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Re: Developing a Drug Supply Network and an Export Restriction Scheme” and “Requiring a Patient-Practitioner Relationship as a Condition of Sale of Prescription Drugs in Canada

To whom it may concern:

On behalf of the Canadian Medical Association (CMA) I would like to respond to Health Canada's papers, released on October 7, 2005, “Developing a Drug Supply Network and an Export Restriction Scheme” and “Requiring a Patient-Practitioner Relationship as a Condition of Sale of Prescription Drugs in Canada,” which invite discussion on the Minister of Health's June 29, 2005 proposals to control cross-border pharmacy and ensure that Canadians have a continued supply of prescription drugs.

The CMA agrees that Canadians must have a supply of drugs adequate to meet their needs. Currently the most serious threat to this supply appears to be the legislative proposals, currently before the United States Congress, that would allow Americans to purchase Canadian drugs in bulk. Proactive measures to protect our drug supplies are warranted to guard against this threat.

In summary, our response to the Minister's three proposals is as follows:

- **Supply monitoring network:** We support supply monitoring as a necessary activity.
- **Export restrictions:** We believe that all Canadian drugs should be subject to export restriction, and the Government of Canada should grant itself the power to enact bans on export as needed.
- **Requiring a patient-physician relationship:** We do not believe this proposal can be enforced, or that it will contribute materially to securing an adequate drug supply for Canada. We recommend that Health Canada instead support the activities of medical and pharmacy regulatory authorities in ensuring that prescribing behaviour is appropriate.

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**Our detailed comments on the proposals are below.**

## **1) Drug supply monitoring system**

The CMA strongly supports the development of a comprehensive strategy and an adequately resourced system for monitoring domestic drug supply. Canada needs such a system to identify shortages and respond quickly to remedy them, and to ensure that policy and regulatory decisions are founded on accurate and reliable knowledge. We recommend that more careful consideration be given to the most effective design and functioning for a supply-monitoring network. It is our understanding that manufacturers and distributors currently monitor supply of their own products. Ideally, a mechanism should be found to unite these individual activities into a robust and effective network without creating a costly parallel effort. Specific comments follow:

- **2.1 Gathering Drug Shortage Information:** Voluntary reporting is a preferred approach. In designing a voluntary scheme, it should be taken into account that soliciting reports from a wide variety of players, including the public, may result in a flood of anecdotal, poorly documented reports that will require expert analysis to verify and put into context. Regardless of who is solicited for shortage reports, the reporting process should be made as clear, simple and user-friendly as possible, and all stakeholders who might be in a position to make reports should be made aware of its existence.
- **2.2 Assessment and Verification:** We agree that a baseline of drug inventory data is required, as are benchmarks for what constitutes an appropriate drug supply for Canada. These should be established as a first step, before the implementation of a voluntary reporting scheme.
- **2.3 Communication of Information:** While physicians may seldom be in a position to report drug shortages, it is essential that they be informed at once when a shortage exists, and how long it is expected to last. Guidance for physicians on measures they might take while the shortage lasts (for example, other drugs they might prescribe as substitutes) is highly desirable. Medical associations could help Health Canada communicate this information to their members.

The paper makes reference to Health Canada's preference for collaboration in this endeavour "without assuming responsibility for becoming the primary source of information for Canadians on drug shortages or for resolving all reported drug shortages." This is not appropriate. Leadership responsibilities and public expectations preclude the Minister from shirking responsibility for these functions. Accountability for such a complex network must be vested in one authority, i.e. Health Canada.

- **2.4 Response measures:** Though the paper lists response capacity as an element of drug supply monitoring, it does not contain practical suggestions for responding in the event of a shortage. This is a crucial element and needs to be developed. There is no point in monitoring supply without a plan for managing shortages.

## 2) Export Restriction

CMA supports this proposal. The power to restrict export of drugs offers Canada its best chance of protection should the U.S. legalize bulk purchasing. This power should be strong and far-reaching. Serious consideration should be given to the June 2005 motion from the House Standing Committee on Health motion to ban all bulk exports of prescription drugs. Specific comments follow:

- **3.4.2 Drug products deemed necessary for human health:** The discussion paper proposes to restrict export only under certain circumstances, e.g. if the drug is deemed necessary to human health, and to establish criteria to determine whether a drug meets this condition. **All** prescription drugs are necessary for human health; certainly those who are taking them consider them so. For equity's sake - and also because establishing and abiding by criteria may prove impossible - we believe every prescription drug in Canada should be considered a candidate for export restriction.
- **3.4.3 Implications for patient care:** We acknowledge that in many cases, other effective therapies can be substituted for drugs in short supply. Many physicians will make these substitutions as needed; but they must first be made aware of the shortages. Physicians must be advised of available alternatives if an unavoidable shortage exists; however, we caution that the existence of alternatives should not be used as justification for not taking action if a drug is in shortage. The final decision as to the most appropriate available therapy should remain a matter to be determined by the patient and physician and consultation.

## 3) Requiring a Patient-Practitioner Relationship

The Minister has expressed his desire to ensure that physicians maintain high ethical and professional prescribing standards. The CMA shares this desire. As discussed in the attached CMA Statement on Internet Prescribing (Appendix I), we hold that prescriptions should be written in the context of an appropriate patient-physician relationship. However, we do not accept that the proposed option of requiring an established patient-practitioner relationship for every prescription issued in Canada will have a meaningful effect on ensuring adequate drug supply, for the following reasons:

- **The proposal does not target the real problem.** Most current drug shortages are caused by raw material shortages, inventory management disruptions, unexpected spikes in demand, and other conditions that have nothing to do with the clinical encounter. More important, targeting the patient-practitioner relationship will not protect Canadians from the impact of U.S. bulk purchasing should legislation pass Congress.
- **Prescribing outside the context of the patient-physician relationship is already subject to sanction by medical regulatory authorities.** The vast majorities of Canada's physicians conduct themselves ethically and only prescribe for patients in the context of a professional relationship. Those who do not, contravene both the CMA's policy and the standards of practice for provincial/territorial regulatory Colleges of Physicians and Surgeons. These regulatory authorities, and the long and effective tradition of professional self-regulation they represent, should be respected and supported.

- **The proposal is burdensome and will be difficult to enforce.** The proposal places the onus for evaluating the patient-practitioner relationship on pharmacists. While pharmacists are required, as part of their professional responsibility, to ensure that a prescription has been written by a physician licensed to practice in that jurisdiction, they are not customarily familiar with the details of the interaction leading up to the prescription. Requiring them to formally screen for this will impose a heavy administrative burden, and will compromise patient confidentiality.

In addition, compliance monitoring by Health Canada will be complex, if feasible at all. For example, despite the Minister's recent comment that prescriptions "can only be signed by a medical practitioner who actually sees and treats the patient in question", it is generally accepted that perfectly legitimate prescribing can take place without a face-to-face encounter (e.g. through telemedicine) or an "ongoing" patient-physician relationship (e.g. in an emergency). While it is easy to detect flagrant infractions (such as a hundred prescriptions a day written for American patients by the same Canadian doctor) it will be much harder to precisely identify the boundary between what is legitimate prescribing behaviour and what is not. Many provincial regulatory authorities have already developed definitions of the patient-physician relationship, which Health Canada includes in the discussion document. It is unlikely that Health Canada will be able to improve on them.

- **Determining an appropriate relationship may be more appropriately a provincial or territorial responsibility.** The patient-physician interaction, like other scope-of-practice issues, is regulated at the provincial level. We do not believe the cross-border prescribing problem justifies Health Canada's overarching federal-level intervention.

In conclusion, we support further exploration of the supply-monitoring and export-restriction options, and believe that existing medical and pharmaceutical regulatory authorities should be respected and supported in enforcing appropriate prescribing behaviour.

We appreciate the opportunity to comment on your proposals. We look forward to further opportunities for input during the development of legislation.

Yours truly,



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