



CANADIAN
PHARMACISTS
ASSOCIATION

ASSOCIATION DES
PHARMACIENS
DU CANADA

CPHA Statement on International Prescription Services and Distance Provision of Pharmaceuticals

INTRODUCTION

Prescription drugs are an essential component of the health care system. Pharmacists play a key role in ensuring that patients use their medications safely and appropriately to improve their quality of life.

Calls are increasing for an expanded role for pharmacists within the Canadian health care system. The Romanow Commission Report on the Future of Health Care in Canada, provincial reports and the First Ministers Accord of February 2003 all call for better medication management for Canadians. The need for pharmacists as part of the primary health care team is recognized, particularly with respect to managing medications in chronic diseases and in home care.

There has been rapid growth in recent years of online pharmacy services in Canada and globally. Pharmacy services available to the public through the Internet include arranging for the dispensing of prescription drugs, the sale of nonprescription medications and other products, online requests for prescription refills, and the provision of drug and health-related information.

Increasingly, some Canadian pharmacies are using the Internet to market their services for dispensing of prescription medications for export to citizens of the United States and other countries. Some others use a “storefront” intermediary or other means to market their services. Much of this growth is driven by the difference in the price of pharmaceuticals between Canada and the US, coupled with the fact that many American seniors do not have a comprehensive drug benefits plan.

There is potential for the existing public protection safety net to be bypassed by illegitimate operators or unaccredited pharmacies, or by licensed pharmacies that do not comply with practice standards and regulation. Such practices can undermine the drug regulatory systems established to protect consumers and could expose the public to improper prescribing, monitoring or dispensing of pharmaceuticals, or to harmful or ineffective drugs. Exportation of Canadian pharmaceuticals to the United States contravenes US federal and state laws.

This issue has received extensive media coverage and is of interest to government agencies, pharmacy and medical organizations, regulatory authorities and the pharmaceutical industry.

Dispensing of pharmaceuticals that does not meet legal and regulatory requirements, as well as ethical and patient care expectations, might adversely affect the view of the public and other health care providers regarding the professional integrity of pharmacists. It might also negatively affect the ability of the profession to respond to government and societal expectations for a greater role for pharmacists in primary health care and medication management.

This statement focuses on international prescription services provided to residents of foreign countries where prescription drugs are dispensed and delivered to patients (or their agents) who do not physically attend that pharmacy. Further related information, including regulation of Internet pharmacy sites, potential benefits, risks/concerns, and preferred conditions for the distant provision of pharmaceuticals can be found in appendices I, II, III and IV respectively.

CPHA POSITION ON INTERNATIONAL PRESCRIPTION SERVICES AND DISTANCE PROVISION OF PHARMACEUTICALS

1. The health and safety of patients is the overriding principle upon which this position is based. A relationship between the patient and pharmacist is essential for medication management and to ensure that patients understand how to use their medications safely and effectively. Pharmacists need to practise in a setting that allows them to assess and advise on the appropriate, effective and safe use of pharmaceuticals based on the patient's medication history and other relevant information.
2. The Canadian Pharmacists Association believes that face-to-face communication between patients and pharmacists builds a relationship that is critical to the optimal management of drug therapy and is a key element of the expanded role of pharmacists on the primary health care team.
3. The Canadian Pharmacists Association endorses the position that all pharmacies operating in Canada, including those that provide distance dispensing or offer prescription drug services over the Internet, must comply with federal/provincial/territorial legal and regulatory requirements as well as meet established standards of practice for patient care and dispensing.
4. The Canadian Pharmacists Association recognizes that the distance provision of pharmacy services from licensed pharmacists that comply with standards of practice for patient care and meet regulatory requirements benefits Canadians and provide opportunities for patients to receive pharmacy services from a distance, particularly those who live in rural and remote areas with limited access to a pharmacy. The Association's position on conditions that must be met for the distance provision of pharmaceuticals is detailed in Appendix IV.
5. The Canadian Pharmacists Association opposes international prescription services where the patient does not have a relationship with the pharmacist and the prescriber, because patient care may be compromised. CPhA also opposes international prescription services if such services violate laws in the jurisdiction that the patient resides in.

RECOMMENDATIONS FOR FUTURE WORK

1. That the Canadian Pharmacists Association (CPhA) continue to work with the National Association of Pharmacy Regulatory Authorities (NAPRA), pharmacy and medical organizations and regulatory authorities, international pharmacy service associations, Health Canada, the United States Food and Drug Administration, the US National Association of Boards of Pharmacy (NABP), policing agencies and others, as appropriate, in initiatives designed to protect the consumer.
2. That CPhA support NAPRA's work to provide consumer protection by developing an identifying "seal of approval" and consumer awareness program for legitimate Canadian pharmacies offering pharmacy services via the Internet, in collaboration with the VIPPS (Verified Internet Pharmacy Practice Sites) program by the NABP.
3. That further work be done to develop standards and security for the electronic transmission of patient data, with respect to online transmission of prescriptions and other health information between prescribers and pharmacists.
4. That CPhA help pharmacists keep pace with future technology and health informatics innovations.

Appendix I:

REGULATION OF INTERNET PHARMACY SITES

In Canada, pharmacy practice is regulated provincially and territorially. In Canada, the National Association of Pharmacy Regulatory Authorities (NAPRA) has approved “Model Standards for Canadian Pharmacists Offering Pharmacy Services via the Internet” (November 2001; www.napra.org), and many provincial pharmacy regulatory authorities have or are developing positions. In general, these require that pharmacists provide professional services in accordance with established standards of practice. Presently, online prescribing or electronic transmission of prescriptions is not permitted.

NAPRA is working with the US National Association of Boards of Pharmacy (NABP) to provide better consumer protection by developing an identifying “seal of approval” program (based on the US VIPPS program – Verified Internet Pharmacy Practice Sites) and a consumer awareness program for legitimate Canadian Internet pharmacy sites. NABP has released a position paper on the importation of foreign prescription drugs (March 2003; www.nabp.net). NAPRA and NABP have issued a joint cross border communiqué regarding the international movement of prescription drugs between Canada and the US (May 2003; www.napra.org), which was endorsed by CPhA and the American Pharmacists Association (APhA).

The United States Food and Drug Administration (FDA) is concerned with the lack of control of so-called Internet pharmacy sites and is working to implement federal requirements (www.fda.gov/oc/buyonline). Of particular concern is the illegal sale of prescription drugs without a prescription, unapproved new drugs, health fraud and counterfeit medications. The FDA sends warning cyberletters to suspicious sites.

The FDA has laws preventing Americans from reimporting medications that have been manufactured in the US and imported back into the US. FDA’s personal use guidance also states that “medication cannot be imported into the US unless it is to treat a life threatening illness and the medication is not available in the US”. Nevertheless, US Customs Service officials often allow Americans to import up to 90 days’ supply of medications for personal use. Many US states require out-of-state pharmacies to register with state boards of pharmacy if they serve residents of that state.

Appendix II:

POTENTIAL BENEFITS OF ONLINE PHARMACY SERVICES

The Canadian Pharmacists Association recognizes that online pharmacy services may provide benefits to consumers, including:

- consumer access to drug and related health information, empowering them to take greater responsibility for their own health. Many online pharmacy sites have reliable health information and links to online medical libraries, government agencies and health associations. This information can be helpful when consulting with a pharmacist, physician or other health care provider about a disease or condition.
- convenience in obtaining information, products, services and price comparison, in particular for seniors, people with disabilities, or people who are home-bound or live in rural and remote areas.
- an opportunity for consumers to order products and contact a pharmacist from the privacy of their homes.

Appendix III:

POTENTIAL RISKS AND CONCERNS WITH PRESCRIPTION DRUG SERVICES OFFERED OVER THE INTERNET

The following concerns have been raised about Internet sites operating in Canada that offer prescription drug dispensing services, in particular those that dispense pharmaceuticals for export to the United States and other countries:

1. Some Internet sites operate illegally and services are not provided by accredited pharmacies. These bypass the comprehensive safety system of premarket drug approval, prescription requirements, patient assessment by a practitioner and pharmacy practice standards. People who purchase medications from the operators of such sites are at risk of adverse effects from inappropriately prescribed medications, drug interactions, contaminated, counterfeit or subpotent drugs, or unapproved drugs for which safety and efficacy have not been established.
2. Some pharmacies operating an Internet pharmacy service may not be in compliance with medical and pharmacy standards of practice. Purchasing medications over the Internet bypasses the opportunity for face-to-face consultation with a pharmacist, physician or other health care provider.
3. The drug distribution process may be compromised (e.g., bulk/stock bottles dispensed without safety caps, improper labelling, storage and handling).
4. Prescriptions are often faxed, and could be faxed to multiple online pharmacies, thereby increasing the potential for drug diversion and illicit drug use.
5. Internet pharmacies may not have complete profiles of patients' medications and allergies, limiting the ability for the pharmacist to monitor drug therapy, including drug interactions and allergies.
6. Some Internet pharmacies require that a patient or agent of the patient sign a waiver or release of any ethical or legal obligation of the pharmacist as a condition of providing a pharmaceutical service to the patient. Others require the signing of a "power of attorney", giving the pharmacy the ability to act as "the patient". Such practices may undermine accountability, which is a key element of the pharmacist-patient relationship.
7. Prescriptions might be issued by a Canadian physician based on prescription and medical information forwarded to them, without speaking to the patient or the foreign prescriber. Physicians may be remunerated for this either directly from the patient, from the pharmacy or through an intermediary. Medical regulatory agencies have informed their members that the practice of cosigning prescriptions without having examined the patient may be considered professional misconduct. Standards of good medical practice require that a physician should not prescribe unless he or she has an appropriate relationship with the patient to permit the physician to form a professional opinion that a prescription is required and appropriate.
8. Liability insurance may not cover such practices. The Canadian Medical Protective Association (CMPA) is a mutual defence organization for Canadian physicians. The CMPA has cautioned Canadian physicians about cosigning foreign prescriptions and warned of the potential for liability in the foreign jurisdiction resulting from an alleged doctor-patient relationship that could result from such action. In the event of an American or other foreign lawsuit a physician may not be eligible for help from the CMPA. CMPA advises its members not to participate in such activities.
9. Some provincial pharmacy regulations require that the pharmacist not contravene a law in the jurisdiction where the patient resides. Many of the US states have legislation that requires a pharmacist or the pharmacy to be licensed in the state to dispense drugs to its citizens and the FDA has indicated that the importation of prescription drugs is illegal.
10. The number of pharmacists dedicated to filling prescriptions and providing care to patients located outside Canada could impact the current shortage of pharmacists across Canada and negatively affect the provision of services to Canadian patients.

11. The privacy and confidentiality of financial and patient health information may be compromised on some sites.
12. There has been speculation that there may be short- and long-term implications for the cost of and access to medications in Canada.

Appendix IV:

CPHA'S POSITION ON PREFERRED CONDITIONS FOR THE DISTANCE PROVISION OF PHARMACEUTICALS

The position of the Canadian Pharmacists Association is that the following conditions must be met for the distance provision of pharmaceuticals, including those offered on the Internet:

1. Distance pharmacy services must be provided within the federal/provincial/territorial legal and regulatory framework for pharmacy practice. This includes standards of practice related to Schedule I, II* and III drugs (e.g., the pharmacist must ensure that the prescription is authentic, accurate, complete and appropriate, and effectively counsel patients about their prescription medications; the pharmacist must make the decision to sell Schedule II drug products; and must be available for consultation regarding Schedule III drugs). [* Note: international sales of codeine-containing analgesics may violate international narcotics control regulations and result in severe penalties].
2. Where a pharmacist does not have face-to-face communication with a patient, the pharmacist must ensure that he or she forms a relationship directly with the patient by other means. If a patient's health or disability makes it impossible for the pharmacist to form a relationship with the patient, the pharmacist must form the relationship with the patient's caregiver so that the patient receives the benefits of that relationship. The patient should be advised to consult a pharmacist, physician or other health care provider if the patient's interests would be better served by a face-to-face consultation.
3. A pharmacist must not be a party to or associate him- or herself with any arrangement in which a physician issues or co-signs a prescription and in which the physician receives compensation directly or indirectly from the pharmacy.
4. A pharmacist must not dispense a drug if he or she knows or should know that the prescriber has not complied with the prescriber's legal duties or required standards of practice in relation to that prescription.
5. A pharmacist must not request or require that a patient or agent of the patient sign a waiver or release of any ethical or legal obligation of the pharmacist as a condition of providing a pharmaceutical service to the client.
6. The pharmacist must ensure that drug and health care information provided on a pharmacy website is of a high professional standard. If specific recommendations are made, the pharmacist should ensure that the patient or caregiver receives the appropriate information about use, precautions, adverse effects, etc. Website information must not be in violation of federal or provincial laws regarding advertising.
7. The confidentiality and integrity of the patient's personal health and financial information must be protected. Patient data transmissions should be encrypted to prevent the possibility of access by the Internet service provider or any other unauthorized party.