

The Common Drug Review: Governments Avoiding Accountability for Rationing

by Courtney Glen &
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Canadian patients suffer delayed access to new medications because of a slow drug safety approval process at Health Canada that is inefficient relative to comparable systems in other countries. The result is that Canadian patients wait significantly longer than patients in other countries to have access to the latest advances in medicines (Graham, 2005). But even after waiting too long for Health Canada to approve medicines that are already in common use months and years earlier in other countries, provincial and territorial governments further delay access to new drugs by refusing to declare them eligible for reimbursement under public drug programs that cover prescription medications.

In September 2003, the provinces authorized the creation of a new quasi-governmental agency called the Common Drug Review (CDR). The rationale behind the CDR was to reduce bureaucratic redundancy by replacing the various provincial

reimbursement approval processes with a new, centralized, national process. However, the provinces have not repealed their reimbursement approval regimes, and so the CDR has only added another layer of bureaucracy, thereby further reducing access to new drugs for those dependent on subsidized pharmaceuticals.

Furthermore, the CDR as a quasi-governmental agency is not formally part of the federal or the provincial governments. Therefore, it is unaccountable to the public. Data measuring the CDR's reimbursement approvals rate and subsequent adoption by public drug programs in the provinces suggest that the CDR is being used as a cost-containment mechanism to ration access to new medicines, not to improve the efficiency of the reimbursement process.

Measuring the CDR's performance

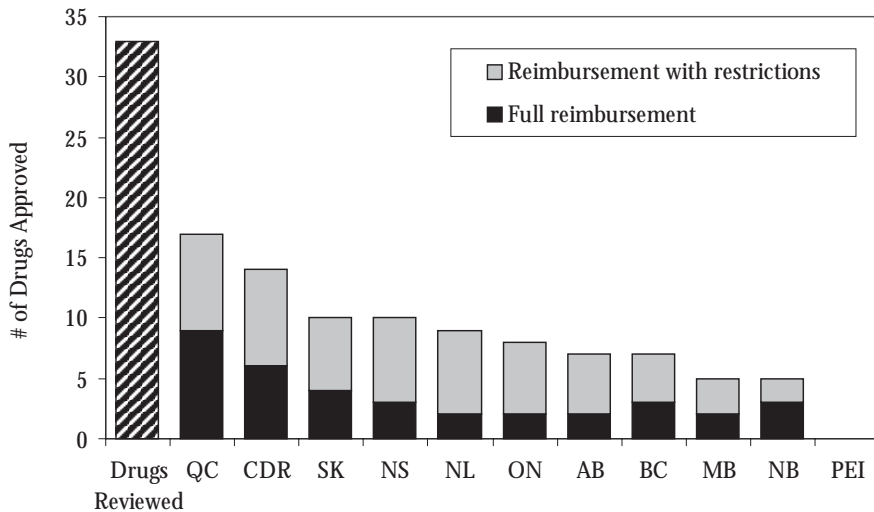
According to an EKOS Research Associates study commissioned by the Canadian Agency for Drugs and Technol-



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**Figure 1: Positive Drug Reimbursement Recommendations—
CDR & the Provinces, May 2004 to December 2005**



Source: Brogan Inc., 2006.

ogies in Health (CADTH), previously known as the Canadian Coordinating Office for Health Technology Assessment (CCOHTA), industry and advocacy groups feel the CDR has not improved the efficiency of the reimbursement process for new medicines. Rather, duplication and delays in the review process have increased, largely due to a lack of timely adoption of positive CDR recommendations on the part of the provinces. The CDR has not streamlined the drug approval process but rather created an unnecessary layer of decision-making that delays the inclusion of new drugs onto provincial formularies (EKOS, 2005).

Empirical research on the CDR's performance demonstrates both the low percentage of success in obtaining the agency's reimbursement approval, as well as the slow pace with which provinces list new medications, even when the drugs receive a positive recommendation from the CDR. Figure 1 shows the number of new drugs reviewed by CDR between May 2004 and December 31, 2005 compared to the number of

drugs approved by the CDR and subsequently adopted for reimbursement in the provinces. The CDR and the provincial bars are stacked to show the number of drugs approved for full listing, or automatic reimbursement compared to those approved with restrictions that require a doctor's application and provincial pre-approval before a prescribed drug can be eligible for reimbursement.

A total of 33 new drugs were reviewed by the CDR. Of these only 14, or 42 percent, received positive reimbursement recommendations from the agency, (Brogan, 2005) even though all the drugs considered had already been approved by Health Canada as safe for use by patients. Furthermore, more than half of these (8) were approved only with restrictions on automatic eligibility for reimbursement.

Of the 42 percent of drugs that were positively recommended by the CDR for either full listing or restricted reimbursement, many fewer were actually accepted for reimbursement by provincial governments. The data show that

Saskatchewan and Nova Scotia listed for reimbursement only 10 of the 14 drugs eventually approved by the CDR, which is only 30 percent of the 33 drugs originally reviewed by the CDR. Newfoundland listed 9 and Ontario 8 of the 14 CDR-approved drugs, or 27 percent and 24 percent respectively of the total number of drugs reviewed by the agency. Alberta and British Columbia each listed 7 of the CDR approvals or 21 percent of the drugs reviewed, while Manitoba and New Brunswick each listed 5 of the positive recommendations from CDR or 15 percent of the drugs reviewed (Brogan, 2005). PEI did not list any of the new medications reviewed by the CDR (Brogan, 2005). Interestingly, Quebec, the only province not participating in the CDR process, demonstrated the highest level of reimbursement between May 2004 and December 31, 2005 approving 17 (or 52 percent) of the drugs reviewed by the CDR (Brogan, 2005).

Of the small number of drugs that were approved for reimbursement by the provinces, many were approved with restrictions that seriously limit their market access. Figure 1 shows that restricted approvals outnumbered full listings for reimbursement in 8 of the 9 provinces participating in the CDR.

No means no; yes means maybe ...

One fundamental flaw in the CDR's operation is that provincial and territorial drug plans are not bound by its recommendations. Although pharmaceutical manufacturers are only required to submit applications to one central body, the final decision on whether or not to list a new medication for public reimbursement ultimately lies with each individual province and territory, and provinces often conduct their own review of new chemical entities. The data show that between May 2004 and



December 31, 2005 British Columbia and Alberta each referred 3 CDR recommended drugs to their own provincial review agency for further consideration. Thus, although the CDR was intended to reduce duplication in the drug approval process, in practice the opposite has occurred. Provinces are replicating the review processes undertaken by the CDR and, in turn, choosing not to reimburse a number of the new medications that have been given positive listing recommendations by the CDR (Laudrum, 2005).

Industry officials and advocacy groups interviewed in the EKOS study contend that provinces and territories are very quick to accept negative reimbursement recommendations by the CDR but tend to delay adopting positive recommendations (EKOS, 2005).

Unsustainable public health expenditures, rationing, and governance

Some patient advocacy groups have argued that because of provincial budgetary restraints, governments are using the CDR to cover for decisions to ration access to new drugs (COPN, 2006). Previous Fraser Institute research confirms that provincial governments are facing unsustainable public health care costs due to the fundamentally flawed design of the medicare system (Skinner, 2005a) and that this is leading to decisions to restrict access to new medicines and other technologies in a misguided attempt at cost-containment (Skinner, 2005b).

Additionally, there is a governance problem related to the CDR. Prior to the CDR, there was variation in provincial government drug reimbursement policies, and patients and voters could hold governments accountable when

they became aware of more generous coverage in neighbouring provinces. By introducing a centralized CDR, governments can hide behind the advice of a non-governmental agency when it recommends against reimbursing a new drug, and ignore its advice when it recommends in favour of public reimbursement.

Reimbursement refusals

The refusal to reimburse a drug is a legitimate option for any responsible insurer in a private competitive market where insured patients can exercise choice if they are dissatisfied with the coverage decisions of their insurer, and where coverage decisions are constrained by their impact on the reputation of an insurer among consumers in the market. However, large public drug programs distort the market, and the impact of their reimbursement decisions can also have negative consequences in the private insurance market.

There are multiple publicly funded drug programs in each of the provinces and territories, as well as the federal government. These public programs account for 46 percent of all prescription drug spending and 38 percent of total spending on prescription and non-prescription drugs together in Canada (CIHI, 2006). Large public drug programs can theoretically preclude the possibility of private insurance options because few people can afford to pay the taxes to support public drug programs in addition to paying private insurance premiums. Therefore, many people are captive to the limited coverage offered by the public program.

The refusal of a large public drug program to reimburse certain drug products can also amount to a barrier to market access for some drug makers, which destroys the business case for

bringing new medicines to market in the first place. Canada represents only 2 percent of the global market for drugs (IMS Health Inc., 2006) and public drug programs account for about half the market for prescription drugs in the country (CIHI, 2006). Therefore, when a province decides not to reimburse a drug, it essentially blocks access for that product to half of an already small market. Doing so might reduce the size of the market to the point that it might not be feasible to incur the costs of introducing a product to the market at all under these conditions, especially if other public policies might be also making the market unattractive. For example, lengthy drug safety approvals can further delay market access, thus reducing the effective patent period left on a new drug, and price controls might reduce the profit potential once a drug finally makes it to market. In this way, market distortions caused by the reimbursement decisions of large public drug programs can have the effect of reducing access for everyone, not just the recipients of public drug benefits.

Recommendations

Instead of implementing new, centralized, unaccountable bureaucracies, governments should dramatically reduce the scope of public subsidies for health care that are causing distortions in the market and negative consequences for patient access to new medicines. Moving to a regulated competitive private market for health insurance like that in Switzerland (see Skinner, 2005b; and Nadeem Esmail's article later in this issue) would introduce the benefits of competitive markets while ensuring universal coverage of the population. Such a health insurance model would also be more comprehensive than Canada's current patchwork of public programs and would eliminate the incentives for governments to ration access to medicines.

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