The Honourable Kevin Sorenson, PC, MP Chair
Standing Committee on Public Accounts
131 Queen Street, 6th Floor
House of Commons
Ottawa, Ontario
K1A 0A6

Dear Mr. Sorenson:

Pursuant to Standing Order 109 of the House of Commons, I am pleased to provide a Government Response to the Standing Committee on Public Accounts' 16th report entitled *Report 4, Drug Benefits – Veterans Affairs Canada, of the Spring 2016 Reports of the Auditor General of Canada*, which will be tabled in the House of Commons.

I would like to take this opportunity to thank you and the members of the Standing Committee for your work and dedication.

Sincerely,

The Honourable Kent Hehr, PC, MP

Enclosure

c.c.: Mr. Michel Marcotte
Clerk, Standing Committee on Public Accounts



Government Response to the Standing Committee on Public Accounts' Sixteenth Report "Report 4, Drug Benefits – Veterans Affairs Canada, of the Spring 2016 Reports of the Auditor General of Canada"

The Government of Canada welcomes the opportunity to respond to recommendations made in the Sixteenth Report of the Standing Committee on Public Accounts which studied Chapter 4 of the Office of the Auditor General's (OAG) Spring 2016 Report concerning the drug benefit component of Veterans Affairs Canada's (VAC) Health Care Benefits Program for Veterans.

The recommendations contained within the report ask VAC to provide your committee with an update on progress made by the Department in addressing the OAG's recommendations. Specifically, the OAG asked for VAC to make improvements to its drug program in the areas of drug formulary decision-making processes, drug acquisition cost-effective strategies, including in the area of VAC's authorization of cannabis for medical purposes, and drug utilization monitoring.

The Government accepts the Auditor General's recommendations and is pleased to provide you with an update on the progress we have made in addressing your recommendations by the themes set out below. The Minister of Veterans Affairs will provide a final status report via a letter to the Chair of the Standing Committee on Public Accounts, on or before May 31, 2017.

Improvements to Drug Formulary Decision-Making Processes

(Responds to recommendations 1, 2, 3)

The Department has reviewed its existing governance and decision-making framework for the review and approval of drugs to be listed on the VAC Drug Formulary and undertaken the following measures:

- Updated Terms of Reference for VAC's Formulary Review Committee which will support
 expert, evidence-based and timely decisions for the eligibility of drugs for coverage in the
 Formulary;
- Created new decision-making tools for reviewing drugs not yet approved on the Drug
 Formulary, including rating criteria for the strength of evidence of efficacy, safety and cost
 or cost-effectiveness of the drug being reviewed;
- Created new standardized operating procedures for formulary drug benefits in line with the new decision-making framework; and
- Created a joint VAC-Canadian Armed Forces (CAF) focus group with membership from
 pharmacists both from VAC and the CAF to review and compare the VAC and CAF drug
 formularies with the aim of aligning drug coverage where possible, ensuring a pre- and
 post-release continuum of care. This focus group will provide a mechanism to review
 targeted classes of medications common to conditions seen in both patient populations.
 Where there are inconsistencies in coverage between the two plans, further evaluation will
 be undertaken, including a drug utilization data review. This analysis will generate
 recommendations on which medications to include or exclude in both plans. Drug

alignment between VAC and the CAF supports seamless transition for releasing CAF members.

Enhancements to Drug Cost-Effectiveness Strategies

(Responds to recommendation 4)

In order to improve the Department's cost-effectiveness strategies, the Department has been working closely with the Non-Insured Health Benefits Program of Health Canada, who is providing ongoing technical, policy and data analysis support to VAC, and as a result, the Department:

- Joined the Pan-Canadian Pharmaceutical Alliance to participate in price negotiation with drug manufactures to negotiate lower drug prices through Product Listing Agreements;
- Developed a framework and process for obtaining rebates on drug costs through Product Listing Agreements;
- Developed a standardized Product Listing Agreement template for drug manufacturers to populate, which outlines the terms of sale, such as price, terms of confidentiality clauses and listing criteria; and
- Is on track to enter into its first two Product Listing Agreements by the end of March 2017, for drugs to treat patients with chronic obstructive pulmonary disease and asthma, which are expected to offer significant savings for VAC.

In addition, VAC has undertaken other steps to be more cost-effective by having:

- Consulted with other publically funded drug programs to incorporate best practices in its own program that would provide access to lower priced drugs; and
- Instituted best practices for cost-effectiveness in formulary management within its drug plan management processes.

Cannabis for Medical Purposes Review and Policy

(Responds to recommendation 1, 2, 5)

The Minister of Veterans Affairs directed the Department in March, 2016, to undertake a comprehensive review of VAC's role in reimbursing Veterans for cannabis for medical purposes. In conducting the review, VAC considered the best evidence and advice available from a variety of sources, including Health Canada, the College of Family Physicians of Canada, as well as consultations with Veteran beneficiaries, licensed cannabis producers, and a panel of medical practitioners.

Based on that review, VAC made the following findings:

- VAC's reimbursement limit of 10 grams per day was, without question, too high based on current medical research;
- VAC should approve the reimbursement of fresh cannabis and cannabis oil;

- VAC staff require the appropriate training material on cannabis for medical purposes so they can better serve Veterans;
- VAC should lower gram limits for the reimbursement of new authorizations; and
- VAC should review current authorized amounts for existing beneficiaries.

On November 22, 2016, the Minister of Veterans Affairs announced the Department's newly implemented *Reimbursement Policy on Cannabis for Medical Purposes* at the Canadian Institute for Military & Veteran Health Research Annual Forum. A copy of the new policy is attached as Appendix 1 for your reference. The new reimbursement policy:

- Establishes a daily maximum for reimbursement of three grams per day of dried cannabis (or the equivalent in fresh cannabis or cannabis oil). The previous daily maximum was 10 grams;
- Outlines exceptional considerations for Veterans who request more than the daily maximum amount;
- Authorizes the reimbursement of dried and fresh cannabis, and cannabis oil. Previously, only dried cannabis was authorized for reimbursement;
- Provides a transition period of six months for Veterans currently above three grams of dried cannabis per day;
- Reimburses the Veteran up to \$8.50 per gram, whether taken in dried cannabis or the equivalent amount of fresh cannabis or cannabis oil, which is in line with average market pricing.

The maximum of three grams per day is based on current scientific evidence and consultations with Veteran beneficiaries, stakeholders, and medical experts. The College of Family Physicians of Canada advised that the upper limit for safe use of dried cannabis is three grams per day. Health Canada also found that the average Canadian is authorized for less than three grams per day of cannabis for medical purposes. Israel and the Netherlands are two countries that have available research on marihuana for medical purposes. Israel's average use of cannabis is 1.5 grams per day, and, in the Netherlands, it is 0.68 grams per day. VAC also heard from Veterans and their families that their well-being and quality of life has improved since they were approved for reimbursement of cannabis. Their experience was an important consideration in the development of this new policy.

As more is learned about the efficacy of cannabis as a therapy, VAC's *Reimbursement Policy on Cannabis for Medical Purposes* will evolve. Within the next year, the Department will establish an expert advisory committee of health and research professionals to monitor the effectiveness of the reimbursement policy and processes based on research and consultation. VAC will closely monitor the implementation of the recommendations made by the Federal Task Force on Cannabis Legalization and Regulation in its final report, entitled *A Framework for the Legalization and Regulation of Cannabis in Canada*, which made a number of recommendations regarding access to cannabis for medical purposes. Also, together with the CAF, VAC will develop a research plan and conduct a study that will strengthen evidence on the effects of cannabis on the health of Veterans.

Improvements to Drug Utilization Monitoring

(Responds to recommendation 6)

In order to improve the Department's drug utilization monitoring, VAC consulted with other jurisdictions to determine best practices in the areas of drug utilization monitoring and as a result the area responsible has:

- Implemented a drug utilization monitoring framework in December 2016 which will include audits to detect fraudulent billing of medications, reviews to identify patients who may be receiving high risk medications that may introduce the potential for adverse effects, and evaluations to assess the appropriateness of drug therapies within the Veteran population; and
- Designed the structure of annual action plans which will set out organizational authorities and reporting structures, as well as, the scope of activities, expected deliverables, and evaluation functions within the year. The first annual action plan for monitoring will be instituted in fiscal year 2017-2018.

REIMBURSEMENT POLICY FOR CANNABIS FOR MEDICAL PURPOSES

Issuing Authority: Director General, Policy and Research

Effective Date: November 22, 2016

Purpose

1. This policy provides direction on the reimbursement of cannabis for medical purposes.

General

- 2. Access to the use of cannabis for medical purposes has been mandated by Canada's courts. Health Canada's Access to Cannabis for Medical Purposes Regulations specify the conditions for authorization and legal possession. Cannabis is not an approved therapeutic product in Canada.
- 3. There have been limited trials which seem to support the use of cannabis in limited circumstances as an option after standard interventions are contraindicated or have been tried and have been unsuccessful and/or have yielded unacceptable adverse effects. Veterans Affairs Canada has heard from Veterans and their advocates that they believe cannabis helps them with their health problems. This information must be balanced with scientific evidence, sound clinical practice, and with the primary concern of the Department the health and general well-being of Veterans and their families.
- 4. Recognizing that the use of cannabis for medical purposes continues to be an emerging practice, Veterans Affairs Canada will continue to monitor developments in research, and medical practice and experience, and adjust the policy provisions as may be required.

Authority

5. Subject to the provisions of this policy, reimbursement may be authorized for eligible Veterans and other qualified individuals in accordance with section 4 of the Veterans Health Care Regulations.

Eligibility

6. Veterans entitled to a Veterans Affairs Canada Disability Pension and/or Disability Award are eligible for the cost of treatment in respect of their pensioned/awarded condition (see Treatment in Respect of a Pensioned or Awarded Condition Policy). Certain Veterans may also be eligible for the cost of treatment for non-pensioned/awarded conditions to the extent the treatment is not available from the province/territory in which they reside (see Eligibility for Health Care Programs – Eligible Client Groups).

Policy

7. Veterans Affairs Canada may reimburse an eligible Veteran for the costs of cannabis for medical purposes, when the health care practitioner's (defined in Health Canada's Access to Cannabis for Medical Purposes Regulations as a medical practitioner or a nurse practitioner) authorization is in accordance with Health Canada's Access to Cannabis for Medical Purposes

Regulations. The authorization document completed by the health care practitioner indicates the amount of grams per day of dried marihuana.

- 8. Veterans Affairs Canada, requires the following documents to confirm the Veteran meets the requirements of Health Canada's Access to Cannabis for Medical Purposes Regulations for the purposes of determining entitlement for reimbursement:
- a. copy of the authorization document completed by the health care practitioner; and
- b. copy of the completed and confirmed registration document with a licensed producer.
- 9. Veterans Affairs Canada will only accept authorization from one health care practitioner at a time. More than one authorization may be considered, but the authorizations must be from the same health care practitioner.
- 10. Eligible forms of cannabis include all forms that are authorized by section 3(1) of Health Canada's Access to Cannabis for Medical Purposes Regulations for sale by licensed producers (with the exception of seeds and plants). Currently, licensed producers may produce and sell dried and fresh marihuana, and cannabis oil.
- 11. The maximum daily Veterans Affairs Canada reimbursement limit is 3 grams per day of dried marihuana (or the equivalent in other eligible forms).
- 12. Requests for reimbursement for more than 3 grams of dried marihuana (or the equivalent in other eligible forms), will require additional information for consideration as set out in Annex A. This applies to those being reimbursed for more than 3 grams per day on the coming into force of this policy, and all new requests.
- 13. Veterans being reimbursed for cannabis for medical purposes on the release date of this policy may continue to be reimbursed at their current level for six months.
- 14. Veterans Affairs Canada will reimburse the Veteran based on a fixed rate per gram of marihuana, when authorized in its dried or fresh form or the same fixed rate per gram equivalent in cannabis oil. In other words, Veterans Affairs Canada will reimburse the Veteran at a fixed rate per gram whether taken in fresh or dried marihuana, or the equivalent in cannabis oil.
- 15. Veterans Affairs Canada does not reimburse the cost of cannabis for medical purposes when the Veteran purchases cannabis outside Canada. The legislative regime established by Health Canada for access to cannabis for medical purposes includes regulatory requirements for the safe production and distribution of cannabis, and for legal possession. Recognizing the complexity and variety of approaches internationally, the Department is not able to adequately ensure the same level of regulatory oversight for the safe production, authorization, distribution, and legalization of cannabis for medical purposes. The health and well-being of Canada's Veterans is paramount, and the varied approaches to cannabis for medical purposes is of concern.
- 16. Veterans Affairs Canada only reimburses the cost of cannabis for medical purposes when the product is purchased from a licensed producer (with the exception of seeds and plants). Canada has established a regulated system of licensed producers that ensures producers are meeting standards for quality and safety. This standardization is an essential consideration when determining whether to reimburse Veterans for cannabis for medical purposes. The health and well-being of Veterans is best ensured through accessing cannabis produced by the licensed producers authorized in accordance with Health Canada's Access to Cannabis for Medical Purposes Regulations.

- 17. No fee is paid to the physician for the completion of the authorization document since VAC considers it to be covered in insured service fees. However, if the Department requires the health practitioner to complete additional documentation, an administrative fee may be paid.
- 18. Veterans Affairs Canada may deny approval of reimbursement when licensed producers are determined to be operating outside of the requirements of Health Canada's Access to Cannabis for Medical Purposes Regulations, the requirements of this policy, and/or any approved provider criteria established by the Department and agreed to by the licensed producer.
- 19. Reimbursement for the cost of the purchase of a vaporizer may be authorized for eligible Veterans up to the established dollar limit. The purchase must be pre-authorized, and prescribed by a health practitioner. Veterans Affairs Canada may consider other "equipment" when the device is medically beneficial, subject to the provisions of the Medical Supplies policy.

Annex A

Exceptional Approval of More than 3 Grams End of Life Treatment

- 1. Reimbursement may be authorized for more than 3 grams of dried marihuana or equivalent when confirmation is received from the treating physician that the Veteran is palliative. In end of life situations, documentation is not required from a medical specialist.
- 2. Palliative care is defined in the Palliative Care policy. The policy also includes additional considerations for Veterans requiring end of life care.

Other Exceptional Requests

- 3. In all cases, other than palliative circumstances as noted above, requests for reimbursement of more than 3 grams of dried marihuana or equivalent must be accompanied by additional documentation from at least one, and in some cases more than one, medical specialist. The required documentation from the medical specialist(s) must indicate:
- a. the rationale for the use of more than 3 grams per day;
- b. there are no contraindications to the use of marihuana; and
- c. alternative treatments were found to be ineffective or contraindicated.
- 4. When authorization of cannabis for medical purposes is for chronic pain, additional documentation will be required from a medical specialist in the area of the treatment of chronic pain.
- 5. When authorization of cannabis for medical purposes is for psychiatric condition(s), additional documentation will be required from a psychiatrist.
- 6. When both chronic pain and a psychiatric diagnosis are present, additional documentation will be required from a medical specialist in chronic pain as well as from a psychiatrist. Both medical specialists must be in agreement for approval of reimbursement.
- 7. For any other health conditions, additional documentation will be required from a medical specialist with expertise in the diagnosed condition, including but not limited to chemotherapy-induced nausea and vomiting, wasting syndrome, or loss of appetite in AIDS and cancer patients.