

## RATIONALE FOR AN EXEMPTION UNDER SECTION 56 OF THE CDSA FOR TRAVELLERS WHO ARE IMPORTING OR EXPORTING PRESCRIPTION DRUG PRODUCTS CONTAINING A NARCOTIC OR A CONTROLLED DRUG

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### ISSUE

There is no provision in the Regulations under the *Controlled Drugs and Substances Act* (CDSA) which allow travellers to import or export a narcotic or controlled drug for their ongoing medical treatment. As a consequence, these individuals may be prevented from entering or leaving the country with these medications, their medications may be seized, and possible legal action could be taken.

### PURPOSE

To permit Canadians and visitors to Canada to export or import prescription drug products containing a narcotic or controlled drug for their own continued medical treatment or the medical treatment of a person for whom they are responsible and who is traveling with them. This exemption is an interim measure to allow for the development of Regulations that will authorize the import/export of narcotic or controlled drugs by travellers.

### BACKGROUND

The *Controlled Drugs and Substances Act* (CDSA) provides a framework for the control of import, export, production, distribution and use of substances that can alter mental processes and that may produce harm to health and to society when distributed or used without supervision. The CDSA is the legislative framework which allows Canada to meet its obligations under the three United Nations Drug Controls Conventions to which it is a signatory<sup>1</sup>.

Section 6 of the CDSA prohibits the import and export of controlled substances and precursors except as authorized under the Regulations to the Act. In the newer Regulations developed under the Act, specifically the *Benzodiazepines and Other Targeted Substances Regulations* and the *Precursor Control Regulations* (PCR), there are provisions that permit individuals to import or export targeted substances and precursors for medical purposes under the prescribed circumstances<sup>2</sup>. Similar provisions do not presently exist in the *Narcotic Control Regulations* (NCR) and the *Food and Drugs Regulations* (FDR) Part G, *Controlled Drugs*, regarding the importation or exportation of products containing a narcotic or controlled drug. Pursuant to section 8 of the NCR and section G.02.001 of Part G to the FDR, only a licensed dealer can import or export a narcotic, and a permit is required for each shipment.

In spite of the foregoing, it has generally been the practice, on a compassionate basis and under certain circumstances, to permit individuals to import or export a quantity of up to the lesser of a 30-day supply or a single course of treatment of prescription drugs containing a narcotic or a controlled drug to avoid interrupting medically necessary treatment. The lack of a clear policies based on explicit regulatory authority to support this practice has resulted in several problems for travellers into and out

of Canada, Health Canada, and the Canadian Border Services Agency (CBSA).

Health Canada has initiated the development of Regulations that will give clear authority and direction as to the circumstances under which narcotic and controlled drugs can be imported by travellers for medical purposes. These Regulations will take into consideration the *International Guidelines for National Regulations Concerning Travellers Under Treatment with Internationally Controlled Drugs* (April 2003) developed under the auspices of the Commission of Narcotic Drugs of the Economic and Social Council of the United Nations<sup>3</sup>; as well as, will bring Canada to the same level as other countries (eg. US). The development of the Regulations will follow the Canadian Regulatory process and will include the pre-publication of the proposed regulations in *Canada Gazette*, Part I, followed by an opportunity for all interested parties to submit comments on the proposal to Health Canada.<sup>4</sup>

As the proposed Regulations would not come into force before the end of 2006, Health Canada is exercising the authority granted to the Minister under section 56 of the CDSA to issue an interim exemption that will permit Canadians and visitors to Canada to carry their medications across Canadian borders subject to the terms and conditions set out in the exemption.

## **SECTION 56 EXEMPTION**

**Section 56 of the CDSA** states that

The Minister may, on such terms and conditions as the Minister deems necessary, exempt any person or class of persons or any controlled substance or precursor or any class thereof from the application of all or any of the provisions of this Act or the regulations if, in the opinion of the Minister, the exemption is necessary for a medical or scientific purpose or is otherwise in the public interest.

In order to permit individuals carrying products containing a narcotic or controlled drug across Canadian borders, all relevant prohibitions and restrictions in the Act and the Regulations must be addressed. This interim class exemption for travelers for medical purposes, issued pursuant to s.56 of the CDSA, will exempt individuals from the prohibition on import and export in section 6 of the CDSA and from the requirements of sections section 8 of the NCR and section G.02.001 of Part G to the FDR, subject to the terms and conditions set out in the exemption included at the end of this document. Import or export except as provided for by the Regulations to the CDSA and this exemption is unlawful and may be subject to enforcement action.

The terms and conditions set out in this exemption which define the circumstances under which the import or export of narcotic or controlled drugs by travellers is permitted, will be reviewed as the proposed Regulations are developed. If deemed necessary, this exemption will be amended. The requirements of the new Regulations may differ from those set out in the exemption based on further analysis and consultation.

This exemption will remain in effect until Regulations under the CDSA, permitting the import and export of specific narcotic or controlled drugs by travellers, come into force or this exemption is

otherwise revised or revoked.

To give effect to this class exemption, Health Canada will give notice to the Canadian Border Services Agency and will post the exemption on the Office of Controlled Substances Website at [http://www.hc-sc.gc.ca/dhp-mps/substancontrol/pol/pol-docs/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/substancontrol/pol/pol-docs/index_e.html).

Questions may be directed to:

The Office of Controlled Substances  
Drug Strategy and Controlled Substances Programme  
Healthy Environments and Consumer Safety Branch  
Health Canada  
Tel: (613) 952-2177  
Fax: (613) 946-4224

August 31, 2005

ENDNOTES:

1. The *Single Convention on Narcotic Drugs*, 1961, as amended by the 1972 Protocol; the *Convention on Psychotropic Substances*, 1971; the *United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances*, 1988
2. Sections 68 and 69 of the *Benzodiazepines and Other Targeted Substances Regulations*; Section 11 of the *Precursor Control Regulations* in respect of ephedra, ephedrine, pseudoephedrine, ergotamine and ergometrine
3. Provisions regarding travellers under medical treatment with drugs containing narcotic drugs and psychotropic substances under international control. CND Res.46/6. [http://www.incb.org/incb/guidelines\\_travellers.html](http://www.incb.org/incb/guidelines_travellers.html)
4. Regulatory Process Guide: Developing a Regulatory Proposal and Seeking its Approval [http://www.pco-bcp.gc.ca/raoics-srdc/default.asp?Language=E&Page=Publications&doc=regguide/regguide\\_e.htm](http://www.pco-bcp.gc.ca/raoics-srdc/default.asp?Language=E&Page=Publications&doc=regguide/regguide_e.htm)