

**CMA's Submission to the House of Commons
Standing Committee on Health**

Common Drug Review

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A healthy population...a vibrant medical profession
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The Canadian Medical Association (CMA) is the national voice of Canadian physicians. Founded in 1867, CMA's mission is to serve and unite the physicians of Canada and be the national advocate, in partnership with the people of Canada, for the highest standards of health and health care.

On behalf of its more than 65,000 members and the Canadian public, CMA performs a wide variety of functions, such as advocating health promotion and disease/injury prevention policies and strategies, advocating for access to quality health care, facilitating change within the medical profession, and providing leadership and guidance to physicians to help them influence, manage and adapt to changes in health care delivery.

The CMA is a voluntary professional organization representing the majority of Canada's physicians and comprising 12 provincial and territorial divisions and 45 national medical organizations.

Submission to House of Commons Standing Committee on Health Regarding the Common Drug Review

1) Introduction

The Canadian Medical Association represents more than 65,000 physicians in Canada; its mission is to serve and unite the physicians of Canada and to be the national advocate, in partnership with the people of Canada, for the highest standards of health and health care. In pursuit of this mission we are developing a growing body of policy on pharmaceutical issues. In November 2003, we presented to the House of Commons Standing Committee on Health during its study of prescription drug issues. In July 2006 CMA, along with four other national organizations representing patients, health professionals, health system managers and trustees, formed the Coalition for a Canadian Pharmaceutical Strategy and released a framework and principles that we believed should govern the development of pharmaceutical strategy in this country.

We understand that the current study of the Common Drug Review (CDR) is part of a larger, more comprehensive study of prescription drugs being contemplated by the House of Commons Standing Committee on Health. We look forward to assisting you with this study. In the meantime, we will note that the CDR is intimately linked to related issues such as catastrophic coverage and a national formulary, and will also briefly discuss these in our presentation.

Pharmaceuticals are important to the health of Canadians. For many patients prescription drugs have prevented serious disease, reduced hospital stays, replaced surgical treatment and improved their capacity to function productively in the community. Pharmaceuticals also offer health-care system benefits by reducing other costs such as hospital expenses and disability payments.

While prescription drugs offer significant benefits, expenditures on them are also growing faster than any other component of health care. It is realistic to expect that the role of prescription drugs in health care will continue to increase and that as a result government expenditures on them will rise accordingly. As patients become increasingly knowledgeable and politically aware, they will continue to expect and demand access to an expanded range of prescription drugs.

CMA believes that any pharmaceutical strategy should be predicated on two pre-eminent principles, which are in keeping with longstanding Canadian values:

- All Canadians should have access to safe and effective prescription drugs; and
- No Canadian should be deprived of medically necessary drugs because of inability to pay.

Whether the CDR serves to further these goals has been a matter of vigorous debate. Federal and provincial representatives have told the House of Commons Committee that the CDR is meeting their needs and has in some cases provided them with a higher-quality review than they could have achieved on their own. On the other hand, patient groups have charged that the CDR is an unnecessary layer of bureaucracy and a barrier between them and potentially life-saving new therapies. It is possible, if not probable, that reforms to the CDR may never completely eliminate the tension between these two viewpoints.

We understand the frustration of patients and their advocates when the CDR recommends against public reimbursement or even more, when the CDR approves a drug but individual provinces refuse to include that drug on their formularies. In both these cases, sustainability of the health care system is an important and valid consideration. It would be unfortunate if our limited health care dollars, which might otherwise have been spent on disease treatment or prevention strategies of proven effectiveness, went instead to funding expensive drugs which ultimately proved no more beneficial to patients than others which cost much less.

2) General principles regarding drug review

The process of reviewing drugs for inclusion in public formularies did not begin with the CDR. Before it was created, each federal and provincial formulary conducted its own review. Without the CDR, separate reviews would still be taking place. To dismantle the review process entirely would be unacceptable, both economically and politically.

Within the context of an overarching goal to enhance access to medically required pharmaceuticals to the extent that they are needed, the primary purpose of a drug review process should be to help ensure access to prescription drugs for which evidence indicates safety and effectiveness in the treatment, management and prevention of disease, and/or significant benefits in quality of life. To help ensure that it achieves this purpose, we believe the following principles should apply to drug review in Canada:

- The review process should be **impartial** and founded on the best available scientific evidence.
- The primary criteria for inclusion in a formulary should be whether the drug **improves health outcomes**, and **offers an improvement** over products currently on the market.
- The review process should also incorporate evaluation of the drug's **cost-effectiveness**.
- Drugs should be evaluated not in isolation but **as an integral part of the health care continuum**. The review should consider:
 - A drug's **impact on overall health care utilization**. If a drug reduces a patient's hospital stay, helps an otherwise disabled patient return to work, or replaces other costlier or more invasive therapies, this should be considered in evaluating its overall cost-effectiveness.
 - **Alternatives to the drug under review**. The review should compare a drug's performance to other drugs in the same class, and to available non-drug therapies.
- The review process should be **flexible**, taking into account the unique needs and therapeutic

outcomes of individual patients, and the expertise of physicians in determining which drugs are best for their patients.

- The review process should be **open and transparent**. We support the CDR's intent to publish the rationales for its decisions, including lay-language versions.
- CDR findings are a valuable source of information on the safety and effectiveness of the drugs physicians prescribe. As such, they should be **communicated to caregivers and patients** as part of an ongoing strategy to encourage best practices in prescribing.
- **Meaningful participation by patients and health professionals** should be part of the review process; we note with approval the expansion of the Canadian Expert Drug Advisory Committee to include members of the public. We also suggest that the CDR experiment with open fora and other means of obtaining public input.
- **A process for appealing the review's decisions** should be established.
- **Ongoing evaluation** of the review process should be required. We note that the CDR has already undergone an evaluation, and is planning to implement some of the key recommendations. Impartial evaluations should continue to take place, to assess whether the CDR is having a positive impact on the health of Canadians and of their health care system.

3) The Larger Picture

The Common Drug Review does not exist in isolation. As the Coalition for a Canadian Pharmaceutical Strategy – of which CMA is a member - stressed in its 2006 statement, the elements of a comprehensive Canadian pharmaceutical strategy are interdependent and should be developed concurrently to ensure that the strategy is coherent and holistic. The CDR is interlinked with other issues concerning access to health care generally and to prescription drugs more specifically, and we suggest that the Committee also consider the following issues:

- a) ***Drugs for Rare Disorders.*** One controversy surrounding the CDR is that its approval rates are low for drugs for very rare disorders, many of which are first-in-class. One reason may be the cost of these drugs, which is often extremely high. It is also alleged that the Canadian Expert Drug Advisory Committee's (CEDAC) current review standards, which place a high value on large-sample clinical trials, are unable to adequately capture the value of these drugs.

It has been recommended that more drugs for rare disorders be approved based on interim targets or surrogate endpoints. The ultimate measure of a drug's effectiveness is its clinical endpoint; this should not be forgotten in any process of drug approval. This issue merits closer consideration, as do all issues related to drugs for rare disorders. CMA recommends that Canada develop a policy on drugs for rare disorders, which:

- Encourages their development;
- Evaluates their effectiveness; and
- Ensures that all patients who might benefit have reasonable access to them.

- b) ***Common Formulary.*** CMA recommends that Canada's governments consider the

possibility of establishing a pan-Canadian formulary. Canadian patients need a national standard; 18 different levels of coverage is not acceptable. Should the CDR form the basis of this formulary? That would depend on whether evaluation proves that the CDR is the most effective vehicle.

We do believe that cost control, though not the primary function of a pan-Canadian formulary, is a valid system concern. If two drugs in the same class are equally effective, it is reasonable to expect that the less expensive drug should be preferentially covered and/or prescribed. On the other hand, a pan-Canadian formulary should be flexible. It should include a process to allow patients access to off-formulary drugs if in the opinion of the attending physician the recommended product is not the right choice for them. This process should be designed so as to minimize the administrative burden on health professionals.

- c) ***Catastrophic Drug Coverage.*** It is now generally accepted that a pan-Canadian catastrophic drug program is needed. The point of discussion now is what type of program should be put in place. To ensure that Canadians can access the drugs they need, regardless of where they live or how much they earn, CMA recommends that federal, provincial and territorial governments, in collaboration with private insurers, assess the drug needs of Canadians, particularly those who are uninsured or under-insured, and agree on an option for providing equitable and comprehensive prescription drug coverage. As a starting point, CMA has recommended that governments give priority to a national pharmacare program to provide necessary drugs for all Canadian children and youth.

Conclusion

In principle, CMA believes that a process for reviewing prescription drugs for their clinical effectiveness and cost-effectiveness can contribute to improving the health of Canada's patients and our health care system. The value of the CDR will be determined by how well it performs this function.