommendations of the CDR. Rather, drug plans may take the CDR recommendation into consideration along with other factors, including, for example, local priorities and resources, when making drug coverage decisions. Because CDR recommendations are advisory only, drug plans can, in theory, decide to cover or not cover a drug before of after the CDR process. In reality, participating drug plans have agreed that all new drugs must first be vetted through the CDR before they make coverage decisions. The individual plans continue to bear ultimate responsibility for all coverage