



A Regulatory Approach to Medical Marihuana – What Has Canada Done?

Carole Bouchard
Executive Director, NAPRA



Table of Contents

- Canadian Situation
- Legislative Authority
- Legal Challenges
- Who Can Apply?
- Supply Options
- Government Supply
- Operational Issues
- Way Forward



Canadian's Situation

- Access to marihuana for medical purposes began in 1999
- 10 years later – over 4000 individuals are authorized to possess dried marihuana
- Of those individuals approximately
 - 60% produce their own supply of marihuana
 - 10% designate someone else to produce marihuana on their behalf
 - 20% purchase dried marihuana from the Government marihuana supply
 - 10% obtain dried marihuana from an unknown source



Legislative Authority

- *Controlled Drugs and Substances Act* – Ministerial exemption used in 1999 to allow individuals to possess and cultivate marihuana for medical purposes
- *Marihuana Medical Access Regulations (MMAR)* came into force on July 30, 2001
 - contain three main components
 - Authorizations to possess dried marihuana
 - Licences to produce
 - Access to supply of marihuana (dried or seeds)

Illegal possession of marihuana is still a criminal offence



Legal Challenges

Charter of Rights and Freedoms forms the basis of many court cases

- Rulings that had significant impact on the evolution of the program
 - *R.V. Parker*, July 2000 – found the prohibition on the possession of marihuana unconstitutional because of the discretionary way in which individuals were authorized (Section 56)
 - *Hitzig et al*, October 2003 – absence of a legal supply of marihuana found to be inconsistent with the principle of fundamental justice
 - *Sfetkopoulos, Dora et al*, January and October 2008 – Request to appeal decision at the Supreme Court of Canada dismissed in April 2009; invalidation of one section of the regulations that limited the one grower to one user ratio took effect



Who Can Apply?

- Individuals with symptoms being treated within the context of providing compassionate end-of-life care or symptoms associated with certain medical conditions as listed in the regulations (e.g. severe pain and/or persistent muscle spasms from multiple sclerosis) and, have a declaration from a medical practitioner to support application
- Individuals with other debilitating symptoms if a medical specialist confirms the diagnosis and that conventional treatments have failed or judged inappropriate to relieve symptoms



Options For Supply?

- A Personal Use Production Licence (grow yourself)
- A Designated Person Production Licence (designate someone to grow on your behalf)
 - With both options marihuana seeds can be purchased from the government (\$20 per 30-seed package)

Number of plants is directly linked with the recommended daily dosage.

- A supply of dried marihuana from the Government (since 2003 it is possible to buy dried marihuana at the cost of \$5/gram)



Government Supply

- Produced by Prairie Plant Systems Inc. under a contract with Health Canada
- Use a selected line comprising of mature flowering heads of female *Cannabis sativa L. Indica* plants
- All aspects of the production follow strict and controlled conditions to ensure product consistency
- Marihuana is irradiated and undergoes testing for THC level, microbial, mycotoxin and metal contents, including heavy metals.
- Dried marihuana provided has a THC level of $12.5 \pm 2\%$ and is packaged into resealable, plastic foiled-lines pouches and labelled



Operational Issues

- Product – smoked form, not approved like other drugs, minimal information available, no recognized dosage and product monograph
- Health Care Practitioners – deal with unfamiliar product distributed outside the traditional drug distribution system. Physicians primarily involved. Liability insurance challenges
- Societal/Environmental/Security – second hand smoke, use within establishments (e.g. long term care facilities, correctional institutions), production in personal residences, storage, shipping and diversion



Operational Issues (cont.)

- Compliance and Enforcement – individuals' privacy versus needs for identification of authorized individuals/production sites to law enforcement agencies
- Financial Administration – price system, handling of payment and collection of past due accounts
- Government Supply – production line, consistency of THC level, manufacturing practices, packaging, product information sheet, patient information leaflet
- Media Scrutiny



Way Forward

- Canadian program never intended to allow more than the production of small amounts of marihuana for medical purposes
- May 2009 – Government reintroduced a new limit on the number of licences a designated person can hold (1 designated person for up to 2 authorized individuals) and acknowledged the need to revisit the overall program and regulations
- Not known what the Government will do – some ideas are to:
 - phase out personal production licence
 - become the only supplier of marihuana
 - establish a new licensing regime for large producers/distributors
 - pursue a pharmacy-based distribution system