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Auditor General of British Columbia

Managing PharmaCare:

Slow Progress Toward Cost-Effective Drug Use and a Sustainable Program

Ministry of Health

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The Honourable Bill Barisoff
Speaker of the Legislative Assembly
Province of British Columbia
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Dear Sir:

I have the honour to transmit herewith to the Legislative Assembly of British Columbia my 2005/2006 Report 8: Managing PharmaCare: Slow Progress Toward Cost-Effective Drug Use and a Sustainable Program.

Wayne Strelioff, FCA
Auditor General

Victoria, British Columbia
March 2006

copy: Mr. E. George MacMinn, Q.C.
Clerk of the Legislative Assembly

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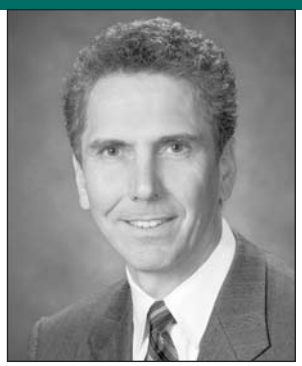

Wayne Strelioff, FCA
Auditor General

Across Canada and in BC, the cost of pharmaceuticals has been one of the largest and fastest growing components of health care. The main reasons for increased drug spending in Canada are the higher volume of drug use and the entry of new drugs (typically at higher prices) into the marketplace. In 2004, Canadians spent an estimated $18 billion on prescription drugs. In British Columbia, we spent $1.8 billion. For many British Columbians, medications play a prominent role in treating chronic conditions, preventing and curing diseases, and in the day-to-day management of their physical and mental health.

While many Canadians pay for their prescription drugs themselves, some are covered by private benefit plans or by federal or provincial government programs. In British Columbia, that program is PharmaCare. The PharmaCare program provides financial support for the purchase of medications and some medical supplies to those who qualify for such support.

The program is important because its responsibility reaches beyond that of its own mandate. Managing the cost and use of drugs not only affects what PharmaCare covers (overall about 50% of the cost) but also what others, such as private insurers and the public, pay. The ministry shares this responsibility with other agencies. The federal government, for example, decides which prescription drugs can be sold in Canada and through the Patented Medicines Review Board, establishes the maximum price that manufacturers can charge pharmacies for each drug. Each province then determines which drugs to provide as benefits through their drug programs and the amount of reimbursement.

In 2005/2006 the government expects to spend almost $900 million on PharmaCare. By 2007/2008 the PharmaCare budget is expected to exceed $1 billion. These are increases of about 10 percent a year. An aging population, an increase in the prevalence of chronic diseases and the emergence of new drugs will put even greater strain on PharmaCare in future.

It is this spectre of increasing costs and concern over the sustainability of the PharmaCare program to continue providing adequate coverage to meet its program goals that led me to undertake this audit. Costs of PharmaCare can be managed in two ways – by managing the program effectively and by helping the population become healthier and less reliant on medications.

Auditor General's Comments

This audit focuses on management of the PharmaCare program. In a future audit, I will assess how well the government manages to prevent illness and promotes actions that lead to a healthier population.

The purpose of this audit was to assess how well the Ministry of Health manages the PharmaCare program in order to achieve its goal of operating a sustainable, evidence-based, prescription drug insurance program that improves the health of British Columbians. Specifically, we considered whether:

- program performance is assessed regularly and changes made where needed,
- drugs covered by the program are continuously assessed for their effectiveness,
- drugs are purchased at a reasonable cost,
- drug use is monitored and cost-effective prescribing practices encouraged,
- eligibility of insured persons is assessed, and those eligible are made aware of and have access to PharmaCare coverage,
- claims submitted by pharmacies are reviewed for compliance with pricing and other agreements including privacy and security of patient information, and
- performance is reported to the Legislative Assembly.

We conducted our field work for this audit between September 2004 and March 2005.

Overall Conclusion

Overall, I concluded that progress toward cost-effective drug use and a sustainable PharmaCare program is being compromised by insufficient management attention.

Although the program has been a leader in implementing a number of initiatives, such as the PharmaNet system, cost containment and drug utilization strategies, and the Therapeutics Initiative, progress to expand these useful initiatives to maximize their benefit, has been slow. Expansion of these and other initiatives can move PharmaCare further towards achieving its strategic objectives. The key factors underlying this slow progress are the lack of sufficient human resources, clear direction, appropriate performance measures and key accountabilities.

Auditor General's Comments

Recent implementation of the Fair PharmaCare program has initially slowed the increase in PharmaCare costs. However, it is important that the Ministry of Health take appropriate steps to ensure the sustainability of the PharmaCare program while providing reasonable access to prescription drugs.

My conclusion is troubling because it echoes of an earlier conclusion my office reached on the PharmaCare program. The conclusion and key findings in our *1998/1999: Report 2 Managing the Cost of Drug Therapies and Fostering Appropriate Drug Use*, available at www.bcauditor.com, bear a striking similarity to those in this report. Those themes included an effective review process for new drugs, but limited review of existing drugs, under-use of information in the PharmaNet system to foster appropriate prescribing, lack of performance measures, and limited evaluation and reporting of program results. Although, over the last six years, I have noted ministry progress in dealing with some of these issues, the issues themselves have become more compelling and PharmaCare's momentum to move on them constrained by regular turnover of PharmaCare's top management and chronic understaffing.

At the time I undertook the audit, PharmaCare had recently implemented the Fair PharmaCare Program, focusing on providing financial assistance to those who need it most—where the lower your income, the more assistance the government provides to cover the cost of your prescription drugs. PharmaCare was also in the process of carrying out a review—commonly referred to as the PharmaCare Program Review—of how it deals with its major stakeholders, including the physicians, pharmacists and the pharmaceutical industry; and of how it decides on what drugs to include in its drug coverage plan. Also underway was selection of a third-party service provider to carry out the day-to-day operations of PharmaCare's registering residents, processing claims, paying pharmacies, and running the help line for physicians, pharmacists and the public. Where applicable, we have included these initiatives in our assessments.

Auditor General's Comments

Key Findings

Managing PharmaCare's performance is hampered by lack of a results-based approach

The ministry has developed strategic objectives for the PharmaCare program that are intended to encompass all aspects of the program's mission—why it exists. However, these objectives are not linked to the actions that need to be taken to accomplish those objectives. Without this direction, it is difficult for the ministry to develop meaningful performance measures with which to define PharmaCare's success or failure. For example, one academic evaluation suggested that drug costs have risen more slowly in British Columbia since PharmaCare has focused drug coverage decisions on evidence of positive patient outcomes (often it is the older drugs that are able to provide a history of success). However, the degree to which PharmaCare actions are responsible for this is unknown because specific measures have not been developed.

Although the ministry is taking steps to develop a results-based approach to planning, monitoring and reporting, other priorities such as the implementation of the Fair PharmaCare program and outsourcing of the PharmaNet operations prevented PharmaCare management from implementing this approach as it had intended in 2004/2005.

In other work my Office has done, we have found general consensus that a focus on results helps an organization demonstrate program relevance, focus improvement in performance, provide better information for decision-making, and facilitate greater transparency. We recognize that issues of capacity prevented PharmaCare from fully implementing this approach; however, had it been given priority, earlier recognition of the effects of its diminished capacity would have been made clear to the ministry.

In November 2004, the Province signed a contract with Maximus, Inc. to run the Medical Services Plan and PharmaNet systems. We reviewed the contract and found that it provided a useful framework for PharmaCare to evaluate the effectiveness of the services provided. This contract should be formally evaluated, to determine its effectiveness. An initial evaluation will provide insights regarding the start-up year of operations, with subsequent evaluations determining its continued effectiveness.

Auditor General's Comments

Drugs initially undergo rigorous review for cost-effectiveness, but limited review later to assess continued cost-effectiveness

The government is always under pressure to provide access to new drugs, yet at the same time must ensure that the drugs covered work effectively at a reasonable price. For new drugs available for sale in Canada, PharmaCare now relies on the work of the national Common Drug Review, established in 2003 to eliminate the need for each province to do its own assessment of a new drug's clinical effectiveness, safety and preliminary cost-effectiveness considerations. Drugs that pass the Common Drug Review are then further scrutinized by PharmaCare to determine their affordability for British Columbia. We concluded that these PharmaCare reviews are carried out in a rigorous manner; but, at times, the process appears laborious.

However, once new drugs are added to the official list of covered drugs (known as the "formulary"), PharmaCare does not have a process in place to assess their continuing cost-effectiveness. As well, because many of these drugs were added to the formulary before such rigorous reviews were carried out, there is a risk that some may have outlived their usefulness and should not necessarily be covered any longer.

Efforts to secure the best prices are limited

A maximum price is set by the national Patented Medicine Prices Review Board for each new and existing patented medicine. In British Columbia, pharmacies are responsible for purchasing drugs. PharmaCare must rely on the pharmacy's skills to get the best price from a manufacturer or wholesaler. PharmaCare pays the pharmacy's actual acquisition cost of the drug, but limits that to 7% above the manufacturers' suggested price. Other methods of procurement, such as bulk or group purchasing, are also being used to some extent by other jurisdictions and within British Columbia's hospital pharmacies and chain pharmacies to successfully reduce costs. However, bulk purchasing and other options have not been explored to any extent by the ministry; although, a recommendation from the recent PharmaCare Program Review has resulted in the ministry starting to evaluate various options.

Auditor General's Comments

More should be done to inform physicians about best practices in drug prescribing and enhance access to PharmaNet

Several ministry initiatives have been successful in guiding physicians to practice cost-effective prescribing. These include the Therapeutics Initiative's drug information letters and workshops aimed at physicians and pharmacists, academic drug detailing with physicians on Vancouver's North Shore and access to the PharmaNet drug information system provided to 100 physicians' offices as a pilot project. My concern is that the ministry has missed an opportunity to expand the scope of these initiatives—over the past five years—to reach a much larger percentage of physicians.

We also concluded that the PharmaNet system—which holds a wealth of information that could be directed at promoting cost-effective prescribing—is underused. It could, for example, be available to physicians to help them learn about their own prescribing practices and the possible results had clinical best practices been followed. The ministry is taking steps to provide better access to this information—which for the most part, has only been used up to now to adjudicate claims and identify potential drug interactions—but progress has been slow. For example, legislative changes have not been put into force, that among other things, would move stewardship of PharmaNet to the ministry.

Eligibility of insured persons is generally adequately assessed but eligibility information is limited for the smaller plans

Within the PharmaCare program, different plans are available for residents to meet different health situation and financial needs, each with its own eligibility criteria. Our review focused on those plans that are processed through pharmacies—the largest being Fair PharmaCare, the universal plan covering the majority of families and seniors. We found that people's eligibility is being adequately assessed for all but one of the smaller plans—Plan G providing no-cost psychiatric medications. We also found that the ministry website provided easily accessible information about eligibility for Fair PharmaCare, but not for the other plans, and that citizens often ask physicians and pharmacists about access and coverage.

Auditor General's Comments

Claims by pharmacies are reviewed for compliance

The PharmaNet system, which is connected to all community pharmacies in the province (those that sell drugs directly to the public), provides information on patients, potential drug interactions, claims adjudication and amounts owing to pharmacies from PharmaCare. PharmaCare has confidentiality agreements with pharmacy owners, and their staff, to protect the privacy and security of patient information. The complexity of the PharmaNet system requires that the ministry have adequate procedures in place to ensure its policies for approving, processing and paying claims are adequate and being followed. We found that analysis of PharmaNet information and on-site audits of pharmacy records are effective in identifying incidents of non-compliance, which are then corrected though payment adjustments, policy clarifications and other sanctions.

Relevant but incomplete performance information is provided

The only specific performance measures we found in the ministry's annual report for 2003/2004 related to people's access to the universal plan–Fair PharmaCare. The baseline of 67% was established as those adequately insured for prescription drug cost—described as no family pays more than 4% of their net income for prescription drugs. Also mentioned is that any potential negative impacts of Fair PharmaCare are being monitored, and that preliminary evaluations indicate that drug use has not decreased in either the senior or non-senior groups since implementation.

No mention was made of how well PharmaCare is maximizing the appropriateness and cost-effectiveness of drug therapy and promoting optimal drug prescribing—two critical aspects of its mission. Nor was there reference to the capacity issues that are central to the difficulties experienced in the policy and management group.

Auditor General's Comments

My Recommendations

Implementing a results-based approach

We recommend that the ministry:

1. **Review PharmaCare's strategic objectives and make necessary adjustments to reflect current thinking.**
2. **Align PharmaCare strategic objectives with statements of actions that describe how the objectives are to be achieved.**
3. **Determine the human resources needed to achieve the program's objectives and build capacity to meet those needs.**
4. **Develop performance measures for, set targets for, and collect information on achievement of program objectives.**
5. **Work with the College of Pharmacists and others to move custodianship of PharmaNet information to the ministry, and provide timely access.**
6. **Formally evaluate the MAXIMUS BC contract on a regular basis, to determine its effectiveness.**

Ensuring cost-effectiveness of drugs

We recommend that the ministry:

7. **Review internal procedures for assessing the cost-effectiveness of new drugs to identify and implement ways to streamline the assessment process, including consideration of a fast-track process.**
8. **Put in place a process to systematically assess the cost-effectiveness of existing drugs in the formulary.**

Purchasing at a reasonable cost

We recommend that the ministry:

9. **Explore and implement ways to ensure best prices are paid for drugs by the province.**

Auditor General's Comments

Promoting cost-effective prescribing practices and drug use

We recommend that the ministry:

10. **Use PharmaNet information to identify trends in prescribing practices and to inform physicians about their own prescribing practices and the projected results had currently recognized clinical best practices been followed.**
11. **Significantly increase support for PharmaCare-sponsored programs that encourage appropriate drug use through physician best practices in prescribing (such as Therapeutics Initiative Letters, physician access to PharmaNet, and the academic drug detailing program).**
12. **Support greater involvement of physicians in developing actions to promote appropriate drug use.**

Assessing eligibility of insured persons

We recommend that the ministry:

13. **Review Plan G – No-charge Psychiatric Medication Program and the supporting policy framework, to ensure they are consistent.**
14. **Ensure that eligibility criteria for Plan G – No-charge Psychiatric Medication Program are clear, and that eligibility is being assessed in accordance with the criteria.**

Meeting accountability responsibilities

We recommend that the ministry:

15. **In its annual report, move toward reporting in a manner consistent with the British Columbia reporting principles on the performance of the PharmaCare program.**

Auditor General's Comments

I carried out this audit in conjunction with seven other provinces' auditors general and that of OAG Canada. We collaborated on the criteria used to assess our respective drug reimbursement programs. Reports have already been issued by the Auditors General of Canada, Quebec, Nova Scotia, Prince Edward Island, Saskatchewan, Newfoundland/Labrador, and New Brunswick on the management of the drug insurance programs in their respective jurisdictions. The remaining report from Manitoba is about to be issued.

I wish to thank everyone who cooperated with my Office and assisted us in gathering the information for this audit. As well, I would like to acknowledge the hard work, professionalism and dedication of my staff in the production of this report.

Wayne Strelioff, FCA
Auditor General

Victoria, British Columbia
December 2005

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Background

What is PharmaCare?

PharmaCare is British Columbia's drug insurance program, assisting eligible residents to pay for certain prescription drugs and certain medical supplies. Because drug therapy is an essential part of many people's medical care, PharmaCare is an integral component of the health care system.

In British Columbia, we have one of the lowest per capita prescription drug expenditures at $421. This has been attributed, partly to the preference of British Columbians to take fewer drugs, and partly to PharmaCare's drug pricing program and generic drug policies that promote low-cost drugs that have a long track record and are proven effective. However, this has also meant that the newest drugs are not always covered by PharmaCare as quickly as in other provinces.

A key role for the Ministry of Health is to manage the performance of the PharmaCare program in meeting the latter's goal of achieving a sustainable, evidence-based, prescription drug insurance program that improves the health of British Columbians. Strategies that PharmaCare uses to do this include:

- Reimbursing clients for prescription drugs and related benefits through sustainable, equitable and effective programs.
- Striving to provide equity of access to its drug insurance plans.
- Implementing policies that maximize the appropriateness and cost effectiveness of drug therapy.
- Promoting optimal drug prescribing by physicians.
- Using evidence-based policy-making through reliance on the best and most up-to-date analysis of scientific research.

This is not the first time we have looked at the ministry's management of PharmaCare. In our *1998/1999: Report 2 Managing the Cost of Drug Therapies and Fostering Appropriate Drug Use*—available at www.bcauditor.com/AuditorGeneral.htm—our key findings have a striking similarity to those in this report. Those themes included an effective review process for new drugs, but limited review of existing drugs, under-use of information in the PharmaNet system to foster appropriate prescribing, lack of

Background

performance measures, and limited evaluation and reporting of program results.

We carried out this audit in conjunction with auditors general in nine jurisdictions in Canada. Through the Health Study Group of the Canadian Council of Legislative Auditors (CCOLA) we collaborated on the criteria used to assess our respective drug reimbursement programs (Appendix A). Reports have already been issued by the Auditor General of Canada, Quebec, Nova Scotia, Prince Edward Island, Saskatchewan, Newfoundland/Labrador, and New Brunswick on the managment of drug reimbursement plans in their respective jurisdictions (Appendix B). The remaining report from Manitoba is about to be issued.

Audit purpose and scope

The purpose of our audit was to assess how well the ministry is managing the PharmaCare program in order to achieve its desired goal of a sustainable, evidence-based program that improves the health of British Columbians.

The PharmaCare program makes different plans available for residents of British Columbia to support their different situations and financial needs (Exhibit 1). Our examination focused on the plans that are processed through community pharmacies. These plans accounted for 95% of claim payments ($675 million) in 2003/04. Although the Digestive Enzymes for Cystic Fibrosis Patients Program and the Children in the At Home Program both fit this criterion, we excluded them from our assessment because of their size. Also excluded, was the BC Centre for Excellence in HIV/AIDS plan, managed outside of community pharmacies. Our fieldwork was conducted between September 2004 and March 2005.

We performed this audit in accordance with assurance standards recommended by the Canadian Institute of Chartered Accountants, and accordingly included such tests and other procedures we considered necessary to obtain sufficient evidence to support our conclusions.

To provide comparability with the other auditor general's reports, we have included PharmaCare transactions for the year ended March 31, 2003 in our analyses wherever applicable. Our systems review work, however, includes activities and transactions for the year ended March 31, 2005.

Background

Overall Conclusion

Overall, we concluded that progress toward cost-effective drug use and a sustainable PharmaCare program is being compromised by insufficient management attention.

Although the program has been a leader in implementing a number of initiatives, such as the PharmaNet system, cost containment and drug utilization strategies, and the Therapeutics Initiative, progress to expand these useful initiatives to maximize their benefit, has been slow. Expansion of these and other initiatives can move PharmaCare further towards achieving its strategic objectives. The key factors underlying this slow progress are the lack of sufficient human resources, clear direction, appropriate performance measures and key accountabilities. Recent implementation of the Fair PharmaCare program has initially slowed the increase in PharmaCare costs. However, it is important that the Ministry of Health take appropriate steps to ensure the sustainability of the PharmaCare program while continuing to provide reasonable access to prescription drugs.

Background

Exhibit 1

PharmaCare Drug Coverage Plans

Plan	Plan B	Plan C	Plan G	Plan I	Plan P
Description	Permanent residents of long-term care facilities	Recipients of income assistance	No-charge psychiatric medications	Fair PharmaCare	Palliative care drugs
Plan Coverage	The full cost of eligible prescription drugs and certain medical supplies	100% of both drug costs and dispensing fees are eligible within the maximums allowed for the drugs	The full cost of certain psychiatric drugs as listed in the formulary for this plan	Assistance available for eligible prescriptions and medical supplies based on a family's net income	100% coverage for drugs listed in the BC Palliative Care formulary
Eligibility at Registration	■ Permanent resident of a licensed long-term care facility ■ Short-term residents in a facility are covered by the applicable plan (for example Plan I)	■ Recipient on income assistance	■ A person not on Plan B or Plan C, and ■ Who is a recipient of Medical Services Plan (MSP) premium assistance	■ Resident of BC for at least three months ■ Registered with MSP ■ Have filed an income tax return for the two years prior to the year in which Fair PharmaCare financial assistance will begin	■ Registered with MSP ■ Living at home ■ Diagnosed as being in the terminal stage of a life-threatening illness ■ Life expectancy of up to six months ■ Consent to focus of care as palliative and not cure
Registration Method	■ Facility processes prescriptions through a pharmacy that has a Participation Agreement with PharmaCare	■ Recipient registers with the Ministry of Human Resources when qualified for income assistance	■ Administered through mental health service centres ■ Application form with a physician's signature	■ Through the Fair PharmaCare registration desk by phone or on line	■ Completed registration form by physician and faxed to PharmaCare
Client Base*	24,432	158,650	20,251	707,714	7,720

* For Fiscal Year 2004/2005. Client's are counted in both plans if a transfer from one plan to another took place during the year.

Source: Ministry of Health and PharmaCare/PharmaNet Policies and Procedures Manual Version 3.0

Background

The World of Prescription Drugs

In Canada, the manufacture, distribution and sale of prescription drug products is a multi-billion-dollar industry. In 2004, Canadians spent an estimated $18 billion on prescription drugs ($1.8 billion in British Columbia). In Canada, we now spend more on these drugs than we pay for physician's services—and of all the major categories of health expenditure, only hospital spending exceeds it.

Prescription drugs are not insured under the Canada Health Act, except when dispensed in a hospital setting. While many Canadians pay for their prescription drugs themselves, some are covered by private benefit plans or by federal or provincial government programs.

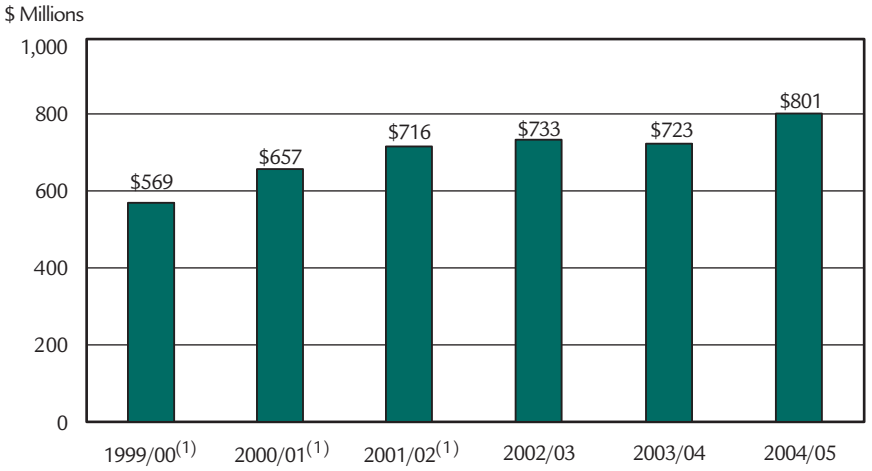
In its most recent report on drug expenditures, the Canadian Institute for Health Information (CIHI) reported that since the prices of older drugs have been relatively stable over the past 10 years, the main reasons for increased drug spending in Canada are the higher volume of drug use and the entry of new drugs (typically at higher prices) into the marketplace.

In British Columbia, PharmaCare's expenditure for prescription drugs has risen from $372 million in 1996 when we first looked at PharmaCare to $713 million in 2004. This represents an overall increase of 92%, with an average yearly increase of 9%. The implementation of Fair PharmaCare, which provides coverage based on citizens' ability to pay, has slowed the increase. However, experts agree that drug cost pressures are continuing to threaten the sustainability of the province's drug insurance program. The following exhibit combines these prescriptions drug costs with annual program operating costs to provide a cost comparison of total PharmaCare costs from 1999 to 2004.

Background

Exhibit 2

Total PharmaCare Costs, 1999—2004



(1) Includes Home Oxygen Program expenditures of $14, $15 and $16 million respectively. Beginning in 2002/03 this program was funded outside of Pharmacare.

Source: Ministry of Health

Our Expectations

We expected PharmaCare, as a prudent manager of the provincial drug insurance program, to take reasonable steps to meet its goal of achieving a sustainable, evidence-based program that improves the health of British Columbians. Specifically, we expected PharmaCare to have processes in place to:

- manage the performance of the drug insurance program,
- ensure drugs covered are managed with due regard for cost-effectiveness,
- monitor the quantity and relevance of drug use and encourage appropriate and economical prescribing practices,
- ensure the eligibility of insured persons,
- ensure reimbursement claims submitted by pharmacies and others are appropriate, and
- report on its performance to the Legislative Assembly.

Background

In the following sections of this report, we present our audit findings and conclusions on the extent to which the ministry is meeting these criteria.

Managing PharmaCare's Performance

Best practices for managing performance suggest that an organization integrate planning and reporting tools into its everyday management practices. To help ministries to do this through a results-based approach, the British Columbia government legally requires that they prepare annual service plans and annual reports.

A companion document, "Guidelines for Ministry Service Plans 2003/04–2005/06" calls for linking goals, objectives, strategies and performance measures in order to manage performance. It defines objectives as the concise, realistic and concrete results to be achieved on the way to accomplishing goals—outcomes that a ministry wants to achieve. Strategies are high-level statements of actions that describe how objectives are to be achieved. And performance measures show the degree of success with which goals and objectives have been met. With this information, a ministry would better know if what it is doing (how it is spending its time and resources) is going to lead to the results it wants. Collecting and looking at this information on a regular basis would provide the opportunity for the ministry to make timely adjustments.

After the end of each fiscal year, each ministry is required to submit an annual service plan report describing the degree to which it has met the goals and objectives set out in its service plan. This completes the cycle of planning and reporting, allowing government to show the public and other stakeholders what has been achieved and at what cost.

Besides the annual service plan and annual reporting processes, other aspects that support the Ministry of Health in delivering the PharmaCare program include enabling legislation, comprehensive policies and procedures, and a good selection and accountability process for third-party service providers.

We expected to find the ministry adhering to these practices.

Conclusion

PharmaCare's ability to manage program performance is limited by the lack of a demonstrated comprehensive results-based approach. It has identified what it wants to accomplish and publicly lists five strategic objectives it is pursuing. However, these objectives are not linked to statements of actions that describe how they are to be achieved. Had this been done, early detection of its diminished capacity to carry out the actions may have received earlier attention.

Also, without linking objectives to actions, it makes it difficult for PharmaCare to develop meaningful performance measures. Therefore, it is not surprising that there are few robust measures in place to gauge PharmaCare's success or failure in achieving its objectives. We find this disturbing since PharmaCare is operating alongside the pharmaceutical industry, where manufacturers practice a very strong results-based approach.

To its credit, the ministry does have processes in place that support compliance with PharmaCare's legislation, policies and procedures. And comparisons with the other provinces indicate that British Columbia has the lowest per capita prescription drug expenditure, with no indication that the health of residents is compromised because of it. As well, the recent move to contract out the operations of the PharmaNet system and other day-to-day operations, followed a rigorous selection process that has resulted in a contract that should support the evaluation of the effectiveness of service delivery. At the time of this report, the ministry had assessed penalties for several months of missed targets on the Medical Services Plan portion of the contract, indicating that services levels are being evaluated.

Findings

PharmaCare has set strategic objectives that are comprehensive, but it is not sure how best to determine if it has achieved them.

PharmaCare Mission:
To improve the health status of British Columbians by providing reimbursement to ensure reasonable access to and appropriate use of prescription drugs and related benefit services for eligible residents of the province.

Objectives:

- Providing reimbursement for prescription drugs and related benefits through sustainable, equitable and effective programs
- Striving for equity of access to its drug insurance plans
- Implementing policies that maximize the appropriateness and cost effectiveness of drug therapy
- Promoting optimal drug prescribing by physicians
- Utilizing evidence-based policy making through reliance on the best and most up-to-date analysis of scientific research

PharmaCare's objectives have not changed substantially since we carried out our audit of the program in 1997. The objectives use terms such as "sustainable" and "evidence-based" now, but in essence the program continues to focus on managing the cost of drug therapies it covers for residents and fostering appropriate drug use. As well, the program still lacks comprehensive performance measures with which to determine how well these objectives are being met. This lack of developing and linking performance measures is directly related to the lack of specific objectives and targets set for the various cost reduction and drug use programs supported by the ministry.

To its credit, the ministry has been carrying out or supporting some evaluations both on the effect of its actions and to direct future actions, see side bar on next page. The ministry is also supporting a joint pilot project with the province of Ontario to develop and implement a way to seek evidence about patient safety and how well drugs and drug coverage policies are working. This study of outcomes in the real world is referred to as post-market surveillance or pharmacosurveillance. The study was started in 2002/03 by the Therapeutics Initiative and Ontario's Institute of Clinical Evaluative Sciences. Separate projects were set up for each of the several drugs under evaluation. To date some results have been published and others expected in 2006.

Overall, however, we believe that the ministry needs to better link PharmaCare evaluation efforts to the objectives it is hoping to achieve. We expect that the ministry will identify many more opportunities to evaluate its actions as it refines its performance management processes.

Managing PharmaCare's Performance

Evaluations Carried Out by the Ministry or Others

- working with the Centre for Health Services and Policy Research (CHSPR) at the University of British Columbia to monitor and assess the impact of the program change regarding "ability to pay"—Fair PharmaCare.
- tracking registration levels for Fair PharmaCare to identify potential access issues.
- through an agreement with Harvard University, tracking the use of proton pump inhibitors (to treat gastrointestinal ailments).
- analysing prescribing trends for thiazide (a class of diuretic) in hypertensive seniors
- looking at how well residents are protected from catastrophic drug costs.
- tracking hypertensive patient medication compliance.
- demonstrating outcomes-based coverage in selecting drugs for the formulary
- looking at the cause of drug expenditure inflation, and
- supporting numerous evaluations of the reference drug program.

The ministry holds a wealth of information in its PharmaNet system, capturing the details of every prescription drug transaction that takes place in the province. As a result, the ministry is able to publish a myriad of statistics in its *PharmaCare Trends* document, including the number of patients reimbursed, ingredient cost paid, dispensing fees paid and number of prescriptions dispensed. *PharmaCare Trends* covers several years, but the information is somewhat dated (with 2003 being the most recent). Also missing is an analysis of what the numbers mean and how they link to PharmaCare's objectives.

The ministry uses its low cost alternative and reference drug policies to contain costs; Therapeutics Initiative letters, academic detailing and the PharmaNet system to foster appropriate drugs use and a rigorous review before coverage of any new drugs. Although these activities move the ministry towards its PharmaCare objectives, it can do better at determining if its efforts are being directed in the best places and are truly effective.

A well-developed service plan—starting with an annual review of the objectives, strategies and actions to meet them, and performance measures with targets to track progress—will enhance decision-making and help direct PharmaCare in using resource effectively. The PharmaNet system has been underused, but the potential for tracking relevant performance measures is enormous—particularly if the information collected were improved to include the disease or condition for which the drugs were prescribed.

The ministry anticipated developing a service plan for the $800 million PharmaCare program in November 2004, but other priorities took precedence and this did not occur. We are concerned that the inadequate staffing levels in the policy branch (as described to us and reaffirmed in the PharmaCare Program Review) may be preventing the ministry from carrying out a vital aspect of the program's management.

We recommend that the ministry:

1. ***Review PharmaCare's strategic objectives and make necessary adjustments to reflect current thinking.***
2. ***Align PharmaCare strategic objectives with statements of actions that describe how the objectives are to be achieved.***

3. ***Determine the human resources needed to achieve the program's objectives and build capacity to meet those needs.***
4. ***Develop performance measures for, set targets for, and collect information to support the achievement of program objectives.***

The ministry has procedures in place to ensure compliance with legislation and policies, but implementation of legislation to improve access to PharmaNet information has been delayed.

Various Acts, regulations and policies provide the ministry with the authority it needs to administer the PharmaCare Program and the framework within which it must operate.

The PharmaCare Policies & Procedures Manual gives pharmacies the guidance they need to comply with the program's policies and procedures. The manual is available on the ministry's website. Each community pharmacy also signs a legal agreement with the ministry that it will stay in compliance.

The PharmaNet system plays a major role in ensuring compliance, by adjudicating patient claims and processing the resulting payments to pharmacies. The ministry also carries out audits of pharmacies to ensure the legitimacy of prescriptions and confirm the accuracy of drug costs submitted, and follow up on concerns identified through PharmaNet or other sources. Identified non-compliance is corrected through billings for overpayments and communication with individual pharmacies, and through the PharmaCare Newsletter, which addresses issues requiring widespread communication.

The Fair PharmaCare program operates under a Memorandum of Agreement with the Canada Revenue Agency for the provision of taxpayer information. The agreement confirms that the information will be used only for determining the level of benefit for eligible participants enrolled in that plan.

Other pieces of relevant legislation regarding access and use of health information include the *Freedom of Information and Protection of Privacy Act* and the *Pharmacists, Pharmacy Operations and Drug Scheduling Act* (PPODA). The latter establishes the purpose of PharmaNet and defines who can access patient information records within the PharmaNet system. The College of Pharmacists of BC regulates access for pharmacists to the PharmaNet database.

This responsibility was initially established because the college is responsible to the public for the practice of pharmacy, and at that time pharmacists were the only ones allowed to regularly access the PharmaNet system.

Through the PharmaNet Committee, the College of Pharmacists also manages the disclosure of data from the PharmaNet system to researchers, regulatory authorities for practitioners and to the ministry. This access is needed by the ministry from time to time to help develop strategies, determine the effect of a policy or obtain information to carry out audits; however, only data for those claims that are paid for by PharmaCare are available.

The college and the ministry agree that, with the expansion in the use of PharmaNet, the stewardship role of PharmaNet should more appropriately reside with the ministry. Recent ministry initiatives have encouraged expanded access to PharmaNet by hospital emergency room departments and physicians to aid in making clinical decisions about patient care. The need to evaluate various aspects of PharmaCare and other health initiatives using PharmaNet information has also expanded.

Changes to the *Health Professions Act* to include pharmacists provided an opportunity to replace the existing legislation (PPODA) with new legislation that includes the transfer of responsibility for the stewardship of PharmaNet to the ministry under a new PharmaNet Stewardship Committee with members appointed by the ministry. Access to PharmaNet information is expected to improve with this change.

In November 2003, the Pharmacy Operations and Drug Scheduling Act received approval. However, since that time, work has been ongoing to write the necessary regulation and the new bylaws for the college; to put this new act into force. Until that work is complete, stewardship of PharmaNet remains with the college.

We recommend that the ministry:

5. ***Work with the College of Pharmacists and others to move custodianship of PharmaNet information to the ministry, and provide timely access.***

The selection process and accountability framework for a third-party service provider comply with established procurement policies and procedures and allow for an evaluation of service effectiveness.

Selection process

In July 2003, the ministry announced it was seeking an alternative service delivery provider to run the existing Medical Services Plan system (MSP), and to build a new system to improve customer services. The service provider would also run the PharmaNet system and related supports. These services in MSP and PharmaCare being contracted out—referred to jointly as Health Benefits Operations (HBO)—include responding to public enquiries, registering clients, updating PharmaNet with new plan coverage information and processing medical and pharmaceutical claims from health professionals.

The Health Benefits Operations project is one of several alternative service delivery projects across government aimed at providing greater efficiency and better value for taxpayers. The Ministry of Management Services—now known as the Ministry of Labour and Citizen Services—is the lead ministry and, through its Alternative Service Delivery Secretariat, is responsible for implementing government's Alternative Service Delivery Strategy. This group developed the Joint Solutions Request for Proposal process that promotes co-development of solutions for delivering services between a service provider and a ministry.

The ministry put together a project team with expertise in the operations of MSP and PharmaCare, technology, law, economics and negotiation. Also included were project management resources, procurement specialists and a fairness monitor to observe the procurement process to ensure fairness and consistency was applied for the proponents. This team defined the scope of the project and determined what bundle of services should be provided.

An evaluation team was developed to review the proponents' submissions, assessing the overall value of the proposed solutions for delivering MSP and PharmaCare services, as well as their demonstrated capability, commitment and capacity to deliver on their proposed solutions. This team included key members from the Ministry of Health and the senior advisor from the Alternative Service Delivery Secretariat.

The two short-listed proponents participated in a series of comprehensive workshops before developing their final presentations and solutions.

In November 2004, the government entered into a contract with Maximus, Inc., Maximus Canada Inc., Maximus BC Health Inc. and Maximus BC Health Benefit Operations Inc. The latter two organizations (collectively referred to as MAXIMUS BC) are responsible for operating the MSP and PharmaNet systems and providing most of the services formerly carried out by Health Benefits Operations. The ministry handed-over services to MAXIMUS BC on April 1, 2005; now operating as Health Information BC.

Almost 90% of the 230 employees in the operations division accepted the option of becoming employees of the new service provider.

Day-to-day, PharmaCare liaises with Health Information BC to request updates to the PharmaNet system for new drug listings, price changes and other updates.

MAXIMUS BC contract accountability framework

The literature indicates that an accountability framework should include responsibilities, objectives, performance measures, reporting requirements, reporting timelines, incentives and consequences.

We found that the contract agreement with MAXIMUS BC provides a useful framework for PharmaCare to use in evaluating the effectiveness of the services provided by MAXIMUS BC.

Components of the MAXIMUS BC Contract

1). Objectives and Guiding Principles of the Parties
2). Service Levels and Performance Metrics
3). Planning, Reporting and Exchange of Data
4). Annual Operating Plan
5). Payment Terms and Fees
6). Benchmarking of the Service Provider
7). Gain Sharing
8). Privacy, Security, Confidentiality and Publicity

The framework includes a comprehensive table of service-level requirements and corresponding penalties if service levels are not met. For example, Fair PharmaCare targets include having 80% of paper-submitted registrations completed within two business days and 99% within five business days with a phase-in date of three calendar months after the hand-over date. Also specified are the incentives for meeting those targets. Another example includes targets for turnaround times to register new pharmacies and for processing payments to pharmacists, along with the penalties that can be applied for missing those targets.

Service levels must be tracked by MAXIMUS BC, and special attention must be paid to failure to meet targets. Under the

Privacy, Security, Confidentiality and Publicity in the Contract

In response to concerns initially raised by stakeholders about British Columbia's contracting with a US-based service provider, the contract specifically addresses privacy, security, confidentiality and publicity in a number of ways. It:

- Notes that security, availability, integrity and confidentiality of information is of paramount importance to the Province, and that MAXIMUS BC will at all times abide by the contract.
- Provides a definition of confidentiality for both the Province and MAXIMUS BC. For example, the economic model, used to determine the value of the contract, is expressly deemed to be confidential information of MAXIMUS BC and is not available for outside review.
- Outlines permitted disclosure & use of confidential information, exceptions to the obligation of confidentiality, and disclosures compelled by law.
- Outlines the requirements of notification of unauthorized use of confidential information.
- Defines the requirements for publicity—for example, MAXIMUS BC must submit all advertising and other publicity material for the Province to review before it is used.
- Provides a privacy overview and framework including privacy obligations and security details.
- Discusses, in particular, the U.S. Patriot Act and the restrictions on Maximus in the event there are demands for confidential information.

protocol for reporting such failure, the cause must be determined, stakeholders informed and a remedy to the situation developed cooperatively. Service levels are reported to the province monthly. In addition to remedying the situation, MAXIMUS BC can be levied credits against its invoices to the province if it fails to meet service level targets.

After the first year, an annual operating plan is to be delivered to the ministry highlighting MAXIMUS BC's risk profile, strategies to meet objectives, and recommendations for changes to reduce costs, improve efficiencies and improve customer and stakeholder satisfaction. This plan must include a budget forecast and proposed major changes to service delivery. This gives the ministry the opportunity to ensure the operating plan can be coordinated with its own plans. It also fosters a relationship of cooperation among all parties, with no surprises.

The MAXIMUS BC contract allows either party to engage a third-party consultant to benchmark services, fees and service levels with North American companies receiving similar services in similar quantities. If both sides agree with the results of the benchmarking, Maximus is committed to providing the services, charging the fees and achieving service levels in a manner consistent with the top 20% of comparable services in North America.

The contract also addresses issues of privacy, security, confidentiality and publicity that were areas of concern raised by stakeholders when MAXIMUS BC was named the successful proponent.

We recommend that the ministry:

6. ***Formally evaluate the MAXIMUS BC contract on a regular basis, to determine its effectiveness.***

Selecting Drugs for Coverage and Managing Their Cost

All drug reimbursement programs across Canada are facing cost pressures. Ten years ago British Columbia was spending less than $400 million per year for PharmaCare. In 2005, it expects to spend almost $900 million on the program.

Some factors affecting the increasing costs are not within PharmaCare's control, such as growth in the size of eligible populations, the aging of beneficiaries and the introduction of new, more costly drugs into the market place. There are, however, some cost factors that PharmaCare can influence by, for example, determining which drugs to include in the formulary (the list of drugs approved for coverage) and what their benefit status is (the circumstances under which that drug's cost will be reimbursed). PharmaCare's drug purchasing practices also effect the amount of control it has over what it pays for drugs approved for coverage.

We expected the ministry to carry out its drug review activities on a timely basis and appropriately manage the cost of drugs, to ensure the program's cost-effectiveness and sustainability.

Conclusion

PharmaCare is properly assessing new drugs under consideration for inclusion on the formulary for cost-effectiveness. However, the ministry's capacity to carry out the work is limited, resulting in a slow approval process and delays in additions to the formulary. This lack of capacity also hinders the ministry's ability to evaluate existing drugs on the formulary to determine whether they should continue to be listed. As a result, PharmaCare could be paying for drugs that are less effective, more expensive or both than an alternative drug.

PharmaCare has policies in place that help with cost containment. Some, for example, encourage the use of lower-cost generic and referenced drugs. Others limit what the program will reimburse pharmacies for drug costs and dispensing fees. Although the policies directed at pharmacies help contain costs, the ministry is not provided the opportunity to obtain the lowest prices through direct negotiation with suppliers. While PharmaCare has begun to negotiate with some manufacturers to reduce the cost of expensive drugs and to determine how drugs will be reimbursed, more needs to be done to manage these costs to ensure the program is sustainable.

Selecting Drugs for Coverage and Managing Their Cost

Findings

Drugs considered for coverage undergo rigorous review for cost-effectiveness but limited review later, to determine their continued cost-effectiveness.

PharmaCare relies on several national organizations to guide it in its drug decision-making processes. New drugs must receive a Notice of Compliance from Health Canada before they can be made available for sale. This provides assurance there is basic evidence of drug safety, efficacy and quality. The Patented Medicine Prices Review Board was established in 1987 and regulates the prices that manufacturers can charge for all patented medicines, new and existing, and by prescription or over the counter, to ensure they are not excessive. And the Common Drug Review, a national body established in 2003 within the Canadian Coordinating Office of Health Technology Assessment, reviews all new drugs, looking at clinical studies, and concluding on their therapeutic advantages and disadvantages and value for money. The results of the Common Drug Review are provided to the Canadian Expert Drug Advisory Committee (CEDAC) which in turn makes recommendations to member plans such as BC PharmaCare on whether to include the new drug in its formulary.

Before the Common Drug Review

Before the Common Drug Review was created in 2003, the ministry funded the Therapeutics Initiative, established by the Department of Pharmacology in 1994 at the University of British Columbia, which provided a therapeutic assessment of the drugs submitted for approval by the pharmaceutical companies. Another organization, the Pharmacoeconomics Initiative, looked at the drug's cost-effectiveness and pharmacoeconomic advantage (e.g. whether a new drug would reduce a patient's days lost at work, reduce the need for hospitalization, or other drugs, or improve the patient's quality of life). Now both processes are carried out at the national level by the Common Drug Review for new drugs.

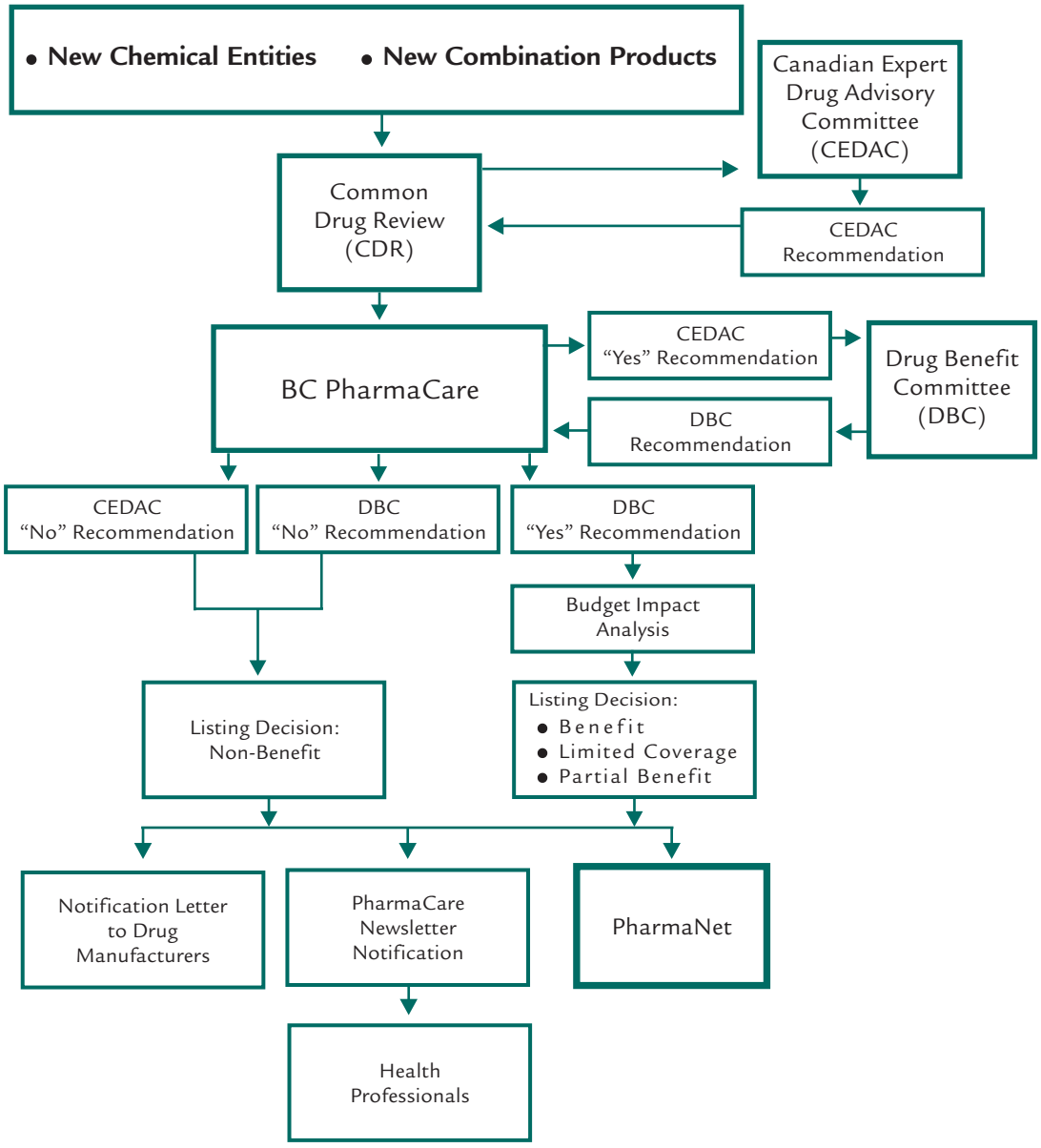
Using the Common Drug Review

At the outset of this new process, all federal, territorial and provincial health ministers except in Quebec agreed to follow the Common Drug Review's Canadian Expert Drug Advisory

Committee (CEDAC) if it recommended a drug not be added to the formulary. If the Committee approves a drug, the drug programs may decide to add it to their formulary or not (Exhibit 3).

Exhibit 3

Drug Manufacturers' Submission to the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) Flow Chart



Source: Ministry of Health

Selecting Drugs for Coverage and Managing Their Cost

Example of the Review Process for a Drug That is Expected to Receive Limited Coverage Benefit Status
(before the Common Drug Review was available)

Drug A

- PharmaCare receives a submission from manufacturer—September 2001.
- Therapeutics Initiative carries out a review.
- Review indicates there are no published drug trials with an active comparator; therefore, there is no evidence to establish a therapeutic advantage.
- Letter sent to the manufacturer rejecting the drug—April 2003.
- Some time later, the manufacturer submits a new clinical, budget impact and health economic analysis.
- Therapeutics Initiative carries out an additional review, and expresses some concern about lack of evidence.
- Therapeutics Initiative consults with medical specialists.
- Drug Benefit Committee recommends limited coverage under a Special Authority requested by medical specialists—July 2004.
- PharmaCare prepares an updated budget impact analysis and examines funding options.
- PharmaCare is completing the listing decision procedures, but has not yet made a public announcement—October 2005.

Source: Auditor General review of documents.

To complete the review process, PharmaCare's Drug Benefit Committee must decide if a new drug with a positive listing recommendation from the CEDAC is needed in the province and is affordable. This is done through budget impact analysis, estimating how much PharmaCare's expenditures would increase or decrease if the drug were added to the formulary. The ministry also takes into consideration existing policies, program priorities and resources.

The ministry may limit the coverage of an approved drug—for example, stipulating that it can only be prescribed by physicians with a particular specialty, and then only for patients whose medical condition meets specific criteria. Access in this case is only gained if the physician submits a Special Authority form documenting the patient's condition. Another option the ministry considers is to accept the drug on the condition that the manufacturer agrees to share in any cost overruns (based on the estimates from the budget impact analysis).

The recent market withdrawal of several popular prescription drugs because of safety concerns—such as the painkiller rofecoxib (Vioxx), popular with arthritis sufferers—provides support for the ministry's rigorous approach to the review of drug submissions. The ministry provided coverage for these drugs only if patients had tried first and second line drug therapies without success or experienced intolerance to them.

Although these effort help to control the cost and use of drugs, the additional work has stretched the ministry's capacity to handle submissions. The result is often lengthy waits for drug coverage decisions and inclusion in the formulary. Stakeholders expressed concerns to us over the delays and noted that the justification for some of the decisions was not always made clear.

Before implementation of the Common Drug Review process, drugs in the queue could stay there from a few months to well over a year awaiting a decision. The new process commits to taking from 99 to 129 days to carry out the review and make a recommendation to the drug programs. However, PharmaCare has not said how long it will take to put a review-approved drug through its internal process. This uncertainty, we think, will cause frustration for the manufacturers and work against creating a cooperative working relationship.

Example of the Review Process for a Drug that Received Non-Benefit Status

Drug B

- Common Drug Review received submission from the manufacturer—December 2003.
- Copies of the submission were sent to all federal, provincial and territorial drug plans.
- Approval sought for restricted category: for treatment after chemotherapy failure.
- Business impact analysis showed total estimated cost to PharmaCare for 2004; 2005, and 2006.
- Review comments include:
  - Drug trials did not include a placebo or comparator.
  - Only two randomized trials comparing 2 different doses
  - There are side effects.
  - Since effectiveness was not established, not possible to demonstrate cost-effectiveness.
  - Drug holds promise.
- CEDAC recommends that the drug not be listed.
- PharmaCare Drug Benefit Committee confirms CEDAC recommendation and passes recommendation on to the BC Cancer Agency—September 2004.

Note—Since Drug B is a cancer drug, the BC Cancer Agency—the funding agency—makes the listing decision.

Source: Auditor General review of documents

The ministry's recent PharmaCare program review also expressed these concerns, and concluded that the ministry should carry out a comprehensive review of the formulary management process. At the time of our fieldwork this assessment was just getting underway. We encourage the ministry to complete the review and implement changes that will ensure the process continues to be evidence-based, encourages stakeholder involvement and produces more timely decisions.

Common Drug Review's Fast-Track Process

The Common Drug Review has a fast-track process for drug submissions. This approach is considered if a drug is a new chemical entity that is effective for the treatment of an immediately life-threatening disease or other serious disease for which no comparable drug is manufactured or if the drug will reduce drug expenditures by a minimum $2.5 million for all participating programs combined. However, PharmaCare does not have a fast-track process in place to be able to quickly move this type of submission forward.

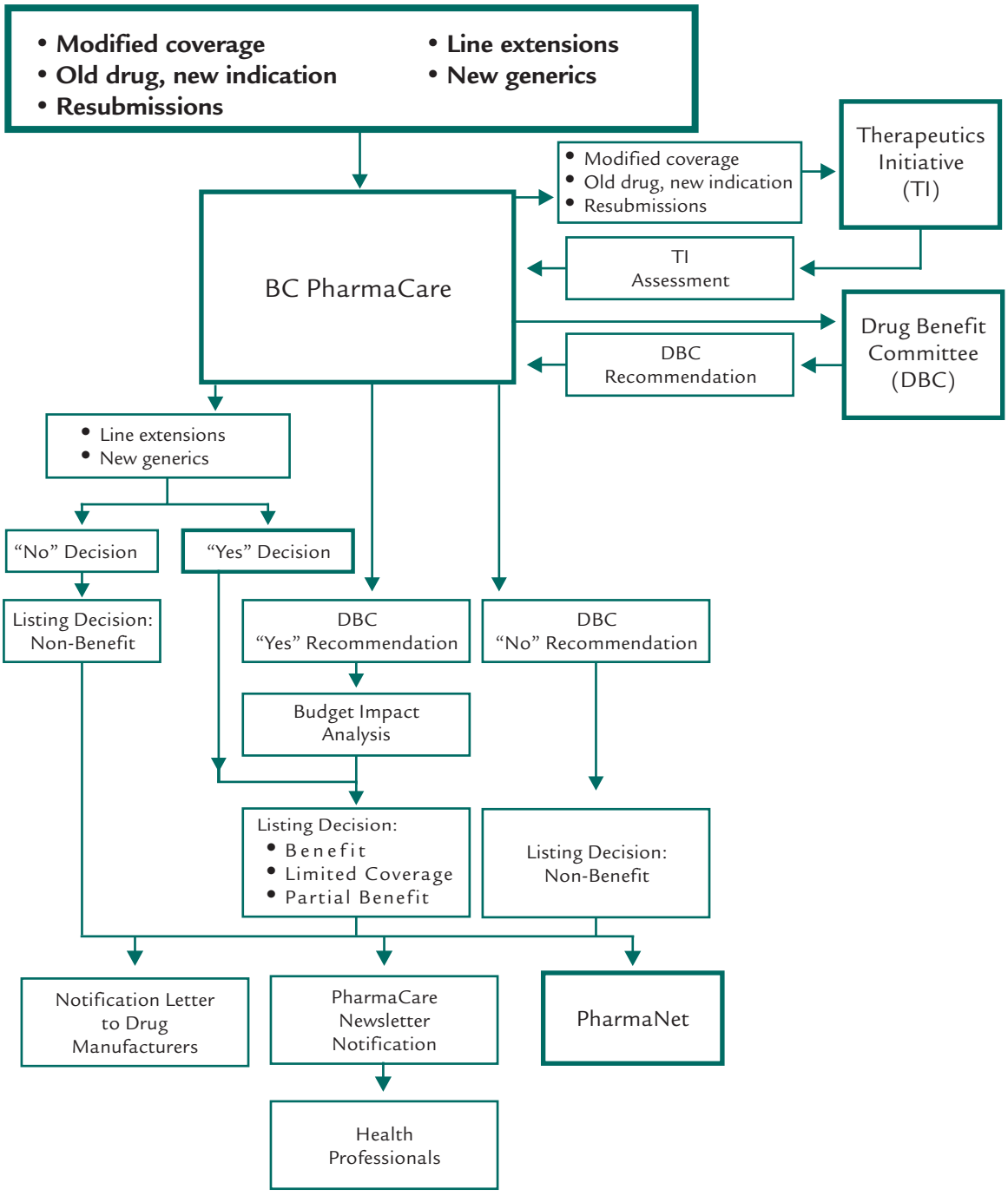
Reviewing Line Extensions, New Uses for Existing Drugs and Generics

The job of reviewing manufacturer's submissions for line extensions, for new uses of existing drugs and for generic drugs, falls directly to the ministry (see Exhibit 4). The Therapeutics Initiative and other experts provide analysis to aid in the decision-making process for many of these reviews.

The ministry expects to complete its reviews for generic drugs in about three months, since the review is only of the ingredients and the ability to supply the product, and not on the efficacy of the drug. We found that the majority of generic drug reviews are being completed within about three months, but some are taking significantly longer.

Exhibit 4

Drug Manufacturers' Submission to PharmaCare



Source: Ministry of Health

Assessing Continuing Cost-effectiveness

Once drugs are added to the formulary, PharmaCare does not have a process in place to assess their continuing cost-effectiveness. Many drugs were added before rigorous reviews were carried out, so there is a risk that some may have outlived their usefulness and should not be available for prescribing. The ministry recognizes that this important function should be part of the PharmaCare drug review process.

A Drug Effectiveness Review Project, currently underway in the U.S., is a collaboration of 12 U.S. states, an American health foundation and the Canadian Coordinating Office for Health Technology Assessment (CCOHTA). This group describes its work as providing unbiased, high-quality information on the comparable effectiveness and safety of drugs in 25 widely used drug classes. CCOHTA will share the results of the review with each of the provinces once it is completed.

The ministry is part of a national pharmaceuticals strategy working group that is looking at the best ways to seek evidence about patient safety and how well drugs and drug coverage policies are working in the real world—known as pharmacosurveillance. And as mentioned previously in this report, the province is supporting a joint pilot project with Ontario carrying out evaluations on certain drugs for rheumatoid arthritis, Crohn's disease, high cholesterol, acid reflux and psychiatric disorders.

We encourage the ministry to focus more of its drug review efforts on drugs already on the formulary, because evolving knowledge as to best use of drugs and development of new drugs requires vigilance to ensure continuing cost-effectiveness.

We recommend that the ministry:

7. ***Review internal procedures for assessing the cost-effectiveness of new drugs to identify and implement ways to streamline the assessment process, including consideration of a fast-track process.***
8. ***Put in place a process to systematically assess the cost-effectiveness of existing drugs in the formulary.***

Selecting Drugs for Coverage and Managing Their Cost

Efforts by PharmaCare to secure the best prices for drugs are limited.

PharmaCare does not have policies in place to ensure that drugs are acquired at the lowest possible cost; however, it does have policies that stipulate what it will pay to pharmacies.

Pharmacy Supply-Chain Model

British Columbia has a pharmacy supply chain model. Each pharmacy buys drugs from wholesalers, then PharmaCare reimburses the pharmacy for providing prescription drugs to eligible residents. Reimbursement includes the amount paid by the pharmacy to the wholesaler to acquire the drug (the actual acquisition cost), plus a wholesale up-charge to a maximum of 7% of the manufacturer's list price (to cover the wholesalers' distribution and storage charges) and lastly a dispensing fee for the pharmacists' professional services (currently set at a maximum of $8.60).

Some jurisdictions use a modified version of this model. In Quebec, legislation requires drug manufacturers to supply drugs to their pharmacare program at the lowest price available in any of the other provinces. Saskatchewan operates a bulk purchasing program for generic drugs.

The recent PharmaCare Program Review in British Columbia confirmed that many pharmacies are in a position to take advantage of PharmaCare's buying power and achieve savings, but that these savings are not being passed on to PharmaCare. The review recommended that PharmaCare explore the potential to eliminate pharmacies as intermediaries and develop direct business relationships with wholesalers, off-patent drug manufacturers and on-patent drug manufacturers. As a result, the ministry is carrying out a PharmaCare supply-chain project.

However, stakeholders indicated to us their concern that PharmaCare may focus only on the cost efficiencies and not consider the impact of pharmacy compensation. In particular, we heard concerns that the dispensing fee may not be adequately compensating pharmacies for the variety of tasks needed to provide patients with prescription drugs (such as following up on a Special Authority not in place or providing explanations to patients about PharmaCare coverage). We understand that there are some difficult issues to be considered and believe that the supply-chain review should include stakeholder participation, consider the effect of any proposed changes on all major stakeholders—and in particular, pharmacies—as well as the effect of keeping the status quo.

Partnering with Manufacturers

During the drug approval process, PharmaCare occasionally enters into negotiations with drug manufacturers to secure a better price. For example, in a 2003 news release, the ministry described a partnering arrangement with Schering Canada to provide Pegetron, a new drug for patients with chronic hepatitis C. The arrangement was for a cost reduction of 33%, bringing the cost in line with that of the closest therapy alternative. Had the full cost of the therapy been paid, it would have ranged from $5,000 to $20,000 per patient per year. PharmaCare recognizes that cost-sharing arrangements are a necessary tool to provide patients with the newer, expensive drugs. And we agree with PharmaCare, that it needs to build its capacity to carry out successful negotiations and develop accountability requirements to ensure compliance with the terms of these arrangements.

A limitation of cost-sharing arrangements is the confidential nature that manufacturers may place on them. This reduces the transparency of drug coverage decisions and also places restrictions on information that can be shared with other drug plans and the academic research community.

Compensation for Compounding

Compounding—the combining of ingredients to produce a product—is a cost paid by PharmaCare. It pays according to the benefit status of each ingredient, plus it pays for preparation time. PharmaCare's internal auditors found that amounts charged by the pharmacies for preparation time varied significantly. The reason for this was determined to be partly the vagueness of its policy that "compounding charges must be reasonable and proportionate to the amount of work involved in the compounding".

We encourage PharmaCare to proceed with its intention to define the term "reasonable" and establish some standards for pharmacies to follow to ensure payment for this service is consistent and fair.

We recommend that the ministry should:

9. ***Explore and implement ways to ensure best prices are paid for drugs by the province.***

The assignment of "partial" and "limited benefit" status, based on scientific evidence, saves money

Assignment of a benefit category to each drug added to the formulary is an important way to control drugs costs. PharmaCare has three benefit categories: full, partial and limited coverage. The full and partial categories define the portion of the cost that will be covered by PharmaCare. The limited coverage benefit defines the patient circumstances that must be met in order for coverage to be provided.

For full benefit prescription drugs, a patient is eligible to receive full coverage for the product, subject to the limits of his or her PharmaCare plan (see Exhibit 1 on page 14 for plan descriptions).

The low-cost alternative program and the reference drug program apply when the prescription drug benefit is partial. In this situation, the patient receives coverage up to the cost of the appropriate low-cost alternative or reference drug. Drugs containing the same active ingredients are subject to the low-cost alternative program meaning PharmaCare provides coverage for the lowest-cost drug in the group. The patient, if choosing to stay with a higher-cost drug, must pay the difference.

The reference drug program deals with drugs in the same therapeutic class—chemically similar and used to treat similar medical conditions, but with different active ingredients. This program applies to five classes: H2 antagonists for gastrointestinal complaints, nitrates for treating heart disease, non-steroidal anti inflammatory drugs (NSAIDS) for inflammation and pain management, and two classes of anti-hypertensive drugs for treating high blood pressure: calcium channel blockers and ACE inhibitors. PharmaCare will cover the cost of the reference drug considered equally effective and with the lowest cost in the specific class.

To ensure that a patient is not denied coverage when he or she does not tolerate a drug covered in the reference drug program, their physician may request a Special Authority from PharmaCare to grant full benefit status to a drug that would otherwise only be a partial benefit.

Limited coverage status is for drugs considered to be second, third or fourth line treatment, based on health outcome results from clinical trials and other information provided by drug manufacturers. Through the Special Authority process, physicians may establish that the patient meets the criteria to receive coverage.

Although the ministry does not regularly measure the cost savings achieved through use of its partial and limited coverage strategy, research teams from Harvard, the University of Washington and McMaster University have analysed provincial data and, based on their investigations, have reported that the reference drug program is controlling costs while also ensuring access and avoiding negative health and health system consequences. PharmaCare estimates that this program has saved taxpayers at least $12 million annually.

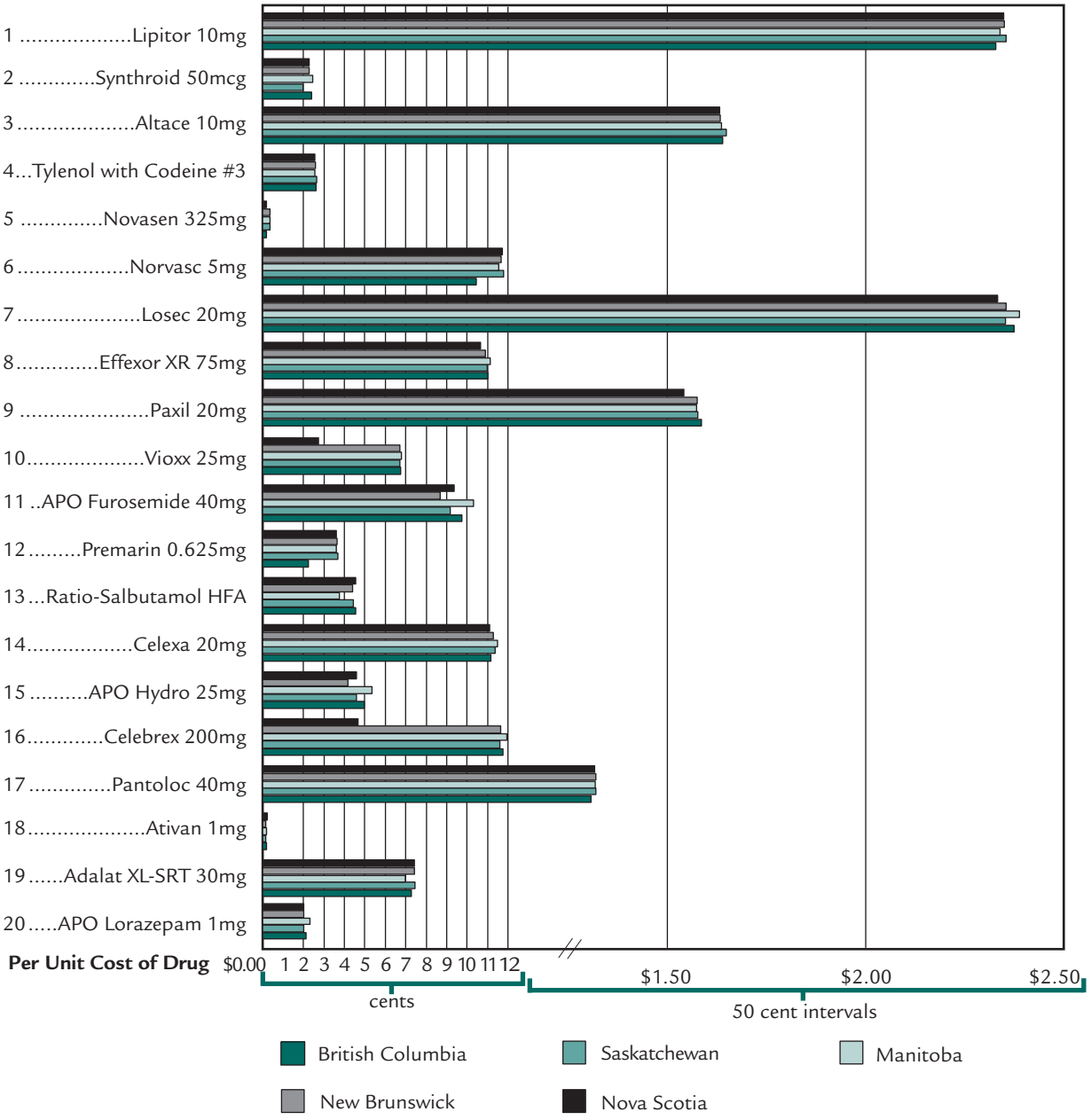
In another study, carried out at the University of British Columbia, restrictions through limited coverage status on COX-2 inhibitors are estimated to be saving taxpayers $23 million annually. The decision to limit access to this more expensive alternative to older NSAIDs was based on the lack of a health outcome advantage when the results of clinical trials were reviewed.

British Columbia pays similar unit prices for the top 20 prescription drugs to other drug programs in Canada

We set out to compare the amounts paid by BC PharmaCare for the top 20 prescription drugs used in Canada with the unit prices paid by other jurisdictions in Canada, for the period 2002/2003. Where applicable, if the drug was subject to the low-cost alternative or reference drug programs, the lower unit price was used (the amount actually paid). Dispensing fees, provincial co-payments and other costs were excluded, to ensure the comparison focused on the ingredient cost of each drug. As indicated by Exhibit 5, British Columbia paid similar unit prices to those paid by the other jurisdictions.

Exhibit 5

Top Twenty Prescription Drugs in Canada



Source: Compiled by OAG BC

Monitoring Drug Use and Encouraging Cost-effective Prescribing

Having decided which drugs to pay for as benefits under PharmaCare, the ministry then needs to encourage and support initiatives that ensure those drugs are used cost-effectively. This means ensuring the right drugs are administered for the right symptoms, in the right amounts, and for the right duration.

Physicians can draw on a variety of sources when choosing a drug therapy for their patients; but, most sources do not provide information about the cost-effectiveness of the options in British Columbia. This can be a daunting exercise with more than 24,000 therapeutic products approved for sale in Canada. Yet, the pharmaceutical industry uses a number of mechanisms to influence physicians' prescribing, especially encouraging them to favour new, often more expensive drugs. We therefore expected the ministry to have reliable mechanisms and programs in place to monitor drug use and support cost-effective prescribing practices.

Conclusion

The ministry has some promising programs and initiatives—designed to monitor drug use and influence physician prescribing practices—although, we expected significantly more progress to have been made to this end since our last audit in 1997/1998. Also, without greater physician and pharmacist involvement in these potentially influential activities, and better utilization of the information available in the PharmaNet system, the ministry will not be able to maximize their usefulness.

Findings

The ministry funds several successful initiatives focusing on educating physicians about best practices in drug prescribing, but it should do much more to expand the scope of these initiatives to impact a larger percentage of physicians.

Therapeutics Initiative Letters

The ministry funds the Therapeutics Initiative (TI), a co-operative venture by the Department of Pharmacology and Therapeutics and the Department of Family Practice at the University of British Columbia. The TI describes itself as an organization dedicated to effecting both immediate and long-term changes in physician prescribing habits that will result in improved health care

in British Columbia. One of the group's activities is carrying out scientific literature reviews to identify best practices in cost-effective drug prescribing. This information is then shared with health professionals through a bi-monthly letter that takes a problematic therapeutic issue, or a selection of new drugs, and lays out the facts for health professionals in a brief, simple and practical message. In addition to the letters, the TI offers courses that focus on drug therapy issues from an evidence-based perspective. These are attended by physicians in family practice or internal medicine and pharmacists. The TI has also committed to evaluate the impact of its educational interventions on patterns of prescription writing. It will use the PharmaCare database to do this.

In October 2004, a study in the *Canadian Medical Association Journal* reported the impact of a series of the TI's news letters on physicians' prescribing to newly-treated patients. It concluded that "the combined effect of an ongoing series of printed letters distributed from a credible and trusted source can have a clinically significant effect on prescribing to newly-treated patients". We encourage the ministry to review the cost-effectiveness of this resource and based on that review, consider expanding its use to further promote better prescribing.

Academic Detailing

"Academic detailing" is another means of communicating best practices in cost-effective drug prescribing. It was developed to provide physicians with unbiased information to counterbalance that delivered by sales representatives from pharmaceutical manufacturers (commonly known as drug detailers). It consists of a review, carried out by pharmacists headquartered in a hospital pharmacy, that makes objective comparison of frequently prescribed medications. The results, printed in newsletter format, are sent to physicians across the province. A pharmacist then makes a brief visit to physicians' offices to highlight information and discuss questions arising from the newsletter.

In 1993, the ministry began funding an academic detailing pilot operated from Lion's Gate Hospital in North Vancouver. It is called the Community Drug Utilization Program (CDUP). This service is provided to family physicians on Vancouver's North Shore. The objective initially was to encourage the use of therapeutically equivalent and less-expensive medications to reduce drug

expenditures, but more recently it has expanded to focus on a drug's impact on health outcomes and health service use. Recently CDUP has been asked to share its academic detailing letters with other jurisdictions across Canada through the Canadian Coordinating Office for Health Technology Assessment.

The program continues to be funded as a pilot at $150,000 annually (the same funding level it attained in 1997). Other jurisdictions that have adopted academic detailing (for example, Saskatchewan, Nova Scotia and Alberta) are providing funding at levels above that in our province, indicating that British Columbia should consider expanding its use of this tool.

The ministry wants a formal evaluation completed first to determine the effect of the program. A preliminary evaluation carried out on heart failure therapies showed, over a two-year period, an increase in the use of the therapies suggested. The formal evaluation of the program is underway, using PharmaNet information, but progress has been slow. We learned that it took over a year to secure access to the information, because of a ministry backlog of requests and an approval committee that did not meet regularly.

As a comparison, we looked at the RxFiles program in Saskatchewan. This province-wide academic detailing program has developed a series of drug comparison charts summarizing practical information on the optimal selection and use of about 40 drug therapy areas. In addition to the charts, the program provides a newsletter to physicians three or four times a year and sponsors brief visits by pharmacists to physicians' offices to discuss questions that arise from the newsletters and drug charts. For ease of access, the charts are available in a pocket edition, with many of these charts also available for Palm-compatible hand-held computers.

The program is funded by Saskatchewan Health, in association with the Department of Family Medicine at the University of Saskatchewan, and managed by the Saskatoon Health Region. To reach physicians across the province, the Saskatoon Health Region contracts with other health regions or individual pharmacists. This has allowed more than 300 family physicians to participate.

The Community Drug Utilization Program has expressed interest in expanding academic detailing across British Columbia

and has identified two Health Authorities whose pharmacists and physicians strongly support academic detailing. There are also plans underway for a collaboration between at least five provinces (British Columbia, Alberta, Saskatchewan, Manitoba, and Nova Scotia) over the next few years to work on national academic detailing projects through the Canadian Coordinating Office for Health Technology Assessment. The first would focus on dyslipidemia—elevated cholesterol, a risk factor for heart disease. It is the CDUP's hope that additional sites will be up and running in British Columbia to deliver this project. The CDUP is also collaborating with the University of British Columbia's Department of Continuing Medical Education to assess the feasibility of expanding academic detailing, and to look at how technology can assist academic detailing.

We believe the ministry should actively support completion of its formal review. If the results indicate that the effort supports better prescribing practices, the ministry has an opportunity to collaborate with Health Authorities to ensure that ministry efforts to promote best prescribing practices compliment those implemented in the regions. And it would also provide an opportunity for better physician and pharmacist involvement in ministry initiatives.

Chronic Disease Management Initiative

The Chronic Disease Management initiative in British Columbia is an approach to patients' health care, through their physicians, to follow clinical best practices for managing chronic diseases such as diabetes, hypertension and congestive heart failure. It includes several ministry-funded initiatives that will provide physicians with tools to access best practices, record patient information and carry out self-assessment of progress. Improved prescribing practices are expected, as participation in this initiative increases. The ministry is working with the College of Physicians and Surgeons, the British Columbia Medical Association, the College of Family Physicians, and others to encourage participation. It is too early to evaluate the success of this initiative; however, this collaborative approach between the ministry and stakeholders is encouraging.

Monitoring Drug Use and Encouraging Cost-effective Prescribing

The information captured by the PharmaNet system is underused, hampering the ministry's ability to identify early trends in prescribing practice and drug use, or to work co-operatively with physicians to influence cost-effective choices.

Identifying Trends in Prescribing Practices

The PharmaNet system has a wealth of information that can be used to promote cost-effective prescribing of drugs, but we found that access to information has been limited. As we noted earlier, the implementation of legislation to improve access to PharmaNet information has been delayed. The PharmaCare Program Review also reported on this matter, concluding that PharmaCare's enabling legislation by not keeping pace with its program scale and scope, has constrained its ability to meet its responsibilities. Improved access to the statistics on drugs being prescribed—statistics such as comparisons within therapeutic categories, percentage of cost covered by PharmaCare, and percentage of prescriptions refilled as intended—would improve the ability of PharmaCare management to identify early trends and make early corrections where negative developments are emerging.

Influencing Physician Prescribing Practices

The PharmaNet system provides pharmacists with a powerful tool to monitor patients' drug use and identify potential drug interactions at the time patients fill their prescriptions. PharmaNet processes all prescriptions dispensed in all community pharmacies and hospital outpatient pharmacies in the province. Once a transaction is completed, PharmaNet returns to the pharmacist a complete medication history, a drug use evaluation and adjudication results—the amount PharmaCare will pay. The drug use evaluation performs six types of checks using drug information and clinical modules from First DataBank, a provider of electronic drug information to the health care industry. The prescription being dispensed is compared to the other active prescriptions on the patient's medication history to assess:

- drug-to-drug interactions,
- drug's relationship to prior adverse reactions,
- duplicate therapy/ingredients,
- dosage too high/too low, and
- compliance issues (refill too soon/too late).

The pharmacist uses this information when evaluating the prescription to ensure patient safety and appropriate use of medication. However, cost-effective prescribing would be improved if this tool also included comparable drug cost information and if the tool was available to physicians to help with initial prescribing decisions. Some physicians told us that they have very little knowledge of the cost of many of the drugs they prescribe. And most do not have ready access to information on the choice of drugs for a particular condition, or their comparative prices. We found that the ministry has made some effort to address these concerns, but much more needs to be done.

In 2000 the ministry initiated a pilot program to give 100 physician offices access to PharmaNet. This allowed physicians and their staff to:

- obtain a record of medications dispensed to a patient,
- obtain patient demographics and Personal Health Number (PHN) or assign a PHN
- perform allergy checks and drug utilization evaluations before ordering medication,
- obtain drug monographs (detailed descriptions), and
- update a patient medication history by adding information on the name of drugs administered in the office or samples provided to the patient.

The ministry considered the pilot successful. But, because of other priorities, did not expand the program. Later, in February 2005, the PharmaNet Patient Record Information Regulation was amended to provide all physicians province-wide access to PharmaNet. However, as of September 2005, the program had not expanded beyond the 100 sites.

Another ministry initiative to influence physician prescribing practices was included in the 2004 Letter of Agreement on Related Matters between the physicians and the British Columbia government. The letter included a reference to "gain sharing" on savings realized through physicians' prescribing practices. The concept involves exploring, evaluating and implementing appropriate and ethical opportunities to share gains achieved through the management of prescription drugs. Any savings realized will be shared with the physicians, with 60% being reinvested back into the PharmaCare program for additions to the formulary and 40% invested in physician-directed care initiatives.

For this agreement to be implemented, physicians will need to know the prices of drugs, so they can prescribe the lowest-cost drugs appropriate for a patient's care. Connecting physicians to PharmaNet and the ministry website is a necessary step to provide up-to-date drug information. One problem is that it is estimated that less than 20% of physicians are connected to the internet, making access to the ministry website problematic. We encourage the ministry to work with physicians and others to resolve the issues that are preventing physicians from accessing PharmaNet from their offices.

Initiatives aimed at monitoring drug use and encouraging cost-effective prescribing are viewed by some stakeholders as cost-saving measures only, that do not always put the patient first.

The ministry influences the cost-effective prescribing of drugs through the drug coverage adjudication process it delivers through the PharmaNet system. This process involves initiatives such as the low-cost alternative, reference drug and limited coverage programs described earlier in this report.

For one of these, the reference drug program (which covers the cost of the least expensive drug within a group of drugs considered therapeutically equivalent) there has been much controversy because it was seen by physicians as overstepping their professional judgement. The program was introduced in 1995. Although it covers only about 40 of the 1700 drugs included in the drug plan and has shown substantial savings with no adverse effects on health outcomes, the stakeholder alienation from being excluded from the development and implementation process remains today. As a result, mistrust overshadows any other initiatives in the province aimed at fostering appropriate drug use, and labels them as cost saving measures that do not necessarily put the patient first.

The ministry is aware of the challenges it faces in gaining stakeholder confidence and cooperation. In 2002, a panel was formed to review the reference drug program. The recommendations from the panel led government to request a broader review of PharmaCare that would engage a full spectrum of PharmaCare stakeholder groups.

The PharmaCare Program Review, completed during our audit, sought the input of all major stakeholders (see side bar on next page). Those we spoke to were encouraged by the process, but

Stakeholder groups included in the PharmaCare Program Review

- Physicians, pharmacists and their associations
- Pharmaceutical manufacturers and distributors
- Citizen/consumer groups
- Academic and educational sector
- Regulatory bodies
- Regional Health Authority hospital pharmacists
- Health insurance companies

we detected a wait-and-see attitude among some, whose main concern was the ministry's capacity to carry out the ambitious implementation plan.

The PharmaCare Program Review has created expectations among stakeholders that they will be kept informed of PharmaCare's progress in implementing the recommendations they helped formulate. It is therefore very important that sufficient resources be allocated and managed to make this project successful, to maintain the confidence and co-operation that has been nurtured throughout this process. If stakeholders' expectations are not met, future initiatives the ministry carries out will be viewed with the same scepticism that has made past programs less effective than hoped.

The ministry uses expert committees of physicians to review utilization and prescribing practices for specific disease groups. One current committee for example, is for rheumatoid arthritis and another is for Crohn's disease and hepatitis. Through the committees, the ministry aims to build trust with the physicians, receive advice from them and use them as supports in educating their peers about PharmaCare's position on specific drug coverage. Although the committee members may not always agree with the ministry's position, they have had the opportunity to understand why the ministry is making a particular decision. We encourage the ministry to find more opportunities, like the use of expert committees, to build trust within the medical community and increase the transparency of drug funding decisions.

We recommend that the ministry:

10. ***Use PharmaNet information to identify trends in prescribing practices and to inform physicians about their own prescribing practices and the projected results had currently recognized clinical best practices been followed.***
11. ***Significantly increase support for PharmaCare-sponsored programs that encourage appropriate drug use through physician best practices in prescribing (such as Therapeutics Initiative Letters, physician access to PharmaNet, and the academic drug detailing program).***
12. ***Support greater involvement of physicians in developing actions to promote appropriate drug use.***

Ensuring Eligibility of Insured Persons

The PharmaCare program has a number of plans, each with different eligibility (see Exhibit 1 on page 14). As a result, the ministry needs to ensure that eligibility requirements are understood by physicians, pharmacists and patients. It also needs to have the mechanisms in place to ensure that those who are receiving benefits are eligible to do so. We expected these to be in place.

Conclusion

Eligibility requirements of the plans are available to the public on the PharmaCare website. However, only the Fair PharmaCare requirements are easily accessible. The ministry has adequate procedures in place to ensure the eligibility of insured persons. The largest plan, Fair PharmaCare, has the most rigorous procedures. The other plans rely on partner organizations for all or part of the eligibility assessment. For those plans, there are some weaknesses in the verification procedures.

Findings

The PharmaCare program communicates eligibility terms and conditions for each plan

PharmaCare's primary mode of getting information out about the eligibility terms and conditions of its plans is the website. The information presented on the website is clear and easily understood. However, only the information about Fair PharmaCare is readily apparent. For the other plans, users must access the information in the online version of the PharmaCare Policy and Procedure Manual, in the chapter on plans. Pharmacists are aware of this, but anyone else using the website likely would not know how to find the information about the other plans.

Eligibility information is also available to the public through pharmacies and physician offices; but some have commented that they find it time-consuming. This may be because many individuals eligible for plan assistance, are those least likely to have or use internet access to get the necessary information.

Ensuring Eligibility of Insured Persons

The PharmaCare program has processes in place to assess eligibility at registration and throughout the covered period

Plan I—Fair PharmaCare

Fair PharmaCare drug coverage is based on a family's net income as reported to the Canadian Revenue Agency. Therefore, a person must register as a family if he or she has a spouse or dependents. A registrant is required to consent to PharmaCare verifying their net income with the Canadian Revenue Agency. Residency is confirmed at the time of registration through the Medical Service Plan's Client Registry system and Registration and Premium Billing system.

On initial registration and until income is verified with the federal revenue agency, coverage is based on the self-reported income. Currently, if benefits provided are greater than the federally verified income warrants, this determination is only noted. Overpayments are not collected yet, but PharmaCare is in the process of developing guidelines and procedures to do so. A data file is sent to PharmaCare weekly from the Canadian Revenue Agency, verifying income.

Once registered, British Columbia residency status and Medical Services Plan (MSP) registration status are monitored daily. Registrant name changes, address changes and marital status are monitored and updated regularly. If a registrant is determined to be no longer eligible for Fair PharmaCare coverage by this monitoring process, coverage is terminated immediately through the PharmaNet system. Monitoring of deductible levels is done once a year by updating income levels using Canadian Revenue Agency data.

These processes adequately assess the eligibility of Fair PharmaCare recipients.

Plan C—Recipients of Income Assistance

The Ministry of Human Resources determines eligibility for income assistance. Once that determination is made, an electronic client file is created in the Ministry of Human Resources' Management Information System (MIS), which is connected with the Medical Services Plan System. The client is then eligible to receive 100% MSP premium assistance, which in turn triggers Plan C coverage.

Ongoing eligibility for income assistance is monitored monthly by the Ministry of Human Resources. When a person is determined to be no longer eligible for income assistance, his or her MIS file is closed and Plan C coverage is stopped immediately.

At the time of our audit, the PharmaCare/PharmaNet policies and procedures manual did not reflect the current process for registering Plan C. The ministry was aware of this and was in the process of updating the procedure in conjunction with the Ministry of Human Resources.

These processes adequately assess the eligibility of income assistance recipients.

Plan B—Permanent residents of long-term care facilities

Under this plan, residents of facilities licensed by Health Authorities under the *Community Care and Assisted Living Act* have the full cost of prescription drugs and certain medical supplies covered. The care facility contracts with a community pharmacy to provide resident medications. In turn, the pharmacy enters into a Pharmacy/PharmaCare Participation Agreement, which links the pharmacy to the long-term care facility's identification number in the PharmaNet system. The pharmacy receives payment for eligible drug costs for each resident, plus a capitation rate. The capitation rate is in lieu of dispensing fees and is based on the number of occupied beds the pharmacy serviced in the month.

We did note that the one agreement we looked at, was effective June 2004, but not signed until August 2004. The ministry should ensure that a pharmacy agrees to the terms of the Pharmacy/PharmaCare Agreement by requiring it be signed before the pharmacy is linked to the facility in the PharmaNet system.

Pharmacy compliance with the terms of each facility agreement, results in an adequate assessment of the eligibility of facility residents.

Plan G—No-charge psychiatric medication program

To be eligible for this plan, individuals must demonstrate both a clinical and financial need. Financial need is defined as being on MSP premium assistance. However, the clinical need is not formally described. Clinical need criteria were described in a draft policy from 1997, which never received final approval, but in practice has formed the basis for eligibility for Plan G. This draft policy states that the client must have had a previous hospitalization for a psychiatric condition, or that without medication the individual is likely to require hospitalization or suffer some other serious consequence.

Clinical need is determined by a physician. Once a client is found to meet the plan's criteria, he or she submits a completed application form to the Mental Health Centre for approval, after which the client is registered for Plan G. Coverage in this plan is for a year and will expire unless a physician authorizes the renewal.

We have concerns about the deterioration of processes used for assessing eligibility for Plan G. The management information system that processes Plan G registration is being phased out and at this time no replacement system has been identified to connect to the PharmaNet system. We were told that since the introduction of Fair PharmaCare, clerical staff are no longer available to assist with determining client eligibility for MSP premium assistance and thus it is no longer done. The matter is now left up to the Director of each mental health centre to decide whether to carry out this step or not. We also found a lack of clarity about where in the ministry responsibility for Plan G resides.

We recommend that the ministry:

13. ***Review Plan G – No-charge Psychiatric Medication Program and the supporting policy framework, to ensure they are consistent.***

14. ***Ensure that eligibility criteria for Plan G – No-charge Psychiatric Medication Program are clear, and that eligibility is being assessed in accordance with the criteria.***

Plan P—Palliative care drugs

The Palliative Care Drug Plan provides assistance to patients eligible under the Palliative Care Benefits Program, funded outside of PharmaCare, through a Home & Community Care program. The plan provides 100% coverage for the cost of medication listed in the palliative care formulary that is managed by PharmaCare.

To be eligible for the program, a person must be enrolled in MSP, living at home, and diagnosed with a terminal illness with a life expectancy of up to six months. As well, he or she must consent to the focus of care being palliative and not treatment aimed at curing. A physician makes the determination of eligibility and submits the application to PharmaCare. The application must be signed by the patient or a legal representative.

Given the nature of the plan, there is no monitoring of continued eligibility. However, it has come to the attention of the ministry that some people have been on the plan much longer than the six months as contemplated in the criteria.

Ensuring the Legitimacy of Claims Submitted

PharmaNet relies on a large, complex computer system. It is connected to hundreds of community pharmacies across British Columbia, and provides comprehensive drug information including that on drug interactions, patient data, claims adjudication and amounts owed to pharmacies from PharmaCare. It is also connected to other computer systems, including that of the Medical Services Plan, and that of income assistance of the Ministry of Human Resources. In recent years, PharmaNet has expanded to provide access for health care providers such as physicians and hospital emergency departments.

This complexity of the PharmaNet system requires that the ministry have adequate procedures in place to ensure that its policies and procedures for approving, processing and paying claims are adequate and being followed. The ministry also needs to ensure that the system operates in a way that protects the privacy and security of patient and clinical information. In addition, the ministry must have a business continuity plan in the event of a complete system failure. We expected the ministry to have these elements in place.

Conclusion

The ministry has adequate procedures in place to ensure PharmaNet complies with legislation and to assess whether its policies and procedures for approving, processing and paying claims are adequate and being followed.

Findings

The ministry's computer environment and application controls provide for complete and accurate processing of data

Application controls of the PharmaNet system are both manual and those within the software components. These ensure the reliability and integrity of transaction processes, for transactions such as pre-registration, registration, validating patients eligibility, adjudication and claim payments processing.

Ensuring the Legitimacy of Claims Submitted

Data integrity and security

PharmaNet is accessed externally by physicians, pharmacies, and other government and private organizations through the Health Network system, which meets industry standard security measures such as firewalls and data encryption. The system also operates under strict privacy and information security measures designed to prevent unauthorized access and to protect the integrity of the information.

The ministry has adopted information technology risk management practices and has a Security Manager in place whose main role is to ensure that privacy, security and integrity of the information are maintained.

In April 2003, a risk and control review was carried out by a contractor on the Fair PharmaCare system. The review focused on mitigating business, security and privacy risk and also covered the general environmental controls common to PharmaCare and PharmaNet. It concluded that the application controls implemented for Fair PharmaCare were adequate, with certain exceptions that were related to the handling of the Canada Revenue Agency's income information.

The review also indicated that the general environmental controls required improvement for information security and protection. And it recommended that a formal business impact analysis be done and a disaster recovery plan developed.

We reviewed the implementation status of these recommendations and found that all of them have either been implemented or are in the process of being implemented.

As indicated earlier in this report, during our audit, the ministry chose and completed contract negotiations with Maximus, to conduct the operations of both the Medical Service Plan and PharmaNet. Conditions of the contract include meeting Systrust control standards, which provide assurance about system reliability and e-commerce activities. These standards have been jointly developed by the America Institute of Certified Public Accountants and the Canadian Institute of Chartered Accountants.

Ensuring the Legitimacy of Claims Submitted

Contingency Planning

The contract with Maximus includes a requirement to review the business continuity and disaster recovery plans during the transition period and to make and test the necessary changes within the first six months.

In the event the PharmaNet system is not available, pharmacies are able to carry on filling prescriptions using their own systems. However, drug interaction and patient medication histories are not available to them. In addition, automatic billing to PharmaCare is not available nor is coverage information. During the period of time the PharmaNet system is down, pharmacies have a choice of batching transactions for billing and inputting them when PharmaNet is back online or collecting full payment from clients and then submitting their claims by paper to PharmaCare. Pharmacies risk incorrect calculation of PharmaCare coverage if back-up systems are used and transactions are batched.

The ministry's identification of system deficiencies needs to be more robust

Because of the complexity of the ministry's computing environment, business units frequently request changes and developments to systems and applications to deal with deficiencies. Current ministry policy has all requests considered as individual projects and, as such, it has developed a formal process to assess the requirements for resources, timing and alternatives. Despite these activities, complexity, scope creep and unrealistic project timeframes are recurring problems causing cost overruns. Another contributing factor is the lack of information available within the ministry to analyse whether changes or requests are necessary.

The ministry recognizes these issues and has started to gather better information on projects in order to mange them more effectively.

Ensuring the Legitimacy of Claims Submitted

The ministry has procedures in place to verify the validity of claims and to ensure the accurate and timely processing of claims

PharmaCare receives over 17 million prescriptions per year submitted for claims purposes. PharmaCare policy ensures that all community pharmacies in British Columbia have agreements in place that require every prescription to be entered on PharmaNet. As a result, every prescription goes through an adjudication process—a series of computerized checks that match elements of the claim with information stored in PharmaNet. Stored information elements include, for example, pharmacy identification number, submitting physician, client health number, date of birth, drug name and identification number. On completion of these checks, the system determines the specific plan the client is eligible for and any rules that may apply for coverage of that particular drug.

If errors are detected through this process, they are logged, the claim is adjudicated to zero and the next step to determine payment amount is bypassed, so no payment is made.

Processing claim payment

A claim that is successfully adjudicated proceeds to the determination of payment amounts. Claimed amounts may differ from amounts actually reimbursed to the pharmacy if, for example, the reference price for a drug is exceeded, the maximum price (manufacturer's list price plus 7%) is exceeded or the generic price is exceeded. Pharmacies are paid weekly following reconciliation of system reports and authorization for payment.

Testing conducted during our financial audit cycle of PharmaCare showed that claims payments (which cover a period from Tuesday to Monday, with payment due on the next Monday) were made on time. The chain drugstore representatives we spoke to confirmed that payments were made on time, but that insufficient information was provided to reconcile the payments to their in-store records.

Our random sample testing of claim payments during that same audit cycle did not find any discrepancies regarding information on patients, practitioners, pharmacies, drugs or drug plans. It did, however, find that there were pharmacy mistakes made in entering drug units for doses that were measured in millilitres (but dispensed in vials) for the drugs Remicade and Avonex. For example, the drug Avonex (1 millilitre equal to a dose) resulted in an overpayment to

the pharmacy of $58.36 per prescription because millilitres were applied to the unit cost when it should have been the number of kits (containing vials of the drug). And for Remicade, millilitres were applied when it should have been the number of vials.

The ministry is aware of this problem and has communicated the solution to the pharmacies through its December 2004 BC PharmaCare news letter.

The ministry has developed an audit plan based on risk mitigation and routinely conducts audits of pharmacies

The audit group is located within the Finance Division of the ministry and is arm's length from PharmaCare which is considered the client. The PharmaCare Audit Review Committee approves the annual audit plan, receives the audit reports and handles any legal issues resulting from the audits. The audit group currently consists of four staff plus the manager. This is compared with just one person when we reviewed the PharmaCare program in 1997.

The 2004 audit plan was developed through a risk review of the policy manual and issues that arose during the 2003 audit work. This assessment identified seven components to focus on, including refill risk analysis, high-use compounding claims and methadone duplicates. (Compounding is the mixing of different active ingredients. PharmaCare reimburses for each ingredient, provided it is covered as a regular benefit or under a Special Authority.)

These components were then weighted by pharmacy, resulting in a final list of pharmacies for possible audit. In 2004, the audit plan included seven on-site pharmacy audits for specific risk issues (one of the seven components), 17 desk audits (in which PharmaNet data is used to compare pharmacy compliance with policy and can be completed at the ministry versus on-site at the pharmacy), and the monitoring of three pharmacies with high prescription refills. In addition, the plan also called for two random audits in the more remote areas of the province (East Kootenay, the northeast, northwest and northern Interior), because they had only received one audit in the last five years. The audit program generally focuses just on issues that will result in the recovery of $100,000 or more.

The audit group has been able to do more province-wide audits with the introduction of Data Mart, a tool that allows the auditors to make their own queries using the HNData Warehouse.

PharmaNet information is downloaded into the HNData warehouse for analyses. This tool has increased the auditors' ability to assess risks. For example, they can look at a particular drug and do pattern analysis or identify pharmacies with the most compounding claims.

The ministry also has a confirmation program, sending letters to patients to confirm that medications are received.

The ministry has processes in place for the timely recovery of claims identified during an audit, however an audit backlog could result in missed opportunities

When an audit is complete, a draft audit report is sent to the pharmacy for a response within 30 days. The response and any additional information are considered and all or part may be incorporated into the final audit report that is approved and issued by the PharmaCare Audit Review Committee. In the event of a recovery of funds, the covering letter of the audit report will outline the repayment options. If necessary, the ministry may reduce a current claim invoice from the pharmacy to recover the amounts identified as overpaid in the audit report.

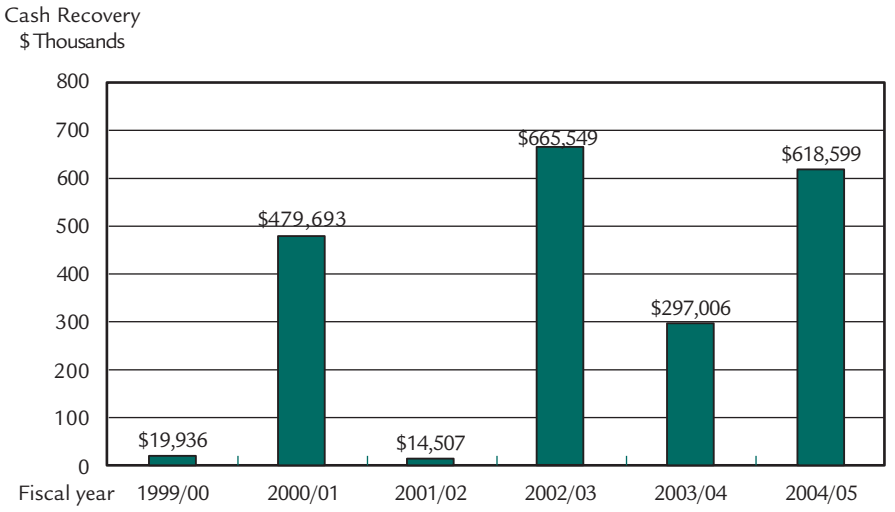
The timeliness of audits is an important factor that must be taken into consideration when developing the annual audit program. Pharmacies are only required to maintain detailed records for a period of three years, thus any delays on the part of the ministry may result in a lost opportunity to collect on any overpayments, resulting from audit backlogs.

The ability of the audit team to complete their planned audit work can be affected by a number of factors. One is the work taking longer than anticipated. This occurred during an audit of quantity errors described earlier in this section of the report. In addition to the quantity errors, the price also went down on the acquisition cost of the particular drug, thus making the audit work even more complicated. The resultant recovery to the ministry from this audit work was over $300,000. However, as a result of the extensive work involved in this example, the 2004 work was pushed into 2005.

Exhibit 6 highlights the recoveries for the period 1999/2000 to 2004/2005.

Exhibit 6

PharmaCare Audit Annual Cash Recovery



Source: Ministry of Health

The low recoveries in 1999/2000 reflect the initial development of the current audit team. Fluctuations in subsequent years are related to the focus of the audit program. For example, in 2001/2002 there were fewer recoveries because the audit team focus was on audits of compliance with the new methadone claims policy. In 2003/2004, in addition to the focus on quantity error described above, three large pharmacy investigations were ongoing, two of which have subsequently resulted in criminal charges being laid by Crown Counsel.

The ministry has not evaluated, in a formal way, the benefits that may be gained from additional audit resources. We encourage the ministry to carry out cost benefit reviews of its audit resources on a regular basis, to determine when it is beneficial and indeed necessary to increase the audit effort.

Reporting to the Legislative Assembly and the Public

The trend in BC government is to promote accountability in government organizations by use of reporting principles endorsed by legislators.

Under these principles the reported information should:

- explain the public purpose served;
- link goals and results,
- focus on the few, critical aspects of performance,
- relate results to risk and capacity,
- link resources, strategies and results,
- provide comparative information,
- present credible information; fairly interpreted, and
- disclose the basis for key reporting judgements.

To address how well the ministry is meeting its accountability responsibilities, we assessed its reporting efforts against these eight principles.

Conclusion

The accountability information for the PharmaCare program needs to be substantively enhanced to meet the expectations under the British Columbia reporting principles.

Findings

The ministry annual report provides relevant but incomplete information to the Legislative Assembly and the public on the performance of the PharmaCare program.

We looked at the ministry's 2003/04 Annual Report first. It describes the public purpose served by PharmaCare, noting that the Fair PharmaCare Program came into effect in 2003 to help ensure the sustainability of the program and to provide for equitable access to drug insurance coverage. The report also identifies some of the key risks faced by the program in meeting those goals. These include the rising use and cost of pharmaceuticals, higher service expectations, rapidly evolving and expensive technology innovations, and the pressure from both health care providers and the public to provide drug coverage regardless of established effectiveness or value for money. As well actual PharmaCare

expenditures were reported for 2003/04. A note explained that actual expenditures of $723 million were $21 million less than expected due to an overestimate of Fair PharmaCare expenditures.

The only specific performance measures we found in the annual report related to either access or appropriate drug therapies for congestive heart failure (part of a chronic disease management initiative). For example regarding access, the plan defined adequate coverage by the Fair PharmaCare program as meaning no family pays more than 4% of their net income for prescription drugs. The measure chosen is the percentage of the population adequately insured, with the baseline established at 67%—the percentage of those registered compared to those eligible for Fair PharmaCare. A note explained that 94% of senior families had registered. Also mentioned is that any potential negative impacts of Fair PharmaCare are being monitored, and that preliminary evaluations indicate that drug use has not decreased in either the senior or non-senior groups since implementation. A partnership with Harvard University to carry out a long-term evaluation of Fair PharmaCare until 2009 was also reported.

For congestive heart failure, the ministry will measured the effect of a collaborative project with physicians to increase the prescribing rate of two classes of drugs known to be effective, ACE inhibitors and beta blockers. The project, started in 2003/04, introduced the BC Congestive Heart Failure Guideline along with a financial incentive program for treating patients according to the guideline. Targets were reported; but, actual results were not available at the report's publication date and will be reported in 2004/05.

No other mention was made of how well PharmaCare is maximizing the appropriateness and cost-effectiveness of any drug therapies or promoting optimal drug prescribing—two critical aspects of its mission. Nor was there reference to the staff-shortage issues that are central to the difficulties experienced in the policy branch.

PharmaCare Trends Report contains a lot of information but is not informative.

From time-to-time the ministry issues a PharmaCare Trends report. While this report is not tabled in the Legislative Assembly, it is available for legislators and the public to review. The current edition of *PharmaCare Trends* provides general information about the program and statistics on each of its insurance plans from 1996 to 2003 including the volume of prescriptions, the number of patients and the amounts paid out. However, the report gives no insight into the meaning of the statistics and trends (e.g. comparison with other provinces or federal trends) or into what the ministry is doing to influence them. The report would be more meaningful if it contained discussion and analysis by PharmaCare program managers.

Many stakeholders want information about PharmaCare's performance. The ministry is losing the opportunity to tell its story—to extol the successes and innovations and inform about the challenges and risks that effect PharmaCare's performance.

We recommend that the ministry:

15. ***In its annual report, move toward reporting in a manner consistent with the British Columbia reporting principles on the performance of the PharmaCare program.***

Response from the Ministry

Response from the Ministry

The Ministry of Health appreciates the opportunity to respond to the report on *Managing PharmaCare* issued by the Office of the Auditor General of British Columbia.

PharmaCare values this external review of the program, but is disappointed by the narrow view taken by the Office of the Auditor General with respect to the management of a cost-effective and sustainable PharmaCare program. Prescription drugs are an increasingly important part of the health care system and they are also the fastest-growing area of health system spending. In British Columbia, for example, between 1996 and 2003, per capita expenditure on prescription drugs more than doubled from $141 to $316. Sustainability of our public drug benefit program is, therefore, an issue of considerable importance to PharmaCare and the Ministry of Health. However, the sustainability of a public drug benefit program depends not only on **what** drugs are covered, but also on **who** in the population is covered and **how much** coverage is provided. By focusing mostly on what drugs are covered and how that process is managed, the Office of the Auditor General concluded that PharmaCare has made little progress since the last audit in 1998/99. In reality, significant strides have been taken towards providing all British Columbians with equitable access to safe and effective prescription drugs, while at the same time ensuring that the program is sustainable for the long term.

Since the previous audit, the ministry has put significant effort into restructuring the PharmaCare program. A major change was necessary to ensure both the sustainability of British Columbia's public drug program and equitable access for all British Columbians to drug coverage that protects them from catastrophic drug costs.

Through this sizeable initiative, British Columbia PharmaCare took on leading edge policy reform and has led the way in defining catastrophic drug coverage in Canada. Given the magnitude of this change to the program, considerable attention was paid to creating a progressive system to protect British Columbians and provide coverage to those who need it most, while also protecting the future of PharmaCare. Hundreds of potential program variations and options were modeled and thoroughly evaluated before the May 1, 2003 introduction of Fair PharmaCare, British Columbia's income-based universal drug coverage plan. Through this plan, PharmaCare shifted its focus to providing greater financial assistance for families with lower incomes. Since

the implementation of Fair PharmaCare, many lower income British Columbia families have lower deductible amounts, and thus pay less for their prescription drugs.

Considerable work was also carried out as part of the PharmaCare Review process that was undertaken between September 2003 and March 2004. The objective of the Review was to refine program design, enhance program efficiency and encourage a more integrated approach to managing the PharmaCare program within the context of broader health care management. This Review process involved extensive stakeholder consultations, and resulted in 13 recommendations.

PharmaCare subsequently launched the PharmaCare Review Implementation (PRI) project in 2004. PRI resulted in the execution of various projects addressing priority areas identified in the PharmaCare Review, as well as highlighting opportunities for enhanced utilization management efforts, and setting the stage for a re-engineered formulary management process.

PharmaCare has also been actively supporting the government of British Columbia in providing leadership to the National Pharmaceuticals Strategy (NPS). The NPS is a collaborative federal/provincial/territorial initiative seeking to ensure that all Canadians have access to safe and effective drugs through the development of a comprehensive and integrated approach to pharmaceutical management and reform. The NPS involves a multi-point plan, with a number of complementary elements addressing issues across the entire drug life cycle (from drug development and market authorization, to pricing, access/reimbursement, and post-market evaluation). Successful implementation of the NPS will result in national solutions to issues of common concern, increased harmonization and alignment of processes and programs, and sustainable and well-managed drug programs that provide all Canadians equitable access to safe and effective medicines, without undue hardship.

While national initiatives do command considerable time and staff resource commitments, it is important to recognize that the effective management and integration of pharmaceutical strategies requires national coordination and collaboration among governments. Some of the other national initiatives that PharmaCare has participated in since the last audit include the Common Drug

Review (which has streamlined the process for reviewing scientific evidence of the effectiveness of new drugs and provides consistent recommendations to provincial drug plans about coverage), the National Prescription Drug Utilization Improvement System (to provide public drug plan managers with critical analyses of price, utilization and cost trends), and the Canadian Optimal Medication Prescribing and Utilization Service (to promote and facilitate best practices in drug prescribing and use among health care providers and consumers).

The province is also fortunate to have a strong foundation for its evidence-based drug formulary. PharmaNet, the Therapeutics Initiative and the Drug Benefit Committee combine to provide PharmaCare with a strong base for a rigorous review of drug submissions and help promote an environment that fosters appropriate drug use. Evidence of the effectiveness of British Columbia's approach to managing the PharmaCare program can be found in the recent report *Drug Expenditure in Canada 1985 to 2004*, by the Canadian Institute for Health Information. According to this report (released in April 2005, and shared with the Office of the Auditor General), British Columbia has been the most effective of all provinces in controlling increases in drug spending, while at the same time continuing to be one of the most generous with regard to public coverage.

In summary, we profoundly disagree with the Auditor General's overall conclusion that little progress has been made by PharmaCare since the last audit. We have described the work PharmaCare has undertaken internally to restructure its benefit programs and make them more equitable and sustainable. We have also described the leadership British Columbia has taken on the national front to promote collaboration and cooperation between jurisdictions, in order to ensure all Canadians have access to safe and effective prescription drug coverage. British Columbia's PharmaCare is one of the most well evaluated public programs (see attached bibliography), and there is strong external validation that British Columbia's management of the PharmaCare program is equitable, cost-effective and sustainable.

While we believe the fundamentals for an equitable and sustainable PharmaCare program are in place, we also recognize that we are faced with some challenges and that improvements can be made. Many of the areas for improvement identified by the

Response from the Ministry

Office of the Auditor General's report were also identified by the PharmaCare Review and, as is outlined below, work on many of the actions recommended by the Office of the Auditor General is already underway.

With regard to the recommendations in the report, the ministry has the following comments:

Recommendation 1:
Review PharmaCare's strategic objectives and make necessary adjustments to reflect current thinking.

In October 2005, the Medical and Pharmaceutical Services (MPS) Division released its *Service Plan, 2005/2006*, outlining PharmaCare's priorities for the coming year. The *Service Plan* outlines a clearly defined set of objectives and links them to PharmaCare's mission of providing British Columbians with a universal drug program that is both cost-effective and evidence-based.

The development of a new set of objectives, and the respective implementation strategies, represents PharmaCare's intention to promote strategic objectives that seek to meet both present and future challenges. In November 2005, a multilateral stakeholder session was held to share the 2005/06 objectives and to provide an opportunity for stakeholders to have an input into the 2006/07 planning process.

Recommendation 2:
Align PharmaCare strategic objectives with statements of actions that describe how the objectives are to be achieved.

The Medical and Pharmaceutical Services (MPS) Division *Service Plan, 2005/2006*, effectively links PharmaCare's objectives to a series of specific strategies and actions that will help achieve these objectives. Significantly, these objectives and their relative statements of action address many of the recommendations contained within this report.

Finally, PharmaCare's mission is linked to specific ministry goals and objectives. This linkage ensures that all PharmaCare resources are directed towards achieving the ministry's vision, goals and objectives.

Response from the Ministry

Recommendation 3:
Determine the human resources needed to achieve the program's objectives and build capacity to meet those needs.

Reflecting PharmaCare's commitment to implement the necessary changes to help meet the program's objectives, the ministry has created a new Assistant Deputy Minister position to lead the newly created PharmaCare Division. The purpose of this new position is to strengthen clinical leadership within the Division and represent PharmaCare at the Ministry Executive table. Throughout the Division, over 20 new positions have been created to increase capacity and address important functional needs. For example, PharmaCare is in the process of establishing a new Utilization Management Unit that would help increase PharmaCare's capacity to monitor drug utilization and health outcomes and promote evidence-based prescribing practices.

Recommendation 4:
Develop performance measures for, set targets for, and collect information on achievement of program objectives.

The Ministry of Health's objectives are strategically linked and guided by five overarching goals set out by government. In order to better assess the ministry's performance *vis-à-vis* these objectives, the ministry's annual *Service Plan* will identify a set of performance measures that have been developed to support the achievement of the ministry's goals.

As part of the PharmaCare Review Implementation, work is underway to collect baseline data on important program elements, such as drug review times, drug distribution and dispensing costs. This information will complement existing information available through the PharmaNet system on drug utilization and population access. As part of its annual planning process, PharmaCare intends to identify and develop a performance measurement system to monitor, report on and improve performance.

Recommendation 5:
Work with the College of Pharmacists and others to move custodianship of PharmaNet information to the ministry, and provide timely access.

PharmaNet is a province-wide network that links all British Columbia pharmacies to a central set of data systems.

Response from the Ministry

PharmaNet contains personal medication history of all citizens of the province. The ministry deems the protection of this information to be a very serious matter. In compliance with the British Columbia *Freedom of Information and Protection of Privacy Act*, PharmaNet is subject to strict privacy and security measures designed to prevent unauthorized access and protect the information in its databases.

PharmaNet supports drug dispensing, drug monitoring and claims processing. To date, PharmaNet has been accessed by community and hospital pharmacies, emergency departments, the College of Pharmacists of BC and the College of Physicians and Surgeons of BC. On December 5, 2005, access to PharmaNet expanded to include physicians as users through the province-wide rollout of the Medical Practice Access to PharmaNet (MPAP) initiative.

Further, the ministry is drafting new PharmaNet access regulations for enactment with the *Pharmacy Operations and Drug Scheduling Act* (PODSA). The timing of the enactment of PODSA is linked to the College of Pharmacists of British Columbia updating and writing their Bylaws for inclusion in the *Health Professions Act*, and is beyond the control of the ministry.

Recommendation 6:
Formally evaluate the MAXIMUS BC contract on a regular basis, to determine its effectiveness.

The ministry made a commitment to report quarterly on the results of Health Insurance British Columbia (HIBC) with respect to its key service areas. The ministry published its third quarterly report in January 2006.

The Alternative Service Delivery (ASD) Secretariat has also proposed a draft report for all ASDs that would report against the objectives of each project. While the form, content and frequency of those reports have not yet been determined, it is expected that there will be formal reporting on the results of these projects.

The ministry has provided all relevant documentation to the Office of the Auditor General (OAG) to keep the office apprised of the contract's progress and governance/contract management activities. The ministry has also engaged Deloitte to conduct

SysTrust audits and that engagement was expanded to provide the OAG with opinions in regard to financial controls and their operation within HIBC.

As this is a ten-year contract, and the first two years will be consumed with change, as MAXIMUS BC undergoes its transformational activities (replacing key legacy systems that support the Medical Services Plan and PharmaCare), it is contemplated that an effectiveness, or value-for-money audit, would not be practical until later on in the term of the contract (i.e. year 3 or 4). The ministry will consult with the OAG on their plans to conduct these audits across government, and will welcome any audits planned for this contract.

Recommendation 7:
Review internal procedures for assessing the cost-effectiveness of new drugs to identify and implement ways to streamline the assessment process, including consideration of a fast-track process.

The Formulary Management Unit of PharmaCare is responsible for managing the evidence-based review of brand name and generic drug submissions that forms the basis for drug listing decisions. In order to be listed for coverage through PharmaCare, there must be evidence that a drug is both therapeutically advantageous and cost-effective relative to currently available treatments.

Over the past eight months, PharmaCare has undertaken a review of the formulary management process in an effort to improve efficiency, increase transparency and integrate stakeholders' participation, while still maintaining and promoting a rigorous evaluation process. A final report with recommendations for addressing effectiveness and efficiency, transparency and communication is nearing completion.

The formulary management process has been streamlined over the past six months in response to implementation of the Common Drug Review providing recommendations on new chemical entities and combination products. Drugs that have been reviewed by the Common Drug Review go through an expedited review process as do most line extensions and generic drug products. Further improvements in efficiency and transparency are expected as the recommendations from the Formulary Management Review are implemented over the next year.

Response from the Ministry

Recommendation 8:
Put in place a process to systematically assess the cost-effectiveness of existing drugs in the formulary.

PharmaCare is presently in the process of establishing a new Utilization Management Unit that would be entrusted with assessing the cost-effectiveness of drugs already on PharmaCare's formulary. This Unit will provide capacity within PharmaCare to systematically monitor drug utilization and health outcomes. The unit will also be responsible for developing and evaluating methods to promote appropriate drug use through physician best practices in prescribing.

Recommendation 9:
Explore and implement ways to ensure best prices are paid for drugs by the province.

Under the Supply Chain project, PharmaCare has committed to 1) analyze the current PharmaCare–pharmacy supply chain for cost efficiency, in the context of full pharmacy remuneration and business models, and 2) model a new cost-efficient PharmaCare–pharmacy supply chain in balance with appropriate pharmacy remuneration.

The desired outcomes of the project are the identification of a feasible model for a cost-efficient supply chain, a common understanding of the PharmaCare–pharmacy supply chain and pharmacy remuneration environment, and stakeholder participation in the process.

As co-chair of the National Pharmaceuticals Strategy (NPS), PharmaCare is working with federal, provincial and territorial partners to achieve international parity of prices and accelerate access to non-patented drugs, and pursue purchasing strategies to obtain the best prices for prescription drugs and vaccines in Canada. To achieve this objective, a NPS Pricing and Purchasing Task Group is working to establish the process and capability to monitor and report on generic pricing. Steps are also being taken to support the development of a comprehensive framework for national pricing and purchasing strategies. The framework will facilitate a national response to pricing and purchasing issues, providing the basis for regulatory, policy and program changes that will result in lower prices for patented and non-patented drugs, and serve as a key step to better pharmaceutical management.

Response from the Ministry

Recommendation 10:
Use PharmaNet information to identify trends in prescribing practices and to inform physicians about their own prescribing practices and the projected results had currently recognized clinical best practices been followed.

The ministry supplies PharmaNet information to the College of Physician and Surgeons of British Columbia for the monitoring of their members' prescribing practices. On December 5, 2005, access to PharmaNet expanded to include physicians as users through the province-wide rollout of the Medical Practice Access to PharmaNet (MPAP) initiative. Medical Practice Access to PharmaNet allows authorized medical practitioners to request and receive up-to-date records of medications dispensed to a patient, in a timely and secure manner. While enrolment into MPAP is optional, PharmaCare continues to promote greater physician access to PharmaNet.

Work has begun on longer-term goals relating to PharmaCare's involvement with the ministry's e-Health Drug Strategy, a pillar of the Electronic Health Record. PharmaCare is a co-chair on the steering committee for this project.

The project's vision includes expanding access to the PharmaNet medication profile for authorized users; developing a complete medication profile; deploying clinical and financial reference tools and the development of e-prescribing.

Recommendation 11:
Significantly increase support for PharmaCare-sponsored programs that encourage appropriate drug use through physician best practices in prescribing (such as Therapeutics Initiative Letters, physician access to PharmaNet, and the academic drug detailing program).

Through the implementation of several programs and projects, PharmaCare has been supporting, exploring and evaluating ways to promote physician best practices in prescribing. As noted by the Auditor General, the existing programs are relatively modest in scope. PharmaCare agrees with the Auditor General regarding the need to encourage physician best practices in prescribing and has done considerable groundwork towards this objective. As described above, the establishment of an Assistant Deputy Minister position for PharmaCare is expected to strengthen clinical leadership and the new Utilization Management Unit will provide increased analytic capacity within the Division.

Response from the Ministry

Over the past two years, PharmaCare has also been actively participating in the Canadian Optimal Medication Prescribing and Utilization Service (COMPUS), launched in March 2004 under the direction of federal, provincial and territorial Deputy Ministers. This is a national project to promote and facilitate evidence-based best practices in drug prescribing and use among health care providers and patients/consumers. National initiatives like COMPUS allow PharmaCare to leverage work across the country and reduce duplication and inconsistency in best practice guidelines. The first evidence-based guidelines from COMPUS are expected to be released in 2006. PharmaCare will be working with stakeholders to determine appropriate mechanisms to disseminate COMPUS guidelines in BC.

Through the province-wide Medical Practice Access to PharmaNet (MPAP) initiative, PharmaCare continues to promote greater physician access to PharmaNet. MPAP is part of a larger e-drug strategy which will help harness the benefits of technology to support physicians in making prescribing decisions in real time and with patient-specific information.

Recommendation 12:
Support greater involvement of physicians in developing actions to promote appropriate drug use.

PharmaCare agrees that physician involvement is critical to success in promotion of appropriate drug use. PharmaCare and the British Columbia Medical Association (BCMA) have developed a proposal for a prescribing program that will provide physicians with education and tools to promote high quality patient care. The Education for Quality Improvement of Patient Care (EQIP) program is expected to be launched in the next few months.

The proposed program has received a strong endorsement from physicians' groups seeking to provide patients with evidence-based information on drug prices, as well as concise prescribing advice.

Response from the Ministry

The Guidelines and Protocols Advisory Committee (GPAC) oversees and coordinates the development and implementation of guidelines and protocols that contribute to the effective use of medical resources. GPAC is co-chaired by the BCMA and most members are practicing physicians. PharmaCare actively contributes to the committee and its working groups in an advisory capacity, as well as receiving feedback from participating members.

Recommendation 13:
Review Plan G—No-charge Psychiatric Medication Program and the supporting policy framework, to ensure they are consistent.

Introduced in 1997, the *No-Charge Psychiatric Medication Program* (Plan G) is available to individuals of any age who are registered with a Mental Health Service Centre and who demonstrate both clinical and financial need. The program provides 100 percent coverage of certain psychiatric medications for clients who qualify for Medical Services Plan (MSP) Premium Assistance (regular and temporary).

PharmaCare is responsible for determining what constitutes eligibility for Plan G coverage, for making policy decisions on eligibility and drugs covered by the plan, and for managing services under the plan. PharmaCare, however, cannot determine eligibility for Plan G. This responsibility is assigned to local Mental Health Service Centres.

PharmaCare acknowledges the need to ensure that the policy framework is consistent with the program and, as such, plans to review the *No-Charge Psychiatric Medication Program* and its supporting policy framework.

Response from the Ministry

Recommendation 14:
Ensure that eligibility criteria for Plan G—No-charge Psychiatric Medication Program are clear, and that eligibility is being assessed in accordance with the criteria.

In accordance with PharmaCare policy, in order to qualify for Plan G coverage an individual must meet two (2) eligibility criteria. The first criterion is clinical. As indicated in the *Application for Psychiatric Medication Coverage* form, a patient's physician must specify which clinical condition applies to the patient from the three criteria listed on the form.

The second criterion for coverage is financial. Once the physician or psychiatrist submits an *Application for Psychiatric Medication Coverage* form to the local Mental Health Service Centre, the Centre is responsible for determining whether the patient is either receiving or qualifies for Medical Services Plan (MSP) Premium Assistance (regular and temporary). Confirmation of assistance can be ascertained by contacting HIBC.

Recommendation 15:
In its annual report, move toward reporting in a manner consistent with the British Columbia reporting principles on the performance of the PharmaCare program.

PharmaCare is working towards this objective in the planning of its first Annual Report, expected to be released in the spring of 2006.

Response from the Ministry

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Appendices

Appendices

Appendix A: Listing of Detailed Audit Criteria

1) Program Management

Criterion 1: The ministry has adequate procedures in place to manage the performance of the PharmaCare program.

Sub-criteria:

1.1) Comprehensive program objectives

1.2) Adequate performance information

1.3) Adequate standards to monitor program performance

1.4) Regular evaluation of program performance

1.5) Compliance with legislation and policies

1.6) Adequate criteria for selection of service providers

1.7) Accountability framework for service providers

1.8) Regular monitoring & evaluation of service providers

2) Drug Selection and Cost

Criterion 2: The ministry has adequate procedures in place to ensure drugs covered are managed with due regard for cost-effectiveness.

Sub-criteria

2.1) Assessment of new drugs for cost-effectiveness before listing on the formulary

2.2) Regular evaluation of existing drugs on the formulary for cost-effectiveness

2.3) Fast-tracking of new drugs with potential for significant cost savings

2.4) Listed drugs & pharmacy services acquired at the lowest possible cost

2.5) Procedures to ensure pharmacies compliance with drug-pricing policies

Appendix A: Listing of Detailed Audit Criteria

3) Drug Use

Criterion 3: The ministry monitors the quantity and relevance of drug use and encourages appropriate and economical practices.

Sub-criteria:

3.1) Monitoring of physician prescribing practices for cost-effectiveness

3.2) Procedures to encourage improved physician prescribing practices

3.3) Monitoring of drug use (prescribing & drug interactions)

4) Eligibility of Insured Persons

Criterion 4: The ministry has adequate procedures in place to ensure the eligibility of insured persons.

Sub-criteria:

4.1) Drug coverage terms & conditions clearly communicated

4.2) Eligibility assessed at registration and during the covered period assessed

5) Claims Submitted by Pharmacies and other Organizations

Criterion 5: The ministry has adequate procedures in place to ensure compliance with legislation and assess whether its policies and procedures for approving, processing and paying claims are adequate and being followed.

Sub-criteria:

5.1) Computer environment and application controls result in authorized, accurate and complete processing of data with appropriate contingency planning

5.2) System deficiencies identified and corrected on a timely basis

5.3) Submitted claims validated, accurately calculated, and processed on a timely basis

5.4) Reasonable assurance that only valid claims are paid in compliance with policies and legislation

5.5) Pharmacy audits identified based on adequate risk assessment

5.6) Pharmacy audits carried out on a consistent basis with timely recoveries where applicable

6) Reporting to Parliament/Legislature

Criterion 6: The ministry reports on the PharmaCare program's performance to the Legislative Assembly.

Sub-criteria:

6.1) Reported information follows the BC reporting principles

6.2) Reported information is presented within the prescribed timeframe

Appendix B: Summary Information from Audit Reports Issued For Seven Canadian Jurisdictions

Canada

Auditor General of Canada

"November 2004 Chapter 4 Management of Federal Drug Benefit Programs"

The Report is available at http://www.oag-bvg.gc.ca.

This audit examined the drug benefit programs of six federal organizations: Health Canada (benefits for First Nations and Inuit), Veterans Affairs Canada (veterans), National Defence (Canadian Forces members), the Royal Canadian Mounted Police (members), Citizenship and Immigration Canada (certain designated classes of migrants), and Correctional Service Canada (inmates of federal penitentiaries and some former inmates on parole).

Main Points:

4.1 Our audit of the federal government's drug benefit programs found a lack of leadership and co-ordination in the provision of drug benefits. The six federal organizations that administer the programs approve most of the same drugs and deliver them through the same pharmacy system in Canada. However, the failure to co-ordinate their efforts has led to missed opportunities to save money and contain costs.

4.2 Studying drug use patterns, and taking appropriate action, can prevent the misuse of drugs and help ensure that clients realize the intended health outcomes of drug benefit programs. The federal government has current, highly informative data on the drug use of each of its clients; however , these data are not being systematically assessed and disseminated to health care professionals. The data provide an important source of medically relevant information for Health Canada, Veterans Affairs, the RCMP and National Defence, all of whom share responsibility for improving or maintaining the health of their respective clientele, in partnership with industry and service providers. Failure to share this information could result in less than optimal health outcomes for many clients.

4.3 In managing these programs, federal organizations have not taken advantage of known cost-savings opportunities in order to ensure the programs' long-term sustainability. As a result, the government may be spending tens of millions of dollars annually more than necessary.

4.4 The federal government is the fourth largest payer of prescription drug benefits in Canada, after Ontario, Quebec, and British Columbia. It spends more than $430 million annually on prescription drugs for about one million Canadians. These costs have risen by 25 percent over the past two years.

4.5 Other than for cost, most federal organizations have neither objectives nor performance measures that are specific to their drug benefit activities. Without specific objectives and related performance information, organizations have no means of assessing whether their activities are meeting intended purposes and are cost-effective.

4.6 Audits of pharmacies have identified significant overcharges owed to the Crown. These amounts owing have not been recorded in the Public Accounts of Canada as required by the Treasury Board Policy on Receivables Management.

Recommendations:

4.21 Health Canada, Veterans Affairs Canada, National Defence, the RCMP, Citizenship and Immigration Canada, and Correctional Service Canada should, either collectively or individually, establish or strengthen objectives and performance measures for their drug benefit activities and report to Parliament as appropriate.

4.58 As a minimum, Veterans Affairs Canada, Health Canada, National Defence, and the RCMP should upgrade their existing claims processing systems, as necessary, to ensure that each system monitors pharmacists' overrides of warning messages for drug use, includes an alert notification when clients access large numbers of prescription drugs, and includes an alert notification for potential misuses of narcotics and benzodiazepines.

4.59 Veterans Affairs Canada, Health Canada, National Defence, and the RCMP should begin to systematically analyze their claims processing databases for high-risk patterns of drug use, including those of narcotics and benzodiazepines. This is particularly important for high-risk groups such as senior citizens. These organizations should seek to use these analyses for communicating drug use information, as appropriate, to health care providers; and providing client-specific, retrospective information on drug use to pharmacists and doctors to assist them in achieving the best possible health care outcomes, while ensuring that client privacy is appropriately respected.

4.106 The federal government should establish an arrangement, characterized by a centrally-managed process, which will permit it to develop and manage a core formulary common to all federal drug benefit programs, develop a common evidence-based process to ensure that all departmental exceptions to the core formulary will be made with appropriate transparency and accountability, obtain the best value for each drug product listed on the core formulary, establish a single federal schedule for dispensing fees, explore less costly means of processing over-the-counter benefits, and develop a common risk-profiling and auditing process for all pharmacy audits.

4.107 Health Canada and Veterans Affairs Canada should identify the amounts owing to the Crown resulting from pharmacy audits in the Public Accounts. In accordance with Treasury Board policy, Health Canada and Veterans Affairs Canada should institute procedures to expeditiously recover these amounts owing (including interest).

Appendix B: Summary Information from Audit Reports Issued For Seven Canadian Jurisdictions

New Brunswick

Office of the Auditor General of New Brunswick

"2005 Auditor General's Report—Volume 2, Chapter 5—Department of Health and Wellness Prescription Drug Program"

The Report is available at http://www.gnb.ca/OAG-BVG/Index-e.asp.

Conclusions and results in brief:

The Department does not have adequate procedures in place to manage the performance of the Prescription Drug Program. The program lacks a clear mission and measurable objectives. Although we found the Department is adequately monitoring the performance of the service provider, a number of other areas are in need of improvement. Information should be analyzed and acted upon. The Department has a significant amount of information available to it, yet no consistent, regular and systematic analysis is performed on the data. Finally, there are no standards for non-financial aspects of the program's performance.

The Department has adequate procedures to ensure the drug assessment process and the amount paid for drugs and dispensing fees are managed with due regard for cost effectiveness.

Reporting on goals, objectives, program relevance, achievement of plans and acceptance by client groups is not adequate. Reporting in these areas is necessary to provide sufficient effectiveness information to the members of the Legislative Assembly and the general public. However, the Department is reporting adequately on the financial performance of the Prescription Drug Program.

Newfoundland/Labrador

Auditor General of Newfoundland and Labrador

2005 Report Chapter 2.1 — Newfoundland and Labrador Prescription Drug Program

The Report is available at http://www.ag.gov.nl.ca/ag/.

The Newfoundland and Labrador Prescription Drug Program (NLPDP) is operated by the Department of Health and Community Services and provides assistance in the purchase of pharmaceuticals

and some related medical supplies. This service is provided to three main groups of residents: income support recipients, senior citizens and special needs patients.

Main points:

Program costs are increasing—by 92% from $53.2 to $101.9 million over the last 9 years.

Poor management practices are not ensuring that program costs are minimized, for example:

- no on-line, real time claims system to provide necessary management information on a more timely basis,
- as a result of not having an on-line, real-time system, unable to take advantage of lower prices related to "deeming" drugs within therapeutic classes as having equal health benefits for the purpose of setting the price for that class at a lower or median level,
- no program to educate doctors on new drugs or provide information on their pattern of prescribing drugs relative to their peers,
- ability to audit a sufficient number of pharmacies is severely diminished because of the lack of cooperation from pharmacies regarding the provision of client information, and
- insufficient system controls in place, which are intended to ensure the accuracy of amounts paid for drugs.

No legislative framework to guide its operations for such things as the responsibilities and accountabilities of Government, pharmacies, and doctors, as well as the provision of enforcement provisions.

No proactive way of dealing with issues regarding the utilization of prescription drugs; for example, the small number of general practitioners suspected of indiscriminate prescribing for over 16 years.

Inadequate control of drug cards provided the potential for drug abuse. Manual cards are left blank for client services officers to fill out, but strict guidelines for their control were not followed in several offices.

Inconsistent application of eligibility criteria resulted from inconsistent policies for determining eligible client expenditures.

Appendix B: Summary Information from Audit Reports Issued For Seven Canadian Jurisdictions

Nova Scotia

Auditor General of Nova Scotia

"December Report 2004 Chapter 7 Pharmacare and Other Drug Programs"

The Report is available http://www.gov.ns.ca/audg/ .

The scope of our audit included the Nova Scotia Seniors' Pharmacare program, disease specific programs, exception drug funding administered by the Department of Health and the Pharmacare program offered by the Department of Community Services.

Our audit did not include drugs which are procured and used in acute care and long-term care facilities. However, we compared the price of drugs bulk purchased for use in acute care facilities in Nova Scotia to those paid by the Provincial Pharmacare programs. It is important to note that the Nova Scotia Pharmacare programs are more restricted in scope than those in other jurisdictions and are targeted towards seniors and income assistance recipients with no private insurance.

The following are the principal observations from this audit.

- The contract with Atlantic Blue Cross Care for administration of the drug programs is not current, and is inadequate. We recommend that the Department of Health finalize a performance-based third party service provider contract that includes clearly defined roles, responsibilities, and performance expectations.
- Although there is now a national Common Drug Review process, Nova Scotia is still responsible for deciding which drugs will be added to the Province's formulary and for reviewing old drugs with new indications, line extensions and class reviews. We noted that the processes for reviewing and assessing drug manufacturers' submissions and approving additions to the formulary are thorough and consistent. The advice of experts is sought and followed. Effectiveness of drugs and costs are considered.

- The controls and processes in place at Atlantic Blue Cross Care (ABCC) over the payment and monitoring of electronic claims are appropriate. Controls could be improved in the payment and monitoring of manual claims at ABCC.
- The Department of Health needs to conduct a comprehensive evaluation of options for reducing drug costs for the pharmacare programs in Nova Scotia. As an example, the Nova Scotia Provincial Drug Distribution Program, which acquires drugs used by District Health Authorities in acute care institutions, has been able to procure drugs at prices approximately 14.8% lower, by purchasing through a national buying group, than prices paid to pharmacies for the same drugs through the Provincial Pharmacare programs. Although we acknowledge that pharmaceutical companies ultimately control the price of drugs and may be unwilling to reduce prices for drugs which are not used in a hospital setting, the potential savings to the program of even modest drug price reductions could be significant and warrants further study. We also acknowledge that bulk purchasing is complex because of the need to consider such factors as warehousing, distribution and uncertainties about how the market would respond to such initiatives.
- We recommend that current Department of Health initiatives to monitor drug utilization and physician prescribing practices should be continued and enhanced.
- We recommend that the Department of Health should explore options to increase physician participation in academic detailing which is a program administered by Dalhousie Continuing Medical Education to provide educational advice to physicians on drug-related topics through visits to physicians' offices.
- The Department of Health needs to improve its information systems for the Pharmacare programs. The current information technology is outdated and unable to produce all information required for appropriate monitoring.

Appendix B: Summary Information from Audit Reports Issued For Seven Canadian Jurisdictions

Prince Edward Island

Auditor General of Prince Edward Island

"Annual Report 2005 Section 3 Provincial Drug Programs"

The Report is available at http://www.assembly.pe.ca/auditorgeneral/index.php.

In accordance with Section 13 of the Audit Act, we conducted as examination of the Department of Health and Social Services' Provincial Drug Programs delivered by retail pharmacies as well as the Provincial Pharmacy.

Recommendations:

- Objectives for each drug program should be documented and clearly defined in measurable terms.
- Key performance indicators should be developed with a focus on program outcomes and the results reported publically on at least an annual basis.
- Program results should be reviewed regularly, compared to objectives, and corrective action taken when required.
- Drug programs should be evaluated on a cyclical basis.
- The Department should review the five percent mark up on generic drugs.
- The Department should determine whether standing offer contracts can be used to achieve cost savings.
- The Department should review the wholesale mark up with the objective of negotiating a lower percentage mark up with retail pharmacies.
- The timing of increases in drug prices should be reviewed.
- The Department should consider introducing a cap on the mark up for drugs costing over $45.
- The Department should further explore Reference Drug Pricing.
- The Department should require retail pharmacies to file their dispensing fees annually.
- The Department should monitor prescribing patterns to identify and follow up unusual practices.
- The Department should develop procedures to monitor and analyse drug use and take corrective action as necessary.

- The Department should ensure that only eligible Financial Assistance clients receive drug benefits.
- The Department should conduct rotational audits of pharmacies on an annual basis.

Quebec

Auditor General of Quebec

"Report to the National Assembly for the Year 2003-2004, Volume 2—Chapter 2 Régime général d'assurance médicaments"

The Report is available at http://www.vgq.gouv.qc.ca/ .

Recommendations:

- The Minister of Health and Social Services should generate, as required by law, a medication policy and define the objectives and indicators which will permit judgement and analysis of the performance of the public drug program.
- The Counsel on Medications should make sure that its annual financial report includes an analysis of its performance.
- The Health Insurance Program should ensure that its accounting records give more exposure to the key risks concerning the public drug program.
- The Quebec Health Insurance Program should:
  - — take steps to improve the population's understanding of the public drug program law,
  - — put in place measures which facilitate access to telephone service, and
  - — ensure that the concepts about parental authority are precise and are uniformly applied.
- The Quebec Health Insurance Program should improve its control procedures, to ensure the admissibility of participants in the public drug program from the moment of their application and during the period of coverage.
- The Quebec Health Insurance Program and Revenue Quebec should pursue efforts to:
  - — ensure that participants in the public drug program pay their premiums, and

- — ensure that all eligible persons participate in the public drug program.

- The Minister of Health and Social Services should:
  - — re-evaluate the amount paid for the application of the rule of 15 years, in order to compensate the public drug program to its proper value,
  - — decide about other methods to control costs.
  - — ensure that the fees decided for wholesale purchases are governed by precise criteria, and
  - — ensure that the agreements with the Quebec Association of Pharmacists (approved by the government) are properly applied.
- The Quebec Health Insurance Program should:
  - — analyse the risks included in its process of selection of pharmacies to audit
  - — increase the number of audits of pharmacies,
  - — review its process of auditing pharmacies
  - — check that services rendered to insured people were really provided, and
  - — make sure that the recovery of costs, which are specified by law, are imposed on the sums due to the pharmacy owners.
- In order to facilitate the optimal use of medication, the Ministry of Health and Social Services, working with the Counsel on Medications and the Quebec Health Insurance Program should:
  - — make its strategy better known, and establish a plan of action concerning the optimal use of medications,
  - — pursue efforts to ensure that consumers are well informed about the optimal use of medications.
  - — analyse opportunities to improve the dissemination of information, in order to encourage appropriate and economic prescribing practices, keeping in mind the legal context;
  - — ensure that available information is better used, especially by the production of utilisation reviews and descriptive analyses,

— analyse opportunities to follow the consumption of all categories of clients, keeping in mind the legal context, and

— in order to improve the optimal use of certain medications, ensure that the agreements with the manufacturers include precise and measurable objectives, and that the objectives are analysed.

Saskatchewan

Provincial Auditor Saskatchewan

"2005 Report Volume 1, Chapter 4—Health"

The Report is available at http://www.auditor.sk.ca/ .

This chapter reports the results of our audit of the Department of Health to monitor the quality and relevance of drug use and to report on the Drug Plan's performance.

Main points:

The Department of Health spends more than $150 million per year on the Saskatchewan Prescription Drug Plan.

The Department should do more analysis to monitor the quantity and relevance of drug use in the population. This analysis would allow the Department to determine the success of specific program efforts. It would also allow it to focus resources to encourage appropriate and economical prescribing practices.

The Department has a Drug Plan claims database with a wealth of information that can provide valuable insights. Currently, the Department is improving its processes to monitor the quantity and relevance of drug use at an individual level. The planned improvements to this system will serve to strengthen this process in the future.

The Department's public reports need to show whether the Drug Plan is achieving its purposes.

Appendix C: Office of the Auditor General: Risk Auditing Objectives and Methodology

The Office has three lines of business:

- Attesting to the reliability of government financial statements;
- Assessing the quality of government service plan reports;
- Examining how government manages its key risks.

Each of these lines of business have certain objectives that are expected to be achieved, and each employs a particular methodology to reach those objectives. The following is a brief outline of the objectives and methodology applied by the Office for assessing the management of risk within government programs and services, that is, risk auditing.

Risk Auditing

What are Risk Audits?

Risk audits (also known as performance or value-for-money audits) examine whether money is being spent wisely by government—whether value is received for the money spent. Specifically, they look at the organizational and program elements of government performance, whether government is achieving something that needs doing at a reasonable cost, and consider whether government managers are:

- making the best use of public funds; and
- adequately accounting for the prudent and effective management of the resources entrusted to them.

The aim of these audits is to provide the Legislature with independent assessments about whether government programs are implemented and administered economically, efficiently and effectively, and whether Members of the Legislative Assembly and the public are being provided with fair, reliable accountability information with respect to organizational and program performance.

In completing these audits, we collect and analyze information about how resources are managed; that is, how they are acquired and how they are used. We also assess whether legislators and the public have been given an adequate explanation of what has been accomplished with the resources provided to government managers.

Appendix C: Office of the Auditor General: Risk Auditing Objectives and Methodology

Focus of Our Work

A risk audit has been described as:

...the independent, objective assessment of the fairness of management's representations on organizational and program performance, or the assessment of management performance, against criteria, reported to a governing body or others with similar responsibilities.

This definition recognizes that there are two forms of reporting used in risk auditing. The first—referred to as attestation reporting—is the provision of audit opinions as to the fairness of management's publicly reported accountability information on matters of economy, efficiency and effectiveness. This approach has been used to a very limited degree in British Columbia because the organizations we audit do not yet provide comprehensive accountability reports on their organizational and program performance.

We believe that government reporting along with independent audit is the best way of meeting accountability responsibilities. Consequently, we have been encouraging the use of this model in the British Columbia public sector, and will apply it where comprehensive accountability information on performance is made available by management.

As the risk audits conducted in British Columbia use the second form of reporting—direct reporting—the description that follows explains that model.

Our "direct reporting" risk audits are not designed to question whether government policies are appropriate and effective (that is achieve their intended outcomes). Rather, as directed by the Auditor General Act, these audits assess whether the programs implemented to achieve government policies are being administered economically and efficiently. They also evaluate whether Members of the Legislative Assembly and the public are being provided with appropriate accountability information about government programs.

When undertaking risk audits, we look for information about results to determine whether government organizations and programs actually provide value for money. If they do not, or if we are unable to assess results directly, we then examine management's processes to determine what problems exist or whether the processes are capable of ensuring that value is received for money spent.

Appendix C: Office of the Auditor General: Risk Auditing Objectives and Methodology

Selecting Audits

All of government, including Crown corporations and other government organizations, are included in the universe we consider when selecting audits. We also may undertake reviews of provincial participation in organizations outside of government if they carry on significant government programs and receive substantial provincial funding.

When selecting the audit subjects we will examine, we base our decision on the significance and interest of an area or topic to our primary clients, the Members of the Legislative Assembly and the public. We consider both the significance and risk in our evaluation. We aim to provide fair, independent assessments of the quality of government administration and to identify opportunities to improve the performance of government. Therefore, we do not focus exclusively on areas of high risk or known problems.

We select for audit either programs or functions administered by a specific ministry or government organization, or cross-government programs or functions that apply to many government entities. A large number of such programs and functions exist throughout government. We examine the larger and more significant of these on a cyclical basis.

Our view is that, in the absence of comprehensive accountability information being made available by government, risk audits using the direct reporting approach should be undertaken on a five- to six-year cycle so that Members of the Legislative Assembly and the public receive assessments of all significant government operations over a reasonable time period. We strive to achieve this schedule, but it is affected by the availability of time and resources.

Planning and Conducting Audits

A risk audit comprises four phases—preliminary study, planning, conducting and reporting. The core values of the Office—independence, due care and public trust—are inherent in all aspects of the audit work.

Appendix C: Office of the Auditor General: Risk Auditing Objectives and Methodology

Preliminary Study

Before an audit starts, we undertake a preliminary study to identify issues and gather sufficient information to decide whether an audit is warranted.

At this time, we also determine the audit team. The audit team must be made up of individuals who have the knowledge and competence necessary to carry out the particular audit. In most cases, we use our own professionals, who have training and experience in a variety of fields. As well, we often supplement the knowledge and competence of our staff by engaging one or more consultants to be part of the audit team.

In examining a particular aspect of an organization to audit, auditors can look either at results, to assess whether value for money is actually achieved, or at management's processes, to determine whether those processes should ensure that value is received for money spent. Neither approach alone can answer all the questions of legislators and the public, particularly if problems are found during the audit. We there-fore try to combine both approaches wherever we can. How-ever, because acceptable results-oriented information and criteria are often not available, our risk audits frequently concentrate on management's processes for achieving value for money.

If a preliminary study does not lead to an audit, the results of the study may still be reported to the Legislature.

Planning

In the planning phase, the key tasks are to develop audit criteria—"standards of performance"—and an audit plan outlining how the audit team will obtain the information necessary to assess the organization's performance against the criteria. In establishing the criteria, we do not expect theoretical perfection from public sector managers; rather, we reflect what we believe to be the reasonable expectations of legislators and the public.

Conducting

The conducting phase of the audit involves gathering, analyzing and synthesizing information to assess the organization's performance against the audit criteria. We use a variety of techniques to obtain such information, including surveys, and questionnaires, interviews and document reviews.

Appendix C: Office of the Auditor General: Risk Auditing Objectives and Methodology

Reporting Audits

We discuss the draft report with the organization's representatives and consider their comments before the report is formally issued to the Legislative Assembly. In writing the audit report, we ensure that recommendations are significant, practical and specific, but not so specific as to infringe on management's responsibility for managing. The final report is tabled in the Legislative Assembly and referred to the Public Accounts Committee, where it serves as a basis for the Committee's deliberations.

Reports on risk audits are published throughout the year as they are completed, and tabled in the Legislature at the earliest opportunity. We report our audit findings in two parts: an Auditor General's Comments section and a more detailed report. The overall conclusion constitutes the Auditor General's independent assessment of how well the organization has met performance expectations. The more detailed report provides background information and a description of what we found. When appropriate, we also make recommendations as to how the issues identified may be remedied.

It takes time to implement the recommendations that arise from risk audits. Consequently, when management first responds to an audit report, it is often only able to indicate its intention to resolve the matters raised, rather than to describe exactly what it plans to do.

Without further information, however, legislators and the public would not be aware of the nature, extent, and results of management's remedial actions. Therefore, we publish updates of management's responses to the risk audits. In addition, when it is useful to do so, we will conduct follow-up audits. The results of these are also reported to the Legislature.

Appendix D:
Office of the Auditor General: 2005/06 reports issued to date

Report 1 — April 2005

Follow-up of the Recommendations of the Select Standing Committee on Public Accounts contained in its Fourth Report of the 3rd Session of the 36th Parliament: Earthquake; Performance Audit

Report 2 — May 2005

Joint Follow-up of 2001/2002: Report 1 Managing Interface Fire Risks and Firestorm 2003 Provincial Review

Report 3 — June 2005

Audit of the Government's Corporate Accounting System: Part 1

Report 4 — July 2005

Building Better Reports: Our Assessment of the 2003/04 Annual Service Plan Reports of Government

Report 5 — July 2005

Keeping the Decks Clean:
Managing Gaming Integrity Risks in Casinos

Report 6 — November 2005

Monitoring the Government's Finances
Province of British Columbia

Report 7 — February 2006

Follow-up of 2003/2004 Report 4: Alternative Payments to Physicians: A Program in Need of Change

Report 8 — March 2006

Managing PharmaCare: Slow Progress Toward Cost-Effective Drug Use and a Sustainable Program

This report and others are available on our website at http://www.bcauditor.com.