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REPORT 4

Drug Benefits—Veterans Affairs Canada

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Introduction

Background

Drug benefits program

4.1 The Government of Canada provides prescription drug coverage for about 1.1 million Canadians who are members of eligible groups. These include First Nations people living on or off reserves, Inuit, some new immigrants, members of the military and the RCMP, some veterans, and inmates in federal penitentiaries. Based on information provided by departments responsible for these programs, in the 2013–14 fiscal year, the federal government spent approximately $501 million providing drug benefits to these populations.

4.2 In our 2004 report entitled Management of Federal Drug Benefit Programs, we reported on the drug benefits programs managed by six federal departments, including Veterans Affairs Canada. The Department's Health Care Benefits Program provides drug benefits for eligible veterans, some of whom are considered vulnerable and have complex health needs such as mental health conditions. Further, approximately 36 percent of its recipients are over 80 years of age. In the 2014–15 fiscal year, the drug component of the Health Care Benefits Program covered **drugs** for roughly 51,000 veterans at a cost of $80 million dollars.

Veterans Affairs Canada's role and responsibilities

4.3 Veterans Affairs Canada is responsible for the care, treatment, and re-establishment into civil life of veterans as outlined in acts and regulations including the *Department of Veterans Affairs Act* (1985). The Department's mission is to provide exemplary client-centred services and benefits that respond to the needs of veterans, its other clients, and their families, in recognition of their services to Canada; and to keep the memory of their achievements and sacrifices alive for all Canadians.

4.4 The health care benefits and services available through the Department are authorized primarily under the Veterans Health Care Regulations (1990). The Health Care Benefits Program is designed to safeguard the health of veterans, promote their well-being, and provide them with timely access to health care benefits. It includes paying for drugs for veterans who have been granted a disability pension or award due to a service-related illness or injury. Some veterans may also receive drug coverage because it is not available to them under a provincial health care system, such as those who have low incomes and those who receive

Drugs—Prescription drugs, as well as prescribed over-the-counter medications such as acetaminophen, approved for coverage by Veterans Affairs Canada where the veteran meets the applicable eligibility criteria.

the Veterans Independence Program benefits. Drug benefits include drugs prescribed by a physician, dentist, or other person authorized to prescribe them.

Operating environment

4.5 Veterans Affairs Canada has a Formulary Review Committee, which is responsible for reviewing, maintaining, and revising, when necessary, its drug benefits program. According to its terms of reference, it is tasked with reviewing

- best practices, treatments, legislation, and policy;
- claim trends that affect veterans; and
- new and existing drugs considered for the Department's drug benefits list, including their cost implications.

The Committee is also responsible for making recommendations and providing guidance to senior management to help maintain and improve the services provided to veterans.

4.6 The Canadian Agency for Drugs and Technologies in Health is an independent, not-for-profit organization that evaluates new drugs through its Common Drug Review process. The Agency makes non-binding recommendations to Canada's federal, provincial (except Quebec), and territorial public drug plans as to which drugs should be covered. The review process examines patient input, clinical evidence, and cost-effectiveness of new drugs. Veterans Affairs Canada relies on the Common Drug Review process to help it determine whether new drugs should be added to the drug benefits list. This list includes about 12,000 drug products that are paid for under the drug benefits program.

4.7 The Department has contracted the day-to-day administration of its Health Care Benefits Program to Medavie Blue Cross, a third-party provider. Medavie Blue Cross makes payments to pharmacies for the prescriptions they have filled.

Focus of the audit

4.8 This audit focused on whether Veterans Affairs Canada managed the drug component of its Health Care Benefits Program to contribute to the health of its veteran population by

- providing coverage for drugs based on evidence,
- using cost-effectiveness strategies, and
- monitoring the utilization of drugs covered.

4.9 This audit is important because Veterans Affairs Canada is responsible for providing coverage for drugs that contribute to the health and well-being of veterans, some of whom are considered vulnerable and have complex health needs such as mental health conditions.

4.10 Our examination did not include veterans of the RCMP, who are eligible to receive health care benefits from Veterans Affairs Canada as a result of a service-related injury or illness. We did not examine Health Canada's process for approving drugs for sale in Canada. We also did not examine the activities of the Canadian Agency for Drugs and Technologies in Health. Further, we did not examine the other components of the Department's Health Care Benefits Program.

4.11 More details about the audit objective, scope, approach, and criteria are in **About the Audit** at the end of this report (see pages 17–19).

Findings, Recommendations, and Responses

Management of the drug benefits list

The Department did not have an adequate process for making evidence-based decisions related to its drug benefits list

Overall finding ➔

4.12 Overall, we found that Veterans Affairs Canada did not have an adequate process for making evidence-based decisions related to its drug benefits list. It did not have procedures in place to help ensure that its Formulary Review Committee systematically reviewed appropriate evidence to support decisions about changes to the drug benefits list. Except for considering the recommendations of the Canadian Agency for Drugs and Technologies in Health, it had not determined what types of evidence the Committee should consider. We reviewed 32 Committee decisions and found that for 17 of them, the Department could not provide evidence that it had appropriately considered veterans' needs, current health practices and policies, clinical research, and cost-effectiveness. We also found that no timelines had been established for updating the drug benefits list with the Committee's decisions.

4.13 Further, Veterans Affairs Canada has done little to analyze the utilization of drugs not available on the drug benefits list but accessible on a case-by-case basis to eligible veterans. This limits its ability to identify which of these drugs are routinely approved when requested and which could be added to the drug benefits list. Doing this would reduce the administrative burden for veterans and lower the Department's administrative costs.

4.14 This is important because the Department is responsible for contributing to veterans' health by providing evidence-based drug therapies. Using a systematic decision-making process would result in consistent evidence-based decision making that considers safety risks and facilitates veterans' access to approved drugs.

4.15 Our analysis supporting this finding presents what we examined and discusses

- decisions related to the drug benefits list,
- analysis of information, and
- decisions related to marijuana for medical purposes.

Context

4.16 Managing the drug benefits list is fundamental to the drug component of the Department's Health Care Benefits Program. To decide which drugs would best meet the needs of the veteran population, the Department's Formulary Review Committee adds and removes drugs from the list and provides special authorization criteria so that certain drugs are covered only under certain conditions. The drugs the Committee considers are approved by Health Canada for sale in Canada based on an assessment of their safety, efficacy, and quality, except for marijuana for medical purposes (see paragraphs 4.26 and 4.27). Some of the drugs the Committee reviews have gone through the Canadian Agency for Drugs and Technologies in Health's Common Drug Review process, while others have not. This review process can result in different types of recommendations for the drug benefits program. Specifically, the Agency may recommend to

- list a drug,
- list a drug with criteria or conditions,
- not list a drug, or
- not list a drug at the submitted price.

4.17 The Department's Formulary Review Committee includes representatives from Veterans Affairs Canada, Medavie Blue Cross, and the Department of National Defence. These representatives include health professionals and other members who provide advice on policy and administrative matters.

4.18 This Committee uses three categories when making decisions about which drugs to include on the drug benefits list.

- **Standard benefits**—drugs that are covered for eligible veterans with a valid prescription. These make up the largest part of the list.
- **Special authorization benefits**—drugs that are covered only if a veteran can demonstrate that they meet a predetermined condition or circumstance.

- **Non-formulary products**—drugs not included on the drug benefits list but that can be approved for coverage on a case-by-case basis.

Recommendations

4.19 Our recommendations in this area of examination appear at paragraphs 4.28 and 4.65.

Analysis to support this finding

4.20 **What we examined.** We examined whether Veterans Affairs Canada used a systematic approach in making evidence-based decisions related to what is on its drug benefits list. We also considered whether it had developed criteria for what would constitute evidence, timelines for updating the drug benefits list, and whether it had analyzed the utilization of drugs not available on the drug benefits list.

4.21 **Decisions related to the drug benefits list.** The Department's Formulary Review Committee is accountable for developing and maintaining the drug benefits list to provide evidence-based drug therapy for veterans. The Committee makes decisions about adding, removing, and tightening or broadening access to the drugs on the list for reasons such as safety, efficacy, or cost. We found that the Department had not clearly defined what types of evidence the Committee should consider. However, the Department agreed with our proposed approach that information about veterans' needs, current health practices and policies, clinical research, and cost-effectiveness were appropriate criteria for the purpose of our examination.

4.22 We examined 32 of the 60 drug benefits decisions the Formulary Review Committee made in the 2013–14 and 2014–15 fiscal years to determine whether the Department had implemented a systematic, evidence-based decision-making approach. While it had a process for managing its drug benefits list, it did not systematically ensure that all decisions were supported by evidence. There were no policies, procedures, or guidelines specifying what type of evidence the Committee should review, the extent of evidence that was required, or the level of assessment that was required. Furthermore, there was no documented process outlining when and how the Committee should assess drug costs. In our review of 32 of the Committee's decisions, we found that 17 were not adequately supported by evidence of veterans' needs, current health practices and policies, clinical research, and cost-effectiveness. For 11 of the 15 decisions that were adequately supported, the Committee relied primarily on the recommendations of the Canadian Agency for Drugs and Technologies in Health.

4.23 Further, we found that there were no timelines established for updating the drug benefits list with the Committee's decisions, and that the Committee did not track how long it takes for changes to be made to the list. We found that it took the Department 12 months or longer to update the list to reflect the Committee's decisions for 5 of the 32 drug

decisions that we examined. In one case, we found that the Committee's decision to limit access to a particular narcotic only to those veterans with cancer or in palliative care had still not been implemented more than two years later. In the meantime, the drug remained available to veterans as a standard benefit.

4.24 The Formulary Review Committee is also responsible for establishing criteria and guidelines that govern access to the drugs the Department pays for. The Department can decide to make certain benefits available only through special authorization, and to limit the quantity of certain drugs that it covers to help protect the health and well-being of veterans. For example, it will not cover claims for acetaminophen that exceed the maximum recommended dose because of the health risks associated with excessive utilization. We found that the Department had not established similar limits for its coverage of narcotics and sedatives, which are commonly utilized and which may pose abuse or safety risks if improperly utilized. Establishing limits for the coverage of these drugs, based on maximum recommended limits, can reduce the risk that they will be utilized inappropriately or diverted for other purposes.

4.25 **Analysis of information.** Veterans must take additional steps to obtain coverage for special authorization benefits and non-formulary products. The Department has noted that requests for non-formulary products can lead to delays and possible out-of-pocket expenses for veterans. However, it has not analyzed the use of non-formulary drugs or the extent of the delays and costs associated with them. It did not track which drugs were routinely approved and thus could be added to the drug benefits list. Doing this would reduce the administrative burden for veterans and lower the program's administrative costs.

4.26 **Decisions related to marijuana for medical purposes.** In 2001, Health Canada's *Marihuana Medical Access Regulations* were enacted. Seven years later, Veterans Affairs Canada began to pay for marijuana for medical purposes, sold by Health Canada for $5 per gram, as part of its drug benefits program. While the Department advised us that it covered only the amount of marijuana for medical purposes recommended by a physician or a medical specialist, as outlined in the Regulations, we found that the Department had not established limits on cost or the amount to be covered. Furthermore, departmental documents indicate that the decision to cover marijuana for medical purposes as a non-formulary product on a case-by-case basis was made at the senior management level, rather than by the Formulary Review Committee. We were unable to determine why this decision did not go through the Committee's normal review process.

4.27 In June 2013, the Health Canada *Marihuana for Medical Purposes Regulations* were enacted, while the old regulations were repealed in March 2014. The new regulations simplified the requirements for obtaining access by permitting any physician or nurse practitioner to authorize the utilization of marijuana for medical purposes, and the

restrictions of use for specific medical conditions were removed. We noted that the Department decided in 2014 to establish a limit on the number of grams of marijuana for medical purposes per day that it would cover for eligible veterans. However, we were unable to determine how it used evidence to support this decision. According to an internal departmental briefing document, Health Canada indicated that more than five grams per day may increase risks with respect to the drug's effect on the cardiovascular, pulmonary, and immune systems, and on psychomotor performance, and may increase the risk of drug dependence. Despite the awareness of these potential risks, we found that the Department had set the limit at 10 grams per day per veteran, and that in rare circumstances it could increase this limit after consulting with a veteran's health care provider. Based on data provided by the Department, we also found that between January and November of 2015, the Department approved coverage for 10 grams per day for 340 veterans. In addition, six veterans who had received marijuana for medical purposes before the Department had established this limit continued to receive more than 10 grams per day. In our view, it is important that the Department be able to support its decisions to pay for drug products based on evidence, or otherwise provide a sound rationale.

4.28 **Recommendation.** Veterans Affairs Canada should implement a decision-making framework that specifies the type of evidence and how it is considered. The Department should use this framework to decide which drugs to pay for and to what extent it will pay for them. The framework should also include requirements that the Department update the drug benefits list on a timely basis.

Veterans Affairs Canada's response. *Agreed. Veterans Affairs Canada is currently developing a decision-making framework that will outline the type of evidence, including cost-effectiveness, to be considered when making formulary decisions, and will establish a governance structure and senior management oversight. The Department will also work with Health Canada and recognized experts in the field of marijuana utilization for medical purposes, and will consult with other federal departments to identify areas of best practices to model.*

In September 2015, a new national pharmaceutical advisor was hired. The new pharmaceutical advisor will lead the development of standardized operating procedures for formulary reviews, which will outline the manner in which decisions are made and implemented. This work will be done in conjunction with our federal partners and other jurisdictions. Veterans Affairs Canada will also add resources to the treatment benefits program management team.

All of these initiatives will be implemented by May 2017.

Cost-effectiveness strategies

Veterans Affairs Canada used some cost-effectiveness strategies to manage drug costs

Overall finding

4.29 Overall, we found that Veterans Affairs Canada used some cost-effectiveness strategies to manage drug costs under its Health Care Benefits Program. The Department has a generic drug substitution policy. In addition, it has entered into agreements with some pharmacy associations to secure lower prices, including reduced markups for some drugs and reduced dispensing fees. However, it has not assessed the results of these strategies. Furthermore, it has not implemented strategies related to expensive new drugs entering the market or to managing the rising costs of marijuana for medical purposes.

4.30 This finding is important because Veterans Affairs Canada is responsible for providing coverage for drugs that contribute to the health and well-being of veterans. Since the drug component of its Health Care Benefits Program is federally funded, the Department must use cost-effectiveness strategies as much as possible to prudently manage public funds.

4.31 Our analysis supporting this finding presents what we examined and discusses

- implementation of cost-effectiveness strategies,
- additional cost-effectiveness strategies, and
- marijuana for medical purposes.

Context

4.32 The overall cost of Veterans Affairs Canada's drug benefits program was significant, at $80 million in the 2014–15 fiscal year, according to departmental data. Although a reduction in the number of veterans accessing the program has led to a decline in these costs over the last five years, the average cost per veteran has remained relatively constant. The average annual cost per veteran was about $1,600 during these years.

4.33 Several factors influence the cost of providing drug benefits. Some are outside of the Department's control, such as growth in the size of eligible populations, aging clientele, and the introduction of new and more costly drugs, such as **biologics**, into the marketplace. However, the Department is responsible for managing the resources expended on drug benefits in a cost-effective manner and for providing drug benefits that meet veterans' needs.

Biologics—A class of drug derived from living organisms. Many biologics are used to treat chronic diseases such as cancer, rheumatoid arthritis, and diabetes.

4.34 Departments that provide federal drug benefits programs can manage taxpayers' money prudently by using strategies to manage the price they pay for drugs. For Veterans Affairs Canada, this includes making decisions about which drugs the Department will cover that meet veterans' needs while containing costs.

4.35 Cost-effectiveness strategies will become more important as public drug benefits programs are expected to face increasing cost pressure in the coming years as costly new drugs enter the market. For example, a new biologic drug used to treat high cholesterol is expected to cost about $10,000 per patient per year.

Recommendations

4.36 Our recommendations in this area of examination appear at paragraphs 4.43 and 4.47.

Analysis to support this finding

4.37 **What we examined.** We examined the cost-effectiveness strategies that the Department had identified and implemented, and whether it had assessed the results of these strategies.

4.38 **Implementation of cost-effectiveness strategies.** The Department's policy is to pay for the generic version of brand name drugs when available, unless otherwise directed by a physician. Generic drugs are usually less expensive than the brand name version. We found that the Department did not know the compliance rate with its generics policy. While it reviewed the level of generic drug utilization in 2015, it did not review compliance with its generics policy or the cost-effectiveness of its strategy.

4.39 As another cost-effectiveness strategy, the Department, in partnership with other federal entities, has entered into agreements with Saskatchewan and British Columbia pharmacy associations to secure lower prices by negotiating lower markups and dispensing fees for drugs. An agreement for lower dispensing fees was also negotiated with the Quebec association of pharmacy owners. Department officials informed us that in the Atlantic provinces, the Department benefits from agreements that Medavie Blue Cross has negotiated with some pharmacies. The Department advised that it pays reduced dispensing fees and markups under these agreements.

4.40 At the time of our audit, we found that Veterans Affairs Canada had not assessed the cost-effectiveness of the various agreements it had in place. We also found that its agreement with British Columbia had expired in 2012. Department officials informed us that despite the expiry, the Department continues to benefit from the agreed-upon reductions. Since the agreement and rates are outdated, they could change with little or no notice, leading to unanticipated increases in drug costs.

4.41 **Additional cost-effectiveness strategies.** To address higher-cost patented drugs, some drug plan providers enter into Product Listing Agreements. These are contracts between a drug plan provider and a pharmaceutical company whereby the provider agrees to add the company's drug to its drug benefits list. In exchange, the pharmaceutical company provides a rebate to the drug plan provider. Most public drug programs in Canada, including those of Health Canada and the Province of Ontario, have used these agreements to reduce the cost of expensive drugs, thereby improving access to them. The Department investigated whether it could also use these agreements as a cost-effectiveness strategy, and in March 2013 determined that it could.

4.42 We found, however, that over the following two years, Department officials did not pursue Product Listing Agreements with pharmaceutical companies. We also found that not using them has limited what it can include on its drug benefits list because the costs of some drugs are too high. Specifically, if the Canadian Agency for Drugs and Technologies in Health recommends that a drug benefits program not list a new drug at the submitted price—which applied to 4 of the 32 drug decisions we examined—the Department's Formulary Review Committee does not approve the addition of the drug to the list. As a result, to obtain coverage for a drug, a veteran must make an individual request supported by a physician, and the Department considers approval on a case-by-case basis. According to the Department, these types of requests can cause delays to veterans in obtaining the drug. In July 2015, the Department began re-examining the use of Product Listing Agreements with Health Canada, which has significant experience in negotiating such agreements.

4.43 **Recommendation.** Veterans Affairs Canada should periodically review its cost-effectiveness strategies to identify whether

- they are up to date and are leading to reduced costs for drugs and pharmacy services, and
- other potential strategies should be pursued alone or in collaboration with other federal departments.

Veterans Affairs Canada's response. *Agreed. Veterans Affairs Canada will enhance its cost-effectiveness strategies through regular assessments and reviews of the formulary, and research strategies used by other drug plans. The Department will leverage its partnerships with other federal government departments and other jurisdictions to pursue efficiencies for the Department, wherever possible, and cost-effective solutions for our veterans. The Department has already commenced working with other federal partners and the pan-Canadian Pharmaceutical Alliance to explore opportunities. All of the above will be completed by May 2017.*

4.44 **Marijuana for medical purposes.** In 2001, Health Canada's *Marihuana Medical Access Regulations* were enacted. Seven years later, Veterans Affairs Canada began to cover the costs of marijuana for medical

purposes, sold by Health Canada for $5 per gram, as part of its drug benefits program. While the Department advised us that it covered only the amount of marijuana for medical purposes recommended by the physician or a medical specialist, as outlined in the Regulations, we found that the Department had not established limits on cost or the amount to be covered.

4.45 In June 2013, the Health Canada *Marihuana for Medical Purposes Regulations* were enacted, while the old regulations were repealed in March 2014. The new regulations simplified the requirements for obtaining access by permitting any physician or nurse practitioner to authorize the utilization of marijuana for medical purposes, and the restrictions of use for specific medical conditions were removed. The Department estimated that the cost rose significantly, from $5 to between $6 and $14 per gram, because commercial producers became responsible for providing the drug and setting prices. We found that before these new regulations were passed, Department officials had identified that they would likely cause an increase in the number of veterans requesting marijuana for medical purposes, increasing the Department's expenditures. Despite acknowledging this in advance, it did not establish a dollar limit for covering marijuana for medical purposes.

4.46 According to the Department, its expenditures for marijuana for medical purposes rose significantly once the *Marihuana for Medical Purposes Regulations* came into effect (Exhibit 4.1). Marijuana for medical purposes became the highest-cost item paid for under the drug component of its Health Care Benefits Program. Shortly after the regulations were implemented, the Department once again identified the need to contain the rising cost of marijuana for medical purposes by imposing a dollar-amount limit that would be paid per gram. We found that although it had identified this cost-effectiveness strategy, the Department did not implement it. It did not establish or try to negotiate any limit on payment per gram. It did, however, establish a cap on the quantity of marijuana for medical purposes (see paragraph 4.27) that a veteran could obtain coverage for through the program. However, at the time of the audit, this limit did not have a significant financial impact because it was capped at 10 grams per day and the Department was paying for less than this amount for the majority of veterans. According to Department documents, expenditures for marijuana for medical purposes are expected to continue to increase. The Department estimates that expenditures could reach $25 million in the 2016–17 fiscal year, which would amount to almost a third of the drug costs under its Health Care Benefits Program. For veterans receiving coverage for marijuana for medical purposes, the average cost, according to Department data, was approximately $9,200 per veteran from 1 April 2015 to 31 December 2015.

Exhibit 4.1 Veterans Affairs Canada's expenditures for providing coverage for marijuana for medical purposes rose significantly after Health Canada implemented new regulations in June 2013

Fiscal year	2013–14	2014–15	1 April 2015 to 31 December 2015 (9 months)
Veterans Affairs Canada's expenditures	$408,810	$5,160,747	$12,156,319
Number of recipients	112	628	1,320
Source: Veterans Affairs Canada (unaudited)			

4.47 **Recommendation.** Veterans Affairs Canada should explore ways in which the costs associated with marijuana for medical purposes can be contained.

Veterans Affairs Canada's response. *Agreed. Veterans Affairs Canada will develop a policy on marijuana for medical purposes, putting the health, well-being, and safety of our veterans at the forefront. The Department will leverage medical expertise to identify the most efficient and effective approach. This may require regulatory consideration. This policy will be developed and implemented by May 2017.*

Monitoring of drug utilization

Veterans Affairs Canada did not have a well-defined approach to monitoring drug utilization

Overall finding

4.48 Overall, we found that Veterans Affairs Canada had implemented most of the recommendations that related to monitoring of drug utilization that we followed up from our 2004 audit on drug benefits programs. However, we found that Veterans Affairs Canada did not have a well-defined approach for monitoring drug utilization among veterans to help identify and prevent the inappropriate utilization of drugs and to detect trends that could inform program management decisions. For example, the Department manages the only publicly funded plan that covers marijuana for medical purposes, but it does not monitor trends that may suggest high-risk utilization.

4.49 This is important because effective drug utilization monitoring can help identify prescription drug abuse, flag potential drug-related problems at the time of dispensing, and help ensure that the Department obtains the information it needs to manage its drug benefits program.

4.50 Our analysis supporting this finding presents what we examined and discusses

- Veterans Affairs Canada's approach to monitoring the utilization of drugs it paid for,
- pharmacy alerts, and
- monitoring the utilization of marijuana for medical purposes.

Context

4.51 Monitoring the utilization of drugs can help a drug program better understand and improve how its clients make use of drug benefits. Utilization information can be used to detect potential drug-related problems, inform decisions about drug coverage, and help manage costs. The Department's drug benefits administrator, Medavie Blue Cross, with direction from Veterans Affairs Canada, is responsible for monitoring how veterans utilize selected drugs over time and for setting up alerts in its drug claims system to identify potential drug-related problems at the time of dispensing.

4.52 Our 2004 audit observed that the Department undertook only a limited review of claims data to detect potentially problematic drug utilization. It also found that the Department's claims system alerted pharmacies to some potential drug-related problems at the time of dispensing, but did not monitor the reasons why pharmacists dispensed drugs to veterans in spite of an alert.

Recommendation

4.53 Our recommendation in this area of examination appears at paragraph 4.65.

Analysis to support this finding

4.54 **What we examined.** We examined whether the Department monitored the utilization of drugs it paid for to detect patterns of inappropriate utilization. We also examined whether the Department obtained the drug utilization information it needed to manage its program. Finally, we examined whether the Department had implemented selected recommendations from our 2004 audit related to pharmacy alerts and to monitoring how veterans utilized drugs over time.

4.55 **Veterans Affairs Canada's approach to monitoring the utilization of drugs it paid for.** Veterans Affairs Canada is responsible for determining the nature and scope of its drug utilization monitoring activities. This includes deciding which drugs should be monitored and developing criteria to detect drug utilization problems. Medavie carries out monitoring to identify veterans whose drug utilization is not consistent with the Department's expectations, and contacts physicians and pharmacists accordingly. Where these steps do not address the potential concerns, Medavie is responsible for referring the case to the Department for follow-up.

4.56 We found that the Department did not have a well-defined approach to monitoring the utilization of drugs it paid for that considered its mandate, the objectives of its drug benefits program, and the risks the program and veterans face.

4.57 The Department told us that since our last audit, it had directed Medavie to monitor claims data for high-risk utilization patterns for some drugs, such as narcotics and sedatives. However, we found that the Department did not document the direction it provided to Medavie regarding the quantities or levels of utilization it considered excessive, or when it is appropriate to intervene and inquire further about a veteran's utilization of a drug.

4.58 We also found that the Department carried out limited monitoring and analyses of program-wide utilization that could help detect trends important to the health and well-being of veterans and to managing the program. For example, the Department had not directed Medavie to monitor and report regularly on trends in the drugs that veterans commonly use, such as antidepressants and non-steroidal anti-inflammatory drugs. A Department official told us that monitoring drugs that veterans commonly use would help the Department detect patterns that might be inconsistent with recommended approaches to treatment. Further, the Department's monitoring activities did not adequately consider the potential financial risks posed by covering newer, more expensive drugs, such as biologics. For example, the Department monitored the utilization of one older biologic drug but it did not monitor biologics more broadly, nor did it monitor the utilization of other costly drug therapies.

4.59 **Pharmacy alerts.** In response to observations from our 2004 audit, Veterans Affairs Canada strengthened its alerts for the potential overuse of narcotics and benzodiazepines, which are sedatives, so that alerts are issued regardless of where the veteran filled the prescription. The Department also partly addressed our recommendation to monitor instances in which pharmacists dispense drugs to veterans in spite of a pharmacy alert. These instances are monitored when they involve potential abuse or overuse of narcotics and benzodiazepines, or when a veteran tries to obtain the same prescription from the same pharmacy within a seven-day period. However, all other instances in which a pharmacist dispenses a drug in spite of an alert, such as those related to a potential drug interaction, were not monitored.

4.60 **Monitoring the utilization of marijuana for medical purposes.** As noted in paragraph 4.48, the drug benefits program managed by the Department is the only publicly funded plan in Canada that provides coverage for marijuana for medical purposes. It is not an approved therapeutic product, and Health Canada has warned that its use involves risks to health, some of which may not be known or fully understood. Further, Veterans Affairs Canada approved coverage for 10 grams per day

of marijuana for medical purposes. This is double the amount identified as being appropriate in Veterans Affairs Canada's consultations with external health professionals, and more than three times the amount that Health Canada has reported as being most commonly utilized by individuals for medical purposes.

4.61 Currently, to obtain marijuana for medical purposes a veteran must obtain a medical document from a physician or nurse practitioner and purchase the product from a producer licensed by Health Canada. Marijuana for medical purposes is authorized by physicians to treat, among other things, chronic pain and post-traumatic stress disorder. Despite this, we found that the Department had not done any monitoring or analysis to determine whether the growing utilization of marijuana for medical purposes for these conditions was contributing to a reduction in the program-wide or veteran-specific utilization of more conventional drugs that treat these conditions, such as narcotics and antidepressants.

4.62 We also found that the Department did not monitor trends in the utilization of marijuana for medical purposes that may suggest higher-risk use. In September 2013, Health Canada recommended that those who have a serious mental health condition such as schizophrenia, psychosis, depression, or bipolar disorder not utilize marijuana for medical purposes. This reinforces the need for the Department to strengthen its monitoring of marijuana utilization, especially for utilization that is concurrent with drugs typically prescribed for these conditions. For example, based on Department data, in 2014–15, 46 percent of the approximately 600 veterans utilizing marijuana for medical purposes were also utilizing antidepressants.

4.63 Although the Department has concerns that veterans are being authorized to utilize marijuana for medical purposes by physicians not responsible for their primary care, it has not systematically monitored authorization trends to determine whether they are of concern. Our examination of departmental data indicated that in the 2014–15 fiscal year, 29 percent of the approximately 600 veterans authorized to utilize marijuana for medical purposes had obtained this authorization from one physician. Therefore we extended our examination to include data for the subsequent period to determine whether this was an anomaly. From 1 April to 31 December 2015, we found that 53 percent of the approximately 1,400 veterans authorized to utilize marijuana for medical purposes had obtained this authorization from four physicians.

4.64 Systematically monitoring the authorization trends of marijuana for medical purposes would give the Department the information it needs to identify unusual authorization patterns. Similarly, monitoring the concurrent use of marijuana and other drugs would help the Department identify potentially higher-risk utilization among veterans. The Department could use this information to support the development of specific criteria for coverage or for limiting the quantities of marijuana it

will cover. In our opinion, given the risks posed by marijuana utilization and the amount that Veterans Affairs Canada pays, the Department did not have a strong approach to monitoring the utilization of marijuana for medical purposes.

4.65 **Recommendation.** Veterans Affairs Canada should develop a well-defined approach to drug utilization monitoring that serves the needs of veterans and helps the Department manage its drug benefits program.

Veterans Affairs Canada's response. *Agreed. Veterans Affairs Canada will enhance its drug utilization monitoring process to support the health, safety, and well-being of its veteran population. The Department recognizes that the individual health of a veteran is the primary responsibility of the physician or regulated health professional and the medical system. The drug utilization monitoring process will be based upon this reality. Accordingly, the Department intends to develop an efficient approach, governance structure, and oversight in order to establish safeguards, monitor trends, and determine potential risks that could affect the health and well-being of its veteran population. This will better inform Departmental decision making at the program level and further support the well-being of the veteran population.*

The Department will leverage its partnerships with other jurisdictions' programs to obtain information on best practices. The Department will review performance data, setting targets and trajectories and implementing routine procedures to track progress on the management of the drug benefits program.

Given that the Department will rely on significant industry research and consultation with other federal jurisdictions and private plan carriers, this approach will be completed by May 2017.

Conclusion

4.66 We concluded that Veterans Affairs Canada did not adequately manage the drug component of its Health Care Benefits Program. The Department used some cost-effectiveness strategies to manage drug costs, but it did not use all the information at its disposal to decide and document which drugs it would cover. The Department monitored the utilization of some higher-risk drugs, but it has not developed a well-defined monitoring approach that could help detect trends important to the health and well-being of veterans as well as to the management of the program.

About the Audit

The Office of the Auditor General's responsibility was to conduct an independent examination of the management of the drug component of Veterans Affairs Canada's Health Care Benefits Program to provide objective information, advice, and assurance to assist Parliament in its scrutiny of the government's management of resources and programs.

All of the audit work in this report was conducted in accordance with the standards for assurance engagements set out by the Chartered Professional Accountants of Canada (CPA) in the CPA Canada Handbook—Assurance. While the Office adopts these standards as the minimum requirement for our audits, we also draw upon the standards and practices of other disciplines.

As part of our regular audit process, we obtained management's confirmation that the findings in this report are factually based.

Objective

The objective of the audit was to determine whether Veterans Affairs Canada has managed the drug component of its Health Care Benefits Program to contribute to the health of its veteran population by providing coverage for drugs based on evidence, by using cost-effectiveness strategies, and by monitoring the utilization of drugs covered.

Scope and approach

The audit focused on drug benefits provided to veterans as part of Veterans Affairs Canada's Health Care Benefits Program. The audit focused on three aspects of providing drug benefits: evidence-based decision making, cost-effectiveness, and monitoring of drug utilization.

We examined the processes used by Veterans Affairs Canada to decide what drugs it covered, including whether decisions taken by the Department to add, reject, or remove drugs from its drug benefits list were documented and based on evidence. We also examined strategies that the Department used to manage the costs of the drugs covered under its drug benefits program. We examined whether the Department systematically monitored and analyzed drug benefits utilization data to support safe and effective drug utilization. This included an examination of the progress made by the Department in implementing selected recommendations from our 2004 report.

The audit approach included interviews with Department officials and an examination of policies and documents related to

- processes established by the Department to support decisions to add, remove, or limit access to drug benefits. We also reviewed 32 of the 60 drug benefits decisions made by the Department's Formulary Review Committee in the 2013–14 and 2014–15 fiscal years to determine whether they were supported by evidence;
- the development and implementation of cost-effectiveness strategies intended to help manage the costs of drugs covered by the Department; and
- the monitoring of utilization of drugs covered by the Department.

We also interviewed representatives from Medavie Blue Cross.

The audit scope did not include an examination of

- veterans of the RCMP who are eligible to receive health care benefits from Veterans Affairs Canada as a result of a service-related injury or illness;
- the Canadian Agency for Drugs and Technologies in Health, which is responsible for providing health care decision makers with objective evidence to help make informed decisions about the optimal use of health technologies, including drugs;
- Health Canada's processes for approving drugs for sale in Canada or for monitoring adverse drug reactions;
- the Patented Medicine Prices Review Board, which is responsible for ensuring that the price of patented drugs in Canada is not excessive;
- processes in place to provide drugs to veterans enrolled in Veterans Affairs Canada's rehabilitation program or admitted to Ste. Anne's Hospital; and
- other components of the Department's Health Care Benefits Program.

Criteria

Criteria	Sources
To determine whether Veterans Affairs Canada managed the drug component of its Health Care Benefits Program to contribute to the health of its veteran population by providing coverage for drugs based on evidence, by using cost-effectiveness strategies, and by monitoring the utilization of drugs covered, we used the following criteria:	
Veterans Affairs Canada makes decisions related to the drugs that are covered under its drug benefits program based on evidence.	• *Department of Veterans Affairs Act* • *Veterans Health Care Regulations* • Formulary Review Committee Terms of Reference, Veterans Affairs Canada • Prescription Drugs Policy, Veterans Affairs Canada • Five-Year Strategic Plan 2009–2014, Veterans Affairs Canada
Veterans Affairs Canada uses cost-effectiveness strategies to manage the cost of drugs covered under its drug benefits program.	• *Department of Veterans Affairs Act* • *Veterans Health Care Regulations* • Prescription Drugs Policy, Veterans Affairs Canada • Formulary Review Committee Terms of Reference, Veterans Affairs Canada • Five-Year Strategic Plan 2009–2014, Veterans Affairs Canada • Policy Framework for Financial Management, Treasury Board • Policy on Financial Management Governance, Treasury Board

Criteria	Sources
To determine whether Veterans Affairs Canada managed the drug component of its Health Care Benefits Program to contribute to the health of its veteran population by providing coverage for drugs based on evidence, by using cost-effectiveness strategies, and by monitoring the utilization of drugs covered, we used the following criteria: (continued)	
Veterans Affairs Canada monitors the utilization of drugs covered under its drug benefits program in order to support their safe and effective utilization.	• *Department of Veterans Affairs Act* • *Veterans Health Care Regulations* • Prescription Drugs Policy, Veterans Affairs Canada • Five-Year Strategic Plan 2009–2014, Veterans Affairs Canada

Management reviewed and accepted the suitability of the criteria used in the audit.

Period covered by the audit

The audit primarily covered the period between 1 April 2013 and 31 March 2015. Audit work for this report was completed on 1 April 2016.

In addition, we extended our examination of authorization patterns of marijuana for medical purposes to include data for the period 1 April to 31 December 2015. This additional information did not change our audit conclusion.

Audit team

Assistant Auditor General: Jerome Berthelette
Principal: Casey Thomas
Directors: Dawn Campbell
Jo Ann Schwartz

Sebastien Bureau
Mark Carroll
Anthony Maki
Kathryn Nelson

List of Recommendations

The following is a list of recommendations found in this report. The number in front of the recommendation indicates the paragraph where it appears in the report. The numbers in parentheses indicate the paragraphs where the topic is discussed.

Recommendation	Response
Management of the drug benefits list	
4.28 Veterans Affairs Canada should implement a decision-making framework that specifies the type of evidence and how it is considered. The Department should use this framework to decide which drugs to pay for and to what extent it will pay for them. The framework should also include requirements that the Department update the drug benefits list on a timely basis. **(4.20–4.27)**	**Veterans Affairs Canada's response.** Agreed. Veterans Affairs Canada is currently developing a decision-making framework that will outline the type of evidence, including cost-effectiveness, to be considered when making formulary decisions, and will establish a governance structure and senior management oversight. The Department will also work with Health Canada and recognized experts in the field of marijuana utilization for medical purposes, and will consult with other federal departments to identify areas of best practices to model. In September 2015, a new national pharmaceutical advisor was hired. The new pharmaceutical advisor will lead the development of standardized operating procedures for formulary reviews, which will outline the manner in which decisions are made and implemented. This work will be done in conjunction with our federal partners and other jurisdictions. Veterans Affairs Canada will also add resources to the treatment benefits program management team. All of these initiatives will be implemented by May 2017.
Cost-effectiveness strategies	
4.43 Veterans Affairs Canada should periodically review its cost-effectiveness strategies to identify whether • they are up to date and are leading to reduced costs for drugs and pharmacy services, and • other potential strategies should be pursued alone or in collaboration with other federal departments. **(4.37–4.42)**	**Veterans Affairs Canada's response.** Agreed. Veterans Affairs Canada will enhance its cost-effectiveness strategies through regular assessments and reviews of the formulary, and research strategies used by other drug plans. The Department will leverage its partnerships with other federal government departments and other jurisdictions to pursue efficiencies for the Department, wherever possible, and cost-effective solutions for our veterans. The Department has already commenced working with other federal partners and the pan-Canadian Pharmaceutical Alliance to explore opportunities. All of the above will be completed by May 2017.
4.47 Veterans Affairs Canada should explore ways in which the costs associated with marijuana for medical purposes can be contained. **(4.44–4.46)**	**Veterans Affairs Canada's response.** Agreed. Veterans Affairs Canada will develop a policy on marijuana for medical purposes, putting the health, well-being, and safety of our veterans at the forefront. The Department will leverage medical expertise to identify the most efficient and effective approach. This may require regulatory consideration. This policy will be developed and implemented by May 2017.

Recommendation	Response
Monitoring of drug utilization	
4.65 Veterans Affairs Canada should develop a well-defined approach to drug utilization monitoring that serves the needs of veterans and helps the Department manage its drug benefits program. **(4.54–4.64)**	**Veterans Affairs Canada's response.** Agreed. Veterans Affairs Canada will enhance its drug utilization monitoring process to support the health, safety, and well-being of its veteran population. The Department recognizes that the individual health of a veteran is the primary responsibility of the physician or regulated health professional and the medical system. The drug utilization monitoring process will be based upon this reality. Accordingly, the Department intends to develop an efficient approach, governance structure, and oversight in order to establish safeguards, monitor trends, and determine potential risks that could affect the health and well-being of its veteran population. This will better inform Departmental decision making at the program level and further support the well-being of the veteran population. The Department will leverage its partnerships with other jurisdictions' programs to obtain information on best practices. The Department will review performance data, setting targets and trajectories and implementing routine procedures to track progress on the management of the drug benefits program. Given that the Department will rely on significant industry research and consultation with other federal jurisdictions and private plan carriers, this approach will be completed by May 2017.