CANADIAN PHARMACISTS ASSOCIATION
ASSOCIATION DES PHARMACIENS DU CANADA
1785, prom. Alta Vista Drive, Ottawa, ON K1G 3Y6
Tel: 1-800-917-9489 or/ou (613) 523-7877; Fax: (613) 523-0445; www.pharmacists.ca

February 28, 2013

Bureau of Medical Marihuana Regulatory Reform
Controlled Substances and Tobacco Directorate
Healthy Environments and Consumer Safety Branch, Health Canada
Sent by e-mail: consultations-marihuana@hc-sc.gc.ca

Re: CPhA's Response to Proposed Marihuana for Medical Purposes Regulations (MMPR)

On behalf of the Canadian Pharmacists Association (CPhA), I am pleased to provide comments to Health Canada's proposed Marihuana for Medical Purposes Regulations (MMPR), as published in Canada Gazette Part 1 on December 15, 2012. CPhA is the national advocacy organization for pharmacists, committed to providing leadership for the profession and improving health outcomes for Canadians. We are also Canada's largest digital and print publisher of objective, evidence-based drug and therapeutic information, authored by physician and pharmacist experts across the country. From the perspective of CPhA and pharmacy practice, there are a number of key changes to the medical marihuana program that are of note, which include:

1. Physicians and some nurse practitioners would be authorized to prescribe medical marihuana (MM) directly and issue a medical document, without authorization from Health Canada. There would no longer be a category of symptoms and conditions for use, or the requirement for a specialist's support for some conditions.
2. Commercial producers licensed by Health Canada would be the only suppliers of marihuana for medical purposes in Canada. The existing means for individuals to access dried marihuana will be phased out.
3. Pharmacists, if authorized by their provincial/territorial government and pharmacy regulatory authority, may obtain MM from a licensed producer and dispense to patients who have a medical document from their MD or NP, similar to the current process for narcotics and controlled drugs.

CPhA empathises with those Canadians who suffer from pain, terminal or chronic conditions. As previously stated, our major concern with the new MMPR regulations continues to be the lack of evidence to support the use of MM. This is acknowledged by Health Canada in the Regulatory Impact Analysis Statement (RIAS): "To date, scientific studies do not demonstrate conclusively that dried marihuana is safe and effective for medical use" and "Dried marihuana has not been authorized as a therapeutic product in Canada or in any other country." This is inconsistent with one of Health Canada's key objectives, which is to treat marihuana as much as possible like a medication.

Medical marihuana should be subject to the same Canadian drug approval and evidence-based requirements as other medications for safety, efficacy and quality. There is little information available on safety, effectiveness, dosage, drug interactions or long-term health risks. Pharmacists, physicians and nurse practitioners need evidence-based information to support safe and effective prescribing and dispensing of MM. Further research is required. CPhA had the opportunity to express these concerns and the need for further evidence to Health Canada's Expert Advisory Committee on Information for Physicians on Marihuana for Medical Purposes on November 23, 2012.

CPhA recognizes that Health Canada is obligated to respond to the Court's decision on the rights of individuals to access marijuana for medical purposes. The RIAS outlines the significant challenges, concerns and the government's costs with the current MM access program. However, the RIAS does not adequately address the safety and effectiveness concerns of health care professionals. Without a process for authorization by Health Canada, the full responsibility and liability would now rest on the prescriber. They are expected to prescribe a product that does not meet the regulatory requirements for prescription medication under the *Food and Drugs Act*. Access by patients to MM may decrease under the MMPR if practitioners are reluctant to prescribe MM without any oversight from Health Canada other than MM production.

CPhA recognizes the very serious public safety concerns and criminal elements with the current program that allows individuals to grow marihuana themselves or to designate a grower. Thus, we support the regulated process for licensed producers with significant manufacturing requirements and enforcement by Health Canada. We fully support the phasing out of personal production or designated person production of MM. We welcome the controls for distribution of MM that would be similar to the current process for narcotics and controlled drugs. We do note that for many patients, the costs to purchase MM from a licensed producer will be significantly more than their current cost of growing MM themselves, which is currently at about two-thirds of users.

The MMPR would allow pharmacists to dispense MM. We are not aware if many pharmacies would be prepared to do this, and many P/T governments and pharmacy regulatory authorities may not allow this. While the distribution process would be regulated, there remains the concern with pharmacists dispensing a product that does not have adequate safety and effectiveness evidence. In addition, the potential security risks to pharmacies due to robberies would need to be considered.

Thank you for the opportunity to comment and share our concerns about the proposed regulations to the marihuana for medical purposes program. Please contact us should you have any further questions.

Sincerely,

Janet Cooper, B.Sc.(Pharm.)
Senior Director, Professional and Membership Affairs

c.c. Paula MacNeil, President, CPhA
Jeff Poston, Executive Director, CPhA