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# Medical Marijuana

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## Background

In 2001 Canada became the first nation to implement a national policy allowing for the legal use and sale of marijuana for medicinal purposes. This policy made Canada the first health system in the world with a government-approved and funded supply of marijuana for medicinal purposes.<sup>1</sup> These regulations establish a framework to allow a compassionate use of marijuana by people who are suffering from serious illnesses and for whom conventional treatments are inappropriate or have been unsuccessful.<sup>2</sup> Patients who qualify under the current policy fall into three categories:

- Have a terminal illness and are expected to pass away within 12 months (Category 1)
- Suffer from specific symptoms associated with certain medical conditions, namely multiple sclerosis, spinal cord injury, spinal cord disease, cancer, AIDS/HIV infection, severe arthritis and epilepsy (Category 2)
- Have symptoms associated with a serious medical condition or conditions, other than those described above (Category 3)

Eligible patients must submit an application in writing to Health Canada for authorization to possess medical marijuana. Depending on the category, a declaration from one or two medical specialists may be required, requesting authorization for the patient to possess

marijuana for medical purposes.<sup>3</sup> Once an application is approved, patients are permitted to buy government-certified marijuana from a Health Canada licensed plant. The licensed plant ships the standardized research grade marijuana either directly to physicians for distribution to their patients with Health Canada permits or via direct delivery to the patient.<sup>4</sup> The distribution system in place currently does not involve pharmacists or provide any pharmaceutical care for the patient.

A notice of change by Health Canada is anticipated in 2004 regarding medical marijuana. This change may include:

- new regulations surrounding the distribution of the government certified product
- the need for pharmaceutical care
- the need for further research to occur

If regulatory changes do take place, the following could occur:

- simplification of the permit application process
- shifting responsibility from the physician to the patient
- development of a pilot program allowing for the distribution of the government certified medical marijuana to eligible patients by pharmacists<sup>5</sup>

*continued...*

position statement

Most drugs that are approved for use in Canada have demonstrated sufficient evidence of safety, efficacy and quality and have been rigorously assessed by the Therapeutic Products Programme, the regulator drug products in Health Canada. This assessment is conducted to verify that the benefits of the product outweigh the risks as presented by the scientific medical evidence.<sup>6</sup> A notice of compliance is issued once the product is approved.

Medical marijuana has not been subjected to the same rigorous product testing as other medicinal products. There have been some questions raised about the quality of the government certified medical marijuana product by patients who are certified to possess and use it.

If Health Canada regulations change, allowing pharmacists to distribute medical marijuana, pharmacists could play an integral role in the safe distribution of the government certified medical marijuana as they already do for a wide range of other pharmaceutical products.

Pharmacists already have experience dispensing synthetic cannabinoids. At the present time in Canada, there are two approved drug products allowed to be dispensed by prescription that contain active ingredients derived from marijuana. One of these drugs is Dronabinol (Marinol®) containing chemically synthesized THC (THC is delta-9 tetrahydrocannabinol, the main psychoactive constituent in marijuana),<sup>7</sup> and the second drug is a synthetic cannabinoid, Nabilone (Cesamet®). Both drug products are used for the treatment and management of severe nausea and vomiting associated with cancer chemotherapy.<sup>8,9</sup>

Pharmacists are actively involved in assisting patients and healthcare providers with disease and medication management and health outcome monitoring. One concern of health care professionals is the respiratory and carcinogenic effects of tars when inhaling smoked marijuana. This makes a non-smoked route of administration for medical marijuana the preferred route. The College of Pharmacists of B.C. in their professional practice policy on medical marijuana supports patient access to standardized medical

marijuana through pharmacies, however discourages the smoked route for medical marijuana but encourages research that includes alternative delivery systems.<sup>10</sup>

Many pharmacists have the knowledge and ability to create and prepare specialized dosage forms of medications. These specially trained pharmacists could play a key role in supplying patients with alternate, non-smoked routes of administration for the use of government certified medical marijuana. Potential alternate dosage forms could include liquids, tinctures, sublingual sprays, suppositories, patches, oral capsules or the use of vaporizers.<sup>11</sup>

There is limited health professional expertise and experience in Canada surrounding the use and distribution of government certified medical marijuana. As a result, a comprehensive program would have to be established by Health Canada and key stakeholder groups. The program would focus on the regulations and economic issues surrounding the distribution of the government certified medical marijuana through pharmacy outlets. Examples of areas needing to be addressed include:

- regulatory processes and procedures
- appropriate labeling and record keeping requirements
- educational, counseling and reference materials for use by pharmacists, patients and other healthcare providers
- economic issues — reimbursement for patients from third party payers, adequate compensation for pharmacists professional services, source(s) of financial assistance to develop and implement program(s)

A training program leading to the accreditation of pharmacists wishing to dispense government certified medical marijuana would have to be developed and implemented. This program could be modeled after the successful B.C. Emergency Contraceptive Pill (ECP) program administered by the British Columbia Pharmacy Association in conjunction with the College of Pharmacists of B.C. It would incorporate a training and certification process for pharmacists who are interested in voluntarily participating in a program to dispense government certified medical marijuana.

A steering committee to develop and implement a pilot project for the distribution of government certified medical marijuana through B.C. pharmacies, is in the process of being created. The committee will include pharmacists and other key stakeholders involved in the process. Guidelines resulting from the work of the steering committee will form the basis for any B.C. pharmacies interested in participating in the medical marijuana pilot project.<sup>1,2</sup>

## BCPhA Position

- The BCPhA supports further discussions with Health Canada and other key stakeholders for the purposes of establishing a pilot project for the distribution of government certified medical marijuana through B.C. community pharmacies.
- The BCPhA supports the development of a steering committee for the purposes of developing and implementing a pilot project allowing for the distribution of government certified medical marijuana through B.C. community pharmacies and agrees to participate on this committee.
- The BCPhA believes that pharmacists participating in the medical marijuana pilot project must be appropriately recognized and compensated for their professional services.

## References

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