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Managing the Cost of Drug Therapies and Fostering Appropriate Drug Use

Ministry of Health and Ministry Responsible for Seniors: Pharmacare Branch

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table of contents

auditor general's comments

Pharmacare is British Columbia's drug insurance plan and residents are automatically eligible for its benefits when they register with the Province's Medical Services Plan. Because drug therapy is an essential part of many people's medical care, Pharmacare forms an integral component of the health care system serving British Columbians.

Thousands of prescription drugs are available worldwide and many new ones are being added each year. While the federal government makes decisions about which prescription drugs can be sold in Canada, each provincial drug insurance plan decides which drugs to provide as benefits to its respective members. In British Columbia, the advent of more and costlier medications in recent years, combined with other factors such as population growth and changing demographics, has resulted in a significant increase in Pharmacare's costs. This has made it increasingly important for the Ministry of Health and Ministry Responsible for Seniors to seek innovative ways to manage prescription drug costs.

The ministry has imposed controls over the availability of prescription drugs since the inception of Pharmacare, but now more than ever it has begun looking for ways to manage the cost of drug therapies and foster appropriate drug use. Although decisions about drug use have been the traditional domain of physicians and pharmacists, the government can also play a role. It can, for example, encourage the medical and pharmacy professions and the pharmaceutical industry to study the extent of, and reasons for, patient non-compliance with drug therapies, and to inform patients and practitioners about ways to improve drug use. Successes in these areas would serve both to improve patient health and to control spending on drugs. One important ministry initiative in this regard was the implementation of the PharmaNet computer system to assist in ensuring the appropriateness of drug use. PharmaNet provides an additional tool to help

pharmacists detect drug misuse and potentially dangerous drug interactions by connecting the ministry and all community pharmacies in the Province. It also provides a wealth of information that can be analyzed to help identify areas where drug use improvements might be achieved.

Our audit looked at the ministry's work in these two areas—managing the cost of drug therapies and fostering appropriate drug use. In the first area, we concluded that the ministry has successfully introduced several programs to manage drug costs; in the second, however, we concluded that the ministry has made significant progress, but could still do more to encourage appropriate drug use.

George L. Morfitt, FCA
Auditor General

Victoria, British Columbia
July 1998

highlights

managing the cost of drug therapies and fostering appropriate drug use

An audit of the provincial drug insurance program

Pharmacare is British Columbia's drug insurance program, assisting residents to pay for prescription drugs. Because drug therapy is an essential part of many people's medical care, Pharmacare is an integral component of the health system that serves British Columbians. Key roles for the Ministry of Health and Ministry Responsible for Seniors are to manage the cost of drug therapies provided under Pharmacare and to foster appropriate drug use.

Audit Purpose and Scope

The purpose of the audit was to assess whether the ministry adequately manages the cost of prescription drug therapies provided under Pharmacare and whether it fosters appropriate drug use. To do this, we examined the processes used by the ministry to:

- decide which drugs to cover;
- foster appropriate drug use;
- ensure cost-effective drug therapies;
- pay the right price for drugs dispensed; and
- evaluate and report program results.

We did not look at the payment of dispensing fees to pharmacists or the issue of "ability to pay" by those receiving benefits. In addition, we did not focus on the broad issue of illegal drug abuse, but did include initiatives aimed at preventing drug fraud and the inappropriate use of prescription drugs. Finally, we did not review the issue of alternatives to drug therapies.

We carried out the audit between July and December 1997. Our examination was performed in accordance with value-for-money auditing standards recommended by the Canadian Institute of Chartered Accountants and accordingly included such tests and other procedures we considered necessary in the circumstances.

Overall Conclusion

We concluded that the Ministry of Health and Ministry Responsible for Seniors is adequately managing the cost of drug therapies, although it could do more to foster appropriate drug use.

The ministry has an independent drug review process that ensures new drugs are provided as Pharmacare benefits only if they provide good value for money and is developing a new process to identify existing drugs that are no longer cost-effective. It also has programs in place to ensure that cost-effective drugs are prescribed and drug waste is reduced. The PharmaNet system, for example, is used to prevent and detect drug fraud and abuse and to reduce duplication of medications. Finally, the ministry ensures that it pays reasonable prices for drugs dispensed by pharmacies, although, additional assurance would be obtained if the ministry carried out audits of community pharmacies. The ministry is currently developing such a program.

The ministry supports several programs aimed at informing physicians, pharmacists and patients about appropriate drug use. However, to further foster appropriate drug use, the ministry needs to:

- encourage the medical and pharmacy professions to investigate the extent of, and reasons for, patient non-compliance with drug therapies and ensure that programs exist to address this issue;
- ensure it receives accountability information from all agencies funded by the ministry to provide programs that foster appropriate drug use;
- include in patient profiles on the PharmaNet system those prescription drugs received by patients from sources other than community pharmacies; and
- encourage more extensive use of the information in the PharmaNet system, to foster appropriate drug use.

We also concluded that the ministry needs to evaluate the performance of its major Pharmacare programs using a comprehensive performance evaluation framework and to report the results to key stakeholders. It is particularly important that the Reference Drug Program be independently evaluated to assess its impact on health outcomes and overall health care costs. We were pleased to find that the ministry is supporting the evaluation proposals of several independent researchers.

Key Findings

The drug review process helps to ensure that the right drugs are available to British Columbians as benefits

The ministry has established two independent agencies, the Therapeutics Initiative and the Pharmacoeconomics Initiative, to provide objective information about new drugs. The Therapeutics Initiative evaluates the therapeutic advantage of a new drug over existing drugs available to treat the same condition. The Pharmacoeconomics Initiative evaluates the cost/benefits of the new drug. The ministry uses the work of these two agencies to help ensure that the drugs eligible as benefits under Pharmacare treat the range of illnesses faced by British Columbians and provide good value for money.

A process for reviewing the cost-saving opportunities of all existing drug therapies needs to be finalized

Many drugs provided as Pharmacare benefits have not undergone the level of review that now is required before a new drug is listed as a benefit—including reviews for therapeutic advantage over existing drugs and for cost-effectiveness. The ministry has used several informal means to help it identify existing drugs that should be de-listed because better alternatives exist, and it has been successful in identifying several such instances. In November 1997, the ministry established the Plan Management Committee to develop and formalize a process for reviewing existing drugs on an annual basis. The ministry needs to finalize the process to ensure that all existing drugs are reviewed for therapeutic advantage and cost-effectiveness within a reasonable time.

Not enough is done to understand the nature and extent of patient non-compliance with drug therapies

Patient non-compliance with drug therapies—not filling a prescription or not taking a drug as directed—is recognized to have a significant impact on the costs of Pharmacare and the general health care system and it could result in negative health consequences. Some work has been done at the federal level to improve understanding of this issue, however, the ministry should encourage and support the medical and pharmacy professions and the pharmaceutical industry to do more to determine the nature and extent of patient non-compliance in British Columbia. Such information would help the ministry decide how much effort it should devote to this matter and where it should focus those efforts.

The PharmaNet system is a valuable tool to foster appropriate drug therapies, but more can be done to improve the system and increase its usefulness

A significant ministry accomplishment, the PharmaNet system links the ministry and all community pharmacies in the Province. The system maintains a profile for each patient showing all drug therapies used by the patient that have been filled by a community pharmacy. The system also helps the ministry administer Pharmacare by, for example, checking drug prices and calculating a patient's portion of the prescription cost. The system would be even more beneficial if it contained information about all prescription drugs used by a patient, including those obtained from sources other than a community pharmacy. Benefits would also be increased if the ministry encouraged greater use of the vast amount of information contained in PharmaNet as a tool to foster appropriate drug use. For example, it could be used to analyze the consumption of specific drug products and to target specific patient groups with drug educational materials.

PharmaNet plans call for the system to be installed in physician offices and hospital emergencies. To this end, the ministry announced an Emergency Department pilot testing project in June 1997 and live testing has now begun. Based on the results of the pilots, the ministry will determine when the system can be installed in all of the locations.

The ministry has introduced two major programs to help ensure that cost-effective drugs are prescribed

In some situations, several drug products may be considered to be chemically identical (a generic product vs. a name brand product, for instance). Under the Low-Cost Alternative Program, the ministry limits the amount it will pay for a drug to the cost of the lowest-price product. This same program is used in other provinces and is generally accepted in British Columbia.

In other situations, several drugs that are used to treat the same condition, even though they are not chemically identical, may be available at significantly different prices. Under the Reference Drug Program, the ministry limits the amount it will pay for the drug portion of a prescription to the cost of the "reference" drug in that class of drugs. Ministry approval can be obtained to switch to a higher-priced product when medically necessary. No other jurisdiction in North America has adopted this policy in the same way, and it is not

supported by all stakeholder groups. Ministry monitoring suggests that the program has achieved savings in drug costs with no significant negative health consequences or significant additional costs in other parts of the health care system. However, the ministry's monitoring has been limited and may be seen by some as biased. To address these concerns, the program needs to be independently evaluated. The ministry is currently supporting the evaluation proposals of several independent researchers.

The ministry has implemented measures to help ensure it pays the right price for drugs dispensed, but a pharmacy audit program is also needed

The ministry limits the amount it pays for a drug dispensed to the actual price paid by a pharmacy up to a maximum of 7% above the manufacturer's list price. The ministry also requires that valid prescriptions exist for all drugs dispensed by a pharmacy. The PharmaNet system helps the ministry ensure that these policies are met, by comparing prices charged by pharmacies against manufacturer price lists and by identifying unusual dispensing trends. Nevertheless, the risk still remains that some pharmacies may not be charging the ministry based on the actual cost of their drugs and that they may be charging the ministry when no prescription exists or a fraudulent prescription has been written. The ministry is aware that these risks exist and it is currently developing a program to conduct periodic pharmacy audits to complement other work it does in this area.

Accountability information has not been received from some agencies funded by the ministry to deliver programs, and reporting overall can be improved

The ministry uses several programs to manage the cost of drug therapies and to foster appropriate drug use, including some programs that are funded by the ministry but delivered by external agencies. The ministry had not obtained recent accountability information from two of those funded agencies —the Prescription Review Program and the North Shore Community Drug Utilization Review Program. In addition, a complete performance evaluation framework is not in place and the programs have not been independently evaluated to assess the extent to which they have achieved their objectives. This limits the extent of useful information that can be reported by the ministry to key stakeholders.

summary of recommendations

Deciding Which Drugs to Cover

The ministry should:

- ***review currently listed drugs periodically to ensure they continue to provide good value for money.***

Fostering Appropriate Drug Use

The ministry should:

- ***obtain appropriate and timely information from organizations receiving ministry funding that describes the activities carried out and the accomplishments achieved.***
- ***encourage and support the medical and pharmacy professions and the pharmaceutical industry to do more to determine the extent of, and reasons for, patients' non-compliance with drug therapies, so that it can ensure programs exist to address this issue.***
- ***implement the recommendations of the PharmaNet Benefits Analysis Workshop that call for the information now collected by the PharmaNet system to be used to evaluate the effects of health policies already implemented and to develop policies to promote appropriate drug use.***
- ***identify all sources of prescription drugs, other than community pharmacies, and determine whether to include the drug information from these sources in the patient profiles contained in the PharmaNet system.***

Ensuring Cost-Effective Drug Therapies

The ministry should:

- ***encourage independent reviews of the Reference Drug Program and report the results to key stakeholders.***
- ***consider expanding the Trial Prescription Program to help minimize drug waste.***

Paying the Right Price for Drugs Dispensed

The ministry should:

- ***conduct field audits of pharmacies to ensure that it pays the right amounts for drugs dispensed.***

Evaluating and Reporting Program Results

The ministry should:

- ***develop a framework of performance indicators that measures the results of its programs for managing the cost of drug therapies and fostering appropriate drug use.***
- ***periodically measure, evaluate and report to key stakeholders on the performance of its programs for managing the cost of drug therapies and fostering appropriate drug use.***

detailed report

about pharmacare

What Is Pharmacare?

The federal government has overall responsibility for the health of Canadians and meets this obligation by setting policy direction and sharing costs with the Provinces. An important aspect of health care in Canada is the use of prescription drugs to treat patients' illnesses. While it is the federal government's Health Protection Branch that makes decisions about which prescription drugs will be available for sale in Canada, it is the provinces that decide which drugs they will fund for their residents.

Pharmacare is British Columbia's drug insurance program, and it assists residents in paying for eligible prescription drugs and designated medical supplies. For hospital inpatients, drugs are an expense of the hospital system. However, once the patient is discharged, Pharmacare becomes the responsible agency. Because drug therapy is an essential part of many people's medical care, Pharmacare is an integral component of the health care system that serves all British Columbians.

In fiscal 1997/98, Pharmacare's expenditures are estimated to be $430.7 million (Exhibit 1). This compares with spending in 1996/97 of $424.8 million.

Exhibit 1

Pharmacare Expenditures ($ Millions)

Expenditure Categories	1997/98 Budgeted	1996/97 Actual
Salaries and benefits	5.0	4.5
Operating costs	7.0	7.0
Asset acquisitions	7.4	2.2
Plan benefits	411.3	411.1
Total Expenditures	**$430.7**	**$424.8**

Source: Province of British Columbia Supplement to the Estimates, Fiscal Year Ending March 31, 1998
Province of British Columbia Public Accounts, Volume 2, 1996-97

Pharmacare Benefits

British Columbia residents automatically qualify for Pharmacare coverage by registering with the Province's Medical Services Plan. Pharmacare assists with the purchase of a variety of prescription drugs and related benefit items in accordance with established administrative policies covering rules pertaining to eligibility of items, eligible quantities, and payment procedures for pharmacists.

Pharmacare provides benefits under several plans:

Plan A provides assistance to permanent residents of British Columbia who are 65 years of age or older and who possess a Gold Care Card issued by the Medical Services Plan. Seniors are responsible for payment of the dispensing fee only, up to a maximum of $200 per person per year.

Plan B provides full reimbursement of eligible benefits for permanent residents of licensed long-term care facilities and private hospitals.

Plan C covers residents, excluding seniors, who hold a valid Medical Services Plan card indicating they are eligible for Ministry of Human Resources or Refugee Status health care benefits. The plan pays for the full cost of drugs and dispensing fees.

Plan D provides benefits to all cystic fibrosis sufferers registered with one of four provincial cystic fibrosis clinics. Members receive digestive enzymes and nutritional supplements and some vitamin and vitamin/mineral preparations free of charge.

Plan E provides coverage for residents registered with the Medical Services Plan who are not in receipt of benefits from any other Pharmacare plan. The plan pays for 70% of annual drug and dispensing fees in excess of a deductible of $600, and 100% of costs in excess of $2,000. Residents receiving Medical Services Plan (MSP) Premium Assistance or Temporary Premium Assistance are not required to pay for drug costs exceeding the annual deductible amount.

Plan F provides benefits through the At Home Program and the Associate Family Program. The plan provides financial assistance for selected medically necessary support and services associated with caring for the severely handicapped at home. The Ministry of Health and Ministry Responsible for Seniors and the Ministry of Human Resources jointly fund this program.

Plan G provides benefits for individuals registered with Mental Health Centres. The plan pays for the full cost of certain psychiatric medications and dispensing fees.

Home Oxygen Program provides 100% reimbursement for home oxygen and related equipment.

Pharmacare's Role

Provincial drug benefit plans have existed in British Columbia in one form or another since 1872. Early versions of the system involved the physician, pharmacist and patient working together to determine the most appropriate drug therapy. Initially, benefits were for seniors and those with low incomes and covered only part of the cost of a drug. The government's role was essentially that of third-party payer.

Over the years, there have been many developments. New diseases have arisen, the number of drugs has increased, benefits have been extended to more groups of British Columbians, the population of the Province has grown, and the demographic make-up of the population has changed. All of these have contributed to a growth in both the size and cost of Pharmacare.

At the same time, another significant development has been the creation of information systems that now allow more and better analysis of drug-related issues from the entire provincial perspective. Program managers can use these systems to manage the cost of drug therapies and encourage appropriate drug use.

All these changes have resulted in Pharmacare expanding its role as an active agent in the delivery of effective and efficient health care. This greater role is reflected in its mission statement and strategic objectives.

Mission Statement

Pharmacare's mission is to improve the health status of British Columbians by ensuring reasonable access to, and appropriate use of, prescription drugs and related benefit services for eligible residents of the Province.

Strategic Objectives

To achieve its mission, Pharmacare has identified several strategic objectives covering the following topics:

- containing drug costs;
- managing a reimbursement system for required prescription drugs and related benefit services which prevents unreasonable access due to financial barriers;

- increasing awareness of the appropriate use of medication;
- promoting optimal drug therapies;
- monitoring the appropriateness and cost-effectiveness of drug therapies and prescribing patterns; and
- making effective and efficient use of human and financial resources to ensure program objectives are met.

PharmaNet System

The PharmaNet system—a computer network linking community pharmacies—is an important tool to help Pharmacare achieve its mission and strategic objectives. PharmaNet was implemented by Pharmacare in September 1995. The system helps to enhance British Columbians' health by providing individual drug profiles. It also eliminates the need for patients to save receipts and submit claims, and automates the pharmacy billing and payment process. PharmaNet provides a comprehensive information base for drug use reviews, program monitoring, fraud detection and cost control. The information is used by health professionals to make better informed decisions, as well as to identify drug duplication, non-compliance with drug regimens, and potentially dangerous drug interactions.

Key Legislation

Pharmacare began operation on January 1, 1974, under the Guaranteed Available Income for Need (GAIN) Act, Regulation 30. In April 1995, the legislative authority for Pharmacare was transferred to the Continuing Care Act.

In the 1995 legislative session, the Pharmacist's Act was repealed and replaced by amendments to the Pharmacists, Pharmacy Operations and Drug Scheduling Act. The revised Act requires that a record of all persons to whom prescriptions are dispensed in the Province be noted on PharmaNet. It also assigns regulatory authority to the College of Pharmacists of British Columbia.

Organization

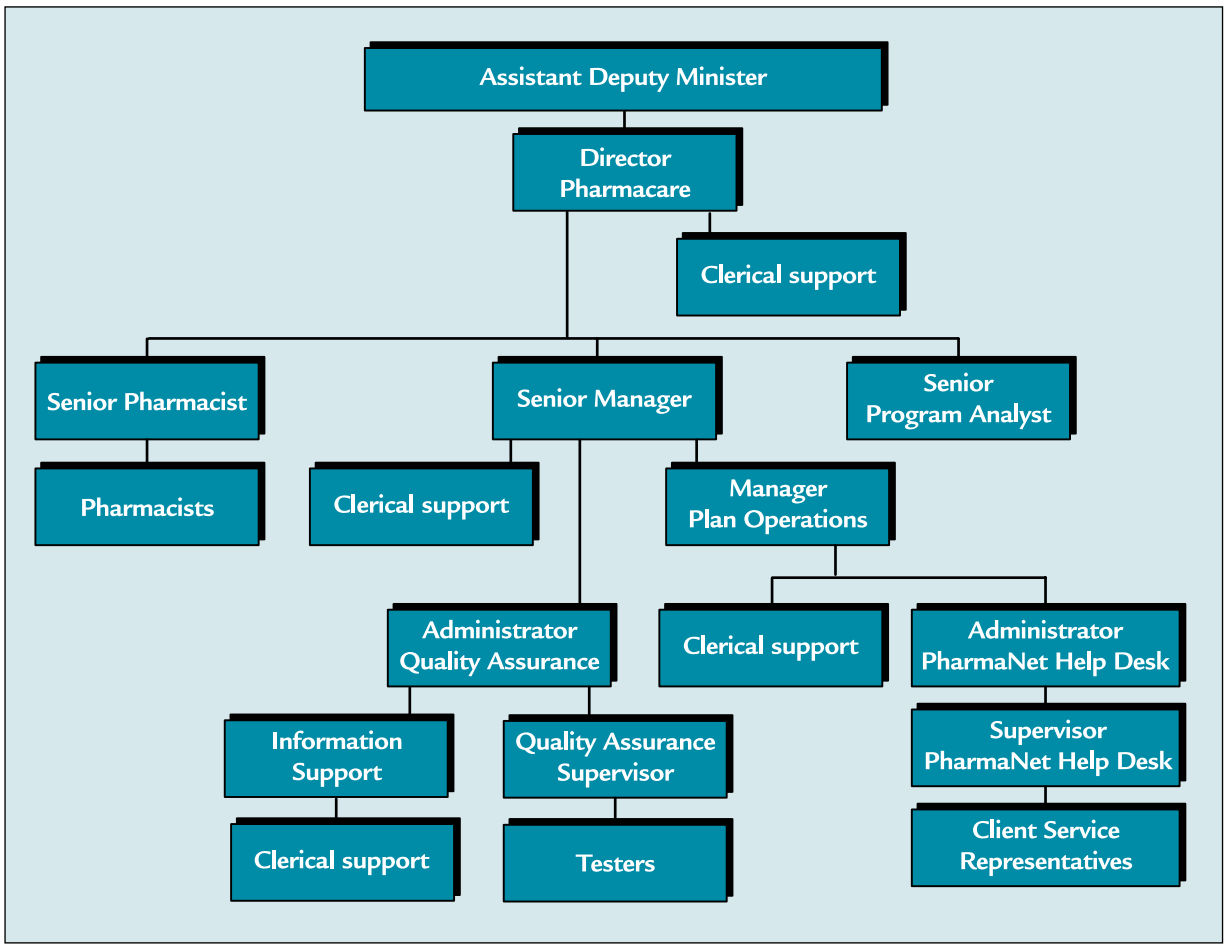
A partial organization chart of the Ministry of Health, depicting the Pharmacare program, is shown in Exhibit 2. Pharmacare staff and services are located in three offices, with two in Victoria and one in Vancouver. The Vancouver office is comprised of primarily professional staff (pharmacists, a medical consultant and clerical support) responsible for professional relations and policy. The Victoria office consists

of primarily operational staff responsible for operating the PharmaNet Help Desk (a telephone information line), adjudicating claims, paying pharmacists for drugs dispensed, monitoring finances and managing information. The executive office of Pharmacare located in Victoria includes an Assistant Deputy Minister, a Director, and clerical staff.

In addition to its own staff, Pharmacare uses a number of consultative/expert advisory committees made up of members of government, industry, medical professionals, consumer groups, and other interested stakeholders. These committees provide recommendations to Pharmacare on matters important to policy development and implementation.

Exhibit 2

Partial Organizational Structure of the Ministry of Health, Showing the Pharmacare Program



Source: Ministry of Health, Pharmacare Trends, 1997

Approving the Sale of Drugs

Before a drug can be sold in British Columbia, it must first be approved for sale in Canada by the federal government. The Health Protection Branch of Health and Welfare Canada is responsible for reviewing new drugs coming into the Canadian market. New products must be scientifically proven safe and effective when used as indicated for the treatment of specified conditions. The branch, therefore, reviews the clinical trials data submitted by manufacturers and, if it is satisfied with the results, grants Notices of Compliance, approving the sale of the drugs in Canada. This does not, however, automatically mean that the drugs become eligible as Pharmacare benefits. Only those that are subsequently approved by the ministry will be added to its list of approved benefits.

Our Expectations

We expected Pharmacare, as a prudent manager of the provincial drug plan, to take reasonable steps to manage the cost of drug therapies and to foster appropriate drug use. Specifically, we expected Pharmacare to have processes in place to:

- decide which drugs to cover;
- foster appropriate drug use;
- ensure cost-effective drug therapies;
- ensure the right price is paid for drugs dispensed; and
- evaluate and report on program results.

These expectations are based on the ministry's mission statement and strategic objectives for its Pharmacare program and on generally accepted management practices. In the following sections of the report, we present our audit findings and conclusions on the extent to which the ministry meets these criteria.

deciding which drugs to cover

Many drugs are available in Canada to treat a variety of illnesses. In some instances, several drugs are available at different costs and different levels of convenience to treat the same conditions. To help ensure that it is getting good value for money, the ministry must choose the right drugs to provide as benefits under Pharmacare. We expected the ministry to have a sound process for deciding which new drugs to make eligible as benefits under Pharmacare and which existing drugs, if any, should have their coverage changed.

Conclusion

Pharmacare ensures that benefits are provided only for new drugs that demonstrate good value for money by reviewing all new drugs for their therapeutic advantage and cost-effectiveness over existing drugs used to treat the same conditions. As well, the ministry has reviewed several existing drugs and changed the level of Pharmacare benefits because the drugs were found to no longer provide good value for money. The ministry has begun to formalize this process but it needs to be finalized to ensure that existing drugs are reviewed in a timely manner.

Findings

Spending on Prescription Drugs

Pharmaceuticals are one of the biggest components of health care expenditure in Canada. It is estimated that Canadians now spend nearly as much on drugs as they do on physicians' services. The growth in spending between 1975 and 1994 was about 12% annually, although in more recent years the rate has slowed to about 4% annually.

According to the federal government's Patented Medicines Prices Review Board, more than 21,000 pharmaceutical products are authorized for sale in Canada, including those that can be sold without a prescription. Ministry of Health records indicate that about 10,800 of these drugs require a prescription, of which Pharmacare provides benefits for about 6,500.

Spending patterns for drugs in British Columbia have been similar to that in Canada overall. During the 1980s and into the early 1990's spending by the ministry on prescription drugs rose rapidly. During the five fiscal years between April 1, 1989, and March 31, 1994, spending doubled, growing

at annual rates ranging from 10% to 21% (Exhibit 3). This growth was much faster than that experienced by other health care costs and was about four times faster than the rate of inflation during the same period.

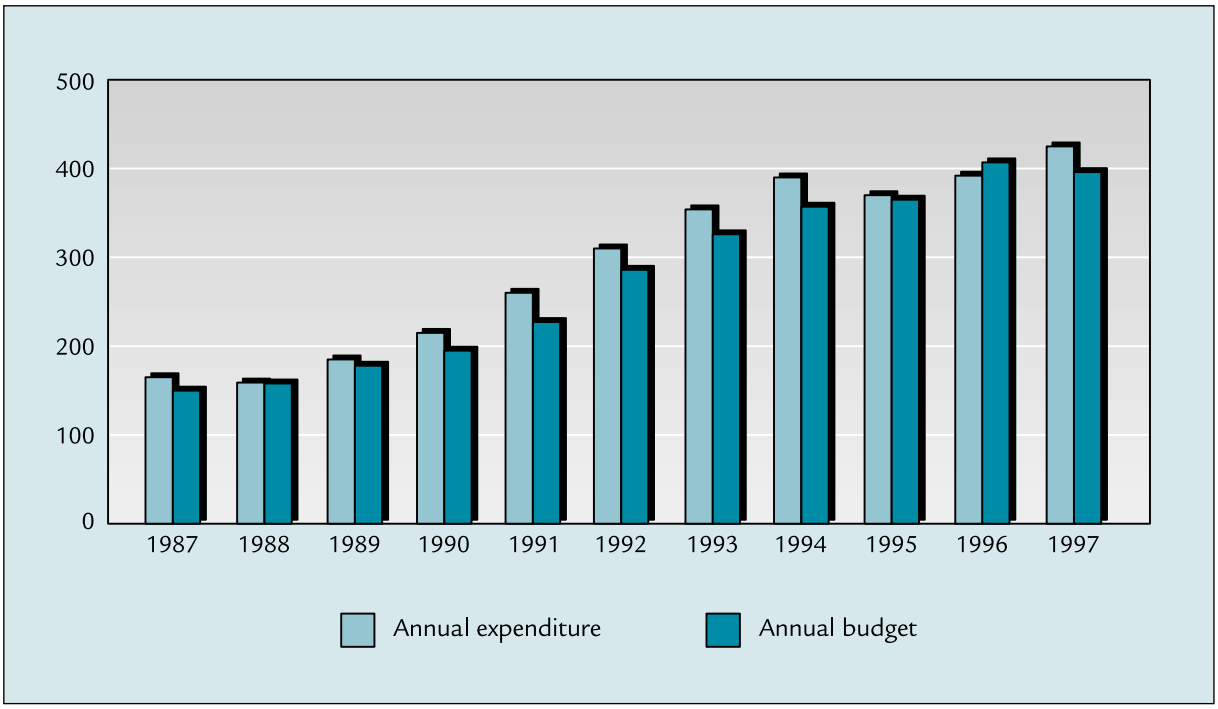
A significant contributor to the rapid growth in spending on drugs has been a general increase in the cost of new products (those entering the market in the current year). The average drug cost per prescription of all drugs has risen steadily over the years except in 1995 and 1996 (Exhibit 4). Over the 10–year period, 1986–1996, the average drug cost per prescription for new drugs has always been higher than that for all drugs and, in many years, significantly higher.

Besides being more expensive than existing drugs, many new drugs are not therapeutically superior to existing medications. According to data produced by the Patented Medicines Prices Review Board, of 566 new drugs introduced in Canada during the period 1988 to 1995:

- 41 (7%) were breakthroughs, meaning the first products to treat particular illnesses effectively or to provide substantial improvement over existing drug products;

Exhibit 3

Pharmacare Spending, 1987–1997 ($ Millions)

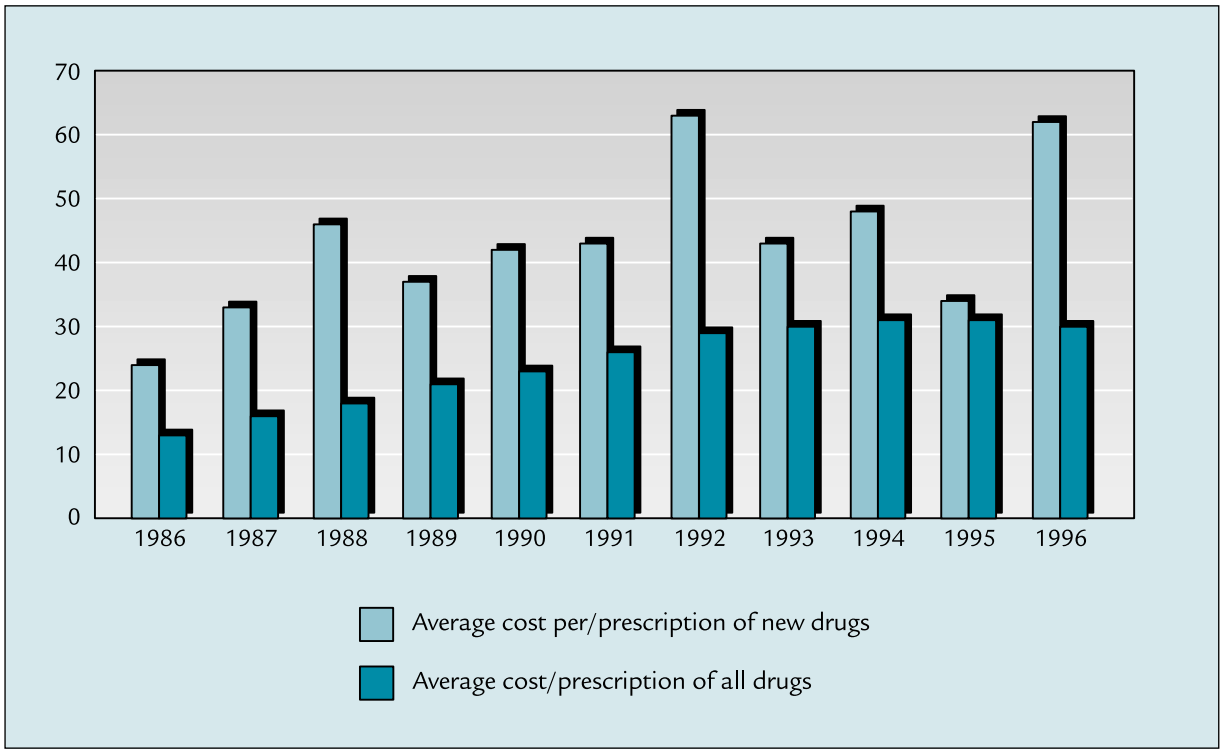


Source: Ministry of Health, Pharmacare Trends, 1997

- 277 (49%) offered moderate, little or no improvement over existing drugs; and
- 248 (44%) were line extensions, usually known drugs in a new strength (Exhibit 5).

Exhibit 4

Average Drug Costs Per Prescription, 1986–1996 ($)



Source: Ministry of Health, Pharmacare Trends, 1997

Exhibit 5

New Drug Categorization in Canada, 1988–1995

Category	1988	1989	1990	1991	1992	1993	1994	1995	Total
Breakthrough	1	4	3	5	15	8	3	2	**41**
Moderate/no improvement	19	29	30	38	50	34	32	45	**277**
Line extension	15	35	26	51	23	35	29	34	**248**
Totals	**35**	**68**	**59**	**94**	**88**	**77**	**64**	**81**	**566**

Source: Patented Medicines Prices Review Board Annual Reports

Deciding Which New Drugs to Cover

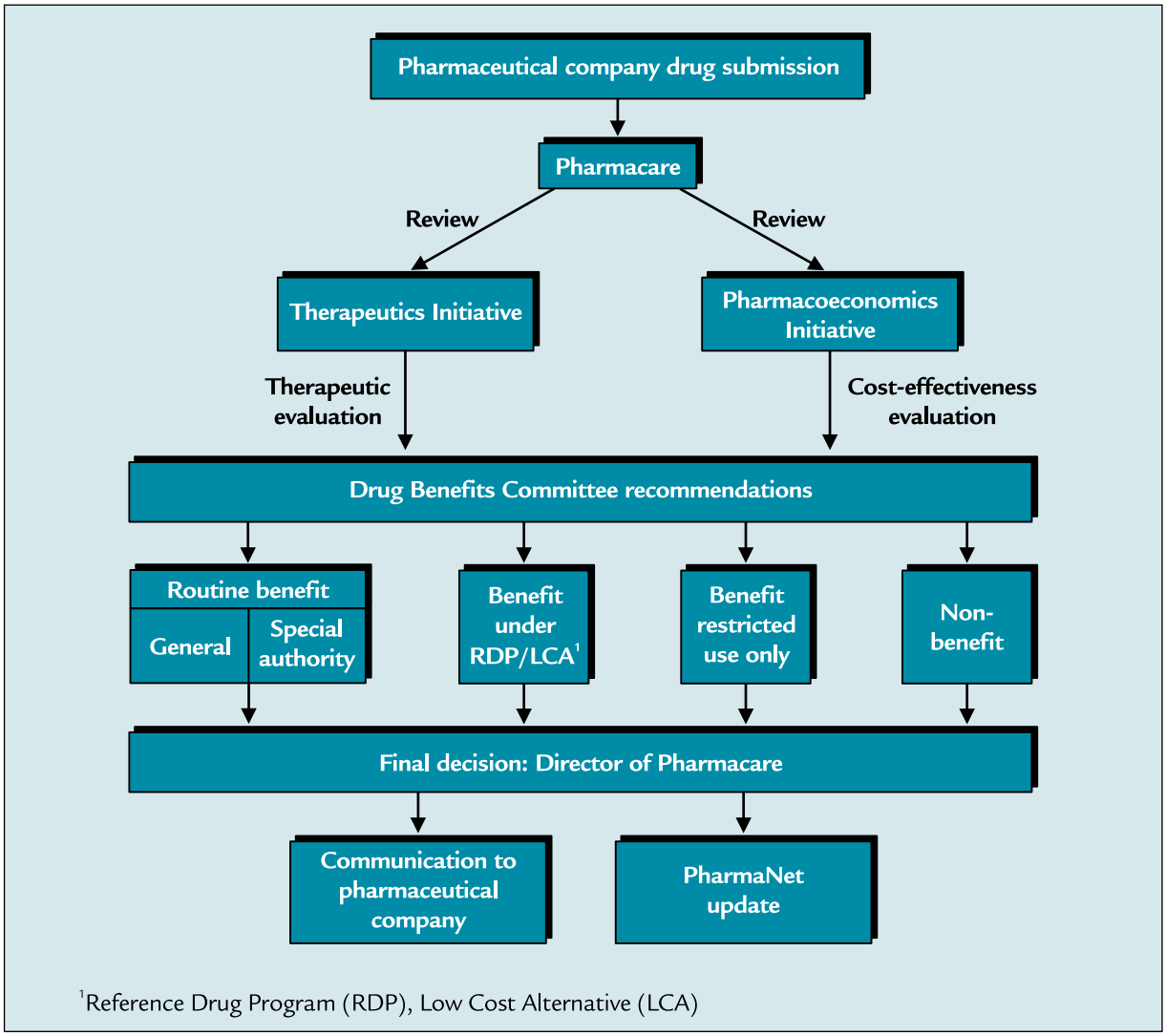
To ensure that benefits are provided only for new drugs that demonstrate good value for money, the ministry has established a drug review process (Exhibit 6).

How the Process Works

All new drugs introduced in British Columbia are now subject to Pharmacare's drug review process. This requires that pharmaceutical companies submit product information to Pharmacare to assess the eligibility for benefits, if any, under the program. The information is reviewed by a pharmacy

Exhibit 6

Drug Review Process



[1]Reference Drug Program (RDP), Low Cost Alternative (LCA)

Source: Ministry of Health

consultant at Pharmacare, who forwards the submission to the Therapeutics Initiative and the Pharmacoeconomics Initiative for evaluation.

The Therapeutics Initiative reviews the new drug to assess its therapeutic benefit based on the evaluation of the best scientific evidence available. The Pharmacoeconomics Initiative reviews the new drug to assess its cost-effectiveness and pharmacoeconomic advantage (e.g. will the new drug reduce a patient's days lost at work, reduce the need for hospitalization or other drugs, and/or improve the patient's quality of life).

Both initiatives provide information to the Drug Benefits Committee of Pharmacare. This committee makes recommendations to the Director of Pharmacare who makes a final decision on whether a new drug should receive full, partial or no benefits under the program. If a drug is determined to be an eligible benefit, coverage is effective from the date of approval, and is subject to the usual Pharmacare eligibility and deductible criteria. Retroactive coverage is not provided for any prescriptions purchased prior to approval of the new drug as a Pharmacare benefit. The ministry's final decision is conveyed to the drug manufacturer, accompanied by the rationale for the decision.

During the year ended March 31, 1997, the Drug Benefits Committee made recommendations on 32 drugs: 17 were recommended for full or restricted benefits, the remaining 15 were recommended as non-benefits.

Assessing the Drug Review Process

To form our opinion about the drug review process, we considered a number of criteria.

Independence

The Therapeutics Initiative and Pharmacoeconomics Initiative operate at arms length from government, the pharmaceutical industry and other vested interest groups and provide the ministry with objective evaluations and recommendations to help it make decisions about which new drugs to provide as benefits. Although both organizations receive ministry funding, we believe that the professional qualifications of the two initiatives' participants, together with the use of external peer reviews, help ensure the objectivity of the decisions made.

Courtesy: Ministry of Health and Ministry Responsible for Seniors

The drug review process helps the ministry decide which drugs to cover under Pharmacare

Evidence-based Decisions

The Therapeutics Initiative bases its advice only on peer-reviewed published clinical trials—unpublished research is not considered. This helps to ensure that the decisions made are based on valid evidence.

The Pharmacoeconomics Initiative bases its advice on the assessment criteria developed by the Canadian Coordinating Office of Health Technology Assessment, located in Ottawa and/or the Ontario Ministry of Health Guidelines for the Economic Evaluation of Pharmaceuticals. This helps to ensure that evaluations are based on generally accepted criteria.

Stakeholder Input

We believe that key stakeholder groups are adequately represented on the two initiatives and that this helps ensure that important views are heard before decisions are made. The Therapeutics Initiative has an advisory committee with members from several key stakeholder groups, including:

- University of British Columbia Faculty of Medicine, Pharmacology and Therapeutics;
- University of British Columbia Faculty of Pharmaceutical Sciences;
- B.C. College of Physicians and Surgeons;
- B.C. College of Pharmacists;

- College of Family Physicians of Canada;
- British Columbia Medical Association;
- British Columbia Pharmacy Association;
- Registered Nurses Association of British Columbia;
- several seniors' and women's health organizations; and
- Ministry of Health.

The Pharmacoeconomics Initiative conducts its work through a Scientific Committee, with members having technical and practical expertise in the associated fields of economics, clinical epidemiology, pharmacoepidemiology, and clinical decision-making. The Scientific Committee functions with up to 15 members, each with two–year renewable terms.

There is no industry representation on either initiative. Both have considered industry representation before, but believe that it would pose confidentiality and credibility problems (e.g. the company represented could have access to confidential drug information of a competitor). As well, they also believe that it would present too much of an opportunity for one drug company to lobby members of the two initiatives. Other provinces with similar organizations have also adopted a policy of no industry representation.

Communication

The extent of communication between industry and the reviewers of drug submissions in British Columbia is consistent with the approach used in other provinces. According to a research paper prepared for the Joint Liaison Committee Between the Pharmaceutical Industry and the Ontario Government, communication with manufacturers about their drug submissions is relatively limited in most provinces. This helps to ensure that objective decisions are made and prevents one company's information being mistakenly released to a competitor.

Reviews of Existing Drugs

While the Therapeutics Initiative and Pharmacoeconomics Initiative review new drugs for therapeutic advantage and cost-effectiveness, they have only been in existence for a few years. During the fiscal year ending March 31, 1997, their work extended to only a small number of new drugs, leaving many existing drugs that have never been subject to such reviews. As a result, previous decisions by the ministry to approve drugs need to be reviewed periodically to determine if better or more cost-effective alternatives now exist.

We found that the benefit levels of several drugs have been changed (e.g. from full benefit to non-benefit or restricted benefit) as a result of the ministry's occasional ad hoc reviews of certain specific existing drugs.

The ministry may be alerted in a variety of ways of the need to review the coverage it provides for an existing drug. For example, the ministry periodically analyzes drug use information in terms of the number of prescriptions filled and their annual cost to Pharmacare (Exhibit 7). This can help to identify unusual trends requiring further investigation.

Pharmacare staff also gain insights into various drugs as a result of their daily work, involvement with ministry expert committees, and discussions with members of other provincial drug plans. These sources of information can identify drugs that staff believe should be reviewed for possible delisting, or to suggest changes to the level of benefits.

A final way in which existing drugs come under review is as a byproduct of the work of the Therapeutics Initiative and the Pharmacoeconomics Initiative. When reviewing new drug submissions, these two organizations will generally look at the existing drugs being used to treat the conditions for which the

Exhibit 7

Cost to Pharmacare of the Top Ten Drugs, 1996

These drugs accounted for 27% of total costs for plans, A, B, C, & F

Drugs	Prescribed For	Number of Prescriptions	Cost ($ Millions)
Enalapril Maleate	Hypertension	177,532	13.8
Diltiazem	Hypertension and angina	101,907	13.2
Omeprazole	Ulcers	75,446	10.4
Lovastatin	Cholesterol	43,453	7.5
Nifedipine	Angina	85,449	6.9
Beclomethasone	Asthma	119,083	6.3
Simvastatin	Cholesterol	30,722	5.2
Amlodipine	Hypertension and angina	43,058	4.8
Ipratropium	Asthma	92,083	4.9
Nitroglycerine	Heart disease	114,138	4.8
Total		**882,871**	**77.8**

Source: Ministry of Health

new drug is intended. This process can result in identifying drugs that should be reviewed for possible delisting, or a change to the level of benefits provided by Pharmacare.

Once drugs are identified for review, the ministry looks to see whether:

- there are equally effective, lower cost alternative treatments available;
- there are products that have recently been made available on a non-prescription basis;
- delisting will provide consistency amongst the different plans provided by Pharmacare; and/or
- delisting will bring Pharmacare more in line with drug programs offered in other provinces.

The ministry's efforts have identified some significant opportunities for cost savings. As a result of its reviews of existing drugs the ministry implemented benefit restrictions for several drugs. And, based on a lack of demonstrated therapeutic advantage and the existence of alternatives, several drugs were also de-listed.

In November 1997, the ministry decided to formalize its approach to reviews of existing drugs and a committee was formed to develop:

- a strategy of identifying drugs for possible delisting or benefit restrictions;
- a strategy for the review;
- a consultation strategy; and
- timeline proposals.

Two meetings were held prior to December 31, 1997 with the first two objectives having been met. Work continues on the remaining two objectives.

Recommendation

The ministry should review currently listed drugs periodically to ensure they continue to provide good value for money.

fostering appropriate drug use

Having decided which drugs to provide as benefits under Pharmacare, the ministry then needs to encourage and support initiatives that ensure those drugs are used appropriately. Appropriate drug use means the right drugs are administered in the right amounts for the right duration and the right symptoms. We expected the ministry to ensure that this occurs by:

- supporting programs that inform physicians and pharmacists on best prescribing practices;
- encouraging the College of Physicians and Surgeons to monitor actual prescribing practices and to make corrections where appropriate;
- supporting programs that inform patients about the importance of following their physicians' and pharmacists' drug therapy directions; and
- controlling high-cost drugs meant for limited uses.

Conclusion

The ministry fosters appropriate drug use by funding agencies to provide programs that inform physicians, pharmacists and patients on ways to improve drug use. It also provides funding for the "prescription reviews" conducted by the College of Physicians and Surgeons of British Columbia, and it controls the use of high-cost/limited-use drugs. However, the ministry needs to collect information from all funded agencies on their activities and accomplishments to be able to identify where it should focus its efforts to produce the best results. The PharmaNet system also assists physicians and pharmacists by preventing and detecting drug interactions, and drug fraud and abuse. The ministry has just begun to tap into the wealth of information collected on the system and should do more to encourage its use to identify initiatives that foster appropriate drug use.

Findings

Factors Influencing Appropriate Drug Use

To foster appropriate drug use, the ministry must address several factors. First, with the vast array of drugs now available, prescribers need to be fully informed about drugs available and their most appropriate use. Also, some critics say there is too much emphasis on drugs being available for every ailment. They question whether there are alternatives to the

use of drugs, and believe that the ministry should address the issue by advocating lifestyle changes such as improved diet, more exercise, and reduced caffeine intake.

Patient non-compliance with their physician's and pharmacist's directions is another factor that needs to be addressed. Studies indicate that significant non-compliance with prescribed drug therapies may increase other health costs substantially and reduce the quality of health. The ministry needs to play a role by encouraging and supporting the medical and pharmacy professions' efforts to ensure that patients are informed of the importance of both filling a prescription and subsequently taking it according to the instructions.

It is not uncommon for patients to be taking more than one prescription at a time. This can result in unintended drug interactions. In some situations, patients may be abusing drugs or obtaining drugs for sale on the street. The ministry needs to continue to encourage and support initiatives aimed at preventing and detecting these forms of inappropriate drug use.

Informing Physicians and Pharmacists

With so many prescription drugs currently available in British Columbia and more being added and deleted on a regular basis, physicians and pharmacists can sometimes find it difficult to stay fully informed about all drugs and their most appropriate use. The pharmaceutical industry provides one-on-one discussions with physicians and pharmacists, which naturally focus on the benefits of the drugs offered by the respective companies (an activity known as "drug detailing").

A University of British Columbia research paper states that the drug industry spends between 15 and 20% of its $6 billion in sales in Canada—that is, over $900 million—on marketing activities, which include visits to physicians and pharmacists. Excessive reliance on brand-name firms for information, however, may clearly result in some bias. This makes it important for the ministry to take an expanded role in ensuring that objective information is provided to physicians and pharmacists on best prescribing practices.

The ministry is involved with a variety of initiatives designed to keep physicians and pharmacists up-to-date on appropriate drug use. This is consistent with findings that show multiple sources of information are most effective at bringing about improvements. For example, it funds independent agencies to provide regular research letters

on drug therapies, continuing education, conferences focused on specific drug-related topics, one-to-one meetings between pharmacists and physicians, and reviews of prescribing practices. However, the ministry needs to ensure it regularly receives information from the funded agencies outlining their activities and accomplishments.

These initiatives are described below:

Therapeutics Initiative

The ministry has contracted with the Therapeutics Initiative, at an annual cost of $525,000, to provide physicians and pharmacists with the best evidence-based drug information available.

We believe that the Therapeutics Initiative provides information to physicians and pharmacists that fosters appropriate drug use. A primary method it uses is to send out "Therapeutics Letters" to practitioners. Between October 1994 and August 1997, the initiative produced 20 letters covering a range of topics. A therapeutics letter contains a practical message based on systematic reviews of published randomized controlled drug trials, to assist physicians and pharmacists in providing optimal care for their patients. The draft letter first undergoes a review by specialists who are expert in the particular therapeutic area addressed in the letter. Once completed, the letter is distributed to over 4,000 physicians and 3,500 pharmacists in the Province.

Other printed information provided to physicians and pharmacists in 1997 included:

- the Ontario Anti-infective Guidelines for Community-acquired Infections, an educational tool to help physicians make informed clinical decisions when prescribing antibiotics; and
- a booklet, organized by illness and followed by first-and second-line therapies and their respective costs, distributed to a sample of physicians.

The Therapeutics Initiative also achieves its goals by providing continuing education through presentations in the community. During the year ended March 31, 1997, it conducted 15 community-based presentations for clinicians and 11 such sessions for the public. Other activities include writing medical journal and newspaper articles, providing a therapeutics telephone information service, and offering an annual drug therapies course.

Courtesy: Ministry of Health and Ministry Responsible for Seniors

The ministry supports initiatives to keep physicians and pharmacists up-to-date on appropriate drug use

Physicians and pharmacists generally accept the Therapeutics Initiative's work as being unbiased. The initiative surveyed physicians and pharmacists in 1996 and found a high degree of reader awareness and acceptance of its work. The physicians and pharmacists we interviewed expressed similar views.

Nevertheless, we think that more needs to be done to encourage physicians to apply the principles disseminated by the Therapeutics Initiative. Two of the therapeutics letters issued in the summer and fall of 1995 were evaluated by the Initiative using 500 physicians from 30 communities. Half were sent the letters three to five months later than the other group. The half receiving the letters later were used as the control group to measure the impact the letters had on the prescribing practices of those 250 physicians who had received the letters earlier. The surveyors wanted to see whether physicians altered their prescribing practices consistent with the information provided in the letters covering the following drugs: diuretics, beta-blockers, calcium channel blockers, and ACE inhibitors.

The result indicated only a small impact on the prescribing practices of physicians who received the letters earlier. Similar levels of impact were found as a result of the Initiative's evaluation of its teleconferences, courses, and one-on-one education. It concluded that multiple sources of information are required if prescribing practices are to be significantly affected. In light of this finding, we believe that the ministry

should encourage the Therapeutics Initiative to use educational methods that supply physicians and pharmacists with multiple sources of information about the best prescribing practices.

Prescription Review Program

This program was initiated in 1979 and was known as the Drug Utilization Review. British Columbia is one of only two provinces to support this type of monitoring, although others are considering it. The purpose of the program is to identify and change inappropriate drug prescribing patterns. The British Columbia College of Physicians and Surgeons is responsible for administering the program, which is funded by the ministry and uses the PharmaNet database.

The College of Physicians and Surgeons reviews patterns of prescribing. The ministry's expectation is that by identifying inappropriate prescribing practices, the College will intervene and encourage change. In this way, it is hoped that patients will benefit from better care and savings will be realized.

The ministry had not received information summarizing the activities carried out to date under the Prescription Review Program. As a result, we were unable to form an assessment of the program.

Sponsorship of Conferences

Within the last two years, the ministry has provided funding to several medical groups for organizing conferences aimed at improving care to patient groups such as the elderly, individuals with asthma and allergies, and chronic pain sufferers. The Conference for Geriatricians, funded solely by the ministry, focused on primary care of the frail elderly, including diagnosing illnesses and prescribing drug therapies. The Physicians and Surgeons Pain Management Workshop, held for physicians prescribing high volumes of pain medication, focused on better ways of treating patients with chronic pain syndrome and on intervention techniques to prevent the syndrome from developing. And Pharmacare provided financial support for the Asthma and Allergy Teaching Unit Conference held May 30, 1996.

In addition to providing specialized training to physicians, these conferences provide opportunities for Pharmacare to familiarize the participants with ministry programs that encourage appropriate drug use such as the Reference Drug Program and the PharmaNet system.

North Shore Community Drug Utilization Review Program

In this ministry-funded program, pharmacists use both newsletters and one-to-one meetings to assist physicians in North Vancouver select the most appropriate and cost-effective drug therapies for their patients. The objectives of the program are to provide unbiased drug information to physicians and to encourage, where appropriate, the use of therapeutically equivalent and less expensive medications to reduce drug expenditures. The program, managed and operated by the Lions Gate Hospital in North Vancouver, was initiated in August 1993 and continues to be run as a pilot. It was recently expanded to include a program at the Nanaimo Regional Hospital.

We received anecdotal evidence that this program was effective in changing the prescribing practices of the physicians involved. There is also research supporting the concept. An extensive study carried out in 1989 across Canada identified one-on-one education as being one of the most effective ways of changing physicians' prescribing patterns. It also stated that these programs have been shown to save more dollars than they cost, and to improve quality of care. Another research paper, prepared at the University of British Columbia in 1996, suggested that a combination of newsletters, conferences and seminars, and physician report cards, used together with individual visits from specially trained pharmacists or physicians, provides the most cost-effective way of improving prescribing patterns.

The ministry had not received information summarizing the activities carried out through the North Shore program. As a result, we were unable to form an assessment of the program.

Recommendation

The ministry should obtain appropriate and timely information from organizations receiving ministry funding that describes the activities carried out and the accomplishments achieved.

Informing Patients

A federal-provincial task force dealing with pharmaceutical issues recently reported that the inappropriate use of medications is a key factor in the drug use problem. A patient may be prescribed the right drug, but if it is not taken the right way—or not taken at all—the patient's health may suffer and additional costs to the health care system may result.

Research by the University of Toronto estimates that as many as 50% of patients do not comply with prescribed drug regimens, a situation that results in substantial cost increases and a reduction in the quality of health care. The most frequent form of non-compliance is not filling a prescription (33%), the remaining types of non-compliance (67%) involve not taking the drugs as directed (altering the timing and dosage, ceasing therapies prematurely, or combining prescription drugs with non-prescription drugs or alcohol when contraindicated).

It is important for several reasons that the ministry obtain information on the degree of non-compliance of British Columbians. If British Columbia has a high percentage of patients not filling prescriptions, it could be an indication that a strategic objective of Pharmacare—preventing unreasonable access to prescription drugs due to financial barriers—is not being met. For example, many patients not filling prescriptions may be low-income residents who do not receive benefits until they meet the deductible limit of $600.

Non-compliance can also be a significant contributor to the cost of British Columbia's overall health care system. A Canadian-based study in 1993 estimated that drug non-compliance costs the system annually up to $2.74 billion in additional drug costs. Another study prepared at the University of Toronto for the Pharmaceutical Manufacturers Association of Canada estimated that the cost of non-compliance nationwide is $7–9 billion annually. This amount includes the direct cost of drugs as well as indirect costs, such as additional doctor visits, hospitalization, and other costs. We did not find any estimate by the ministry of the extent and reasons for non-compliance in British Columbia. However, given the magnitude of the estimate in the above study, the extent of non-compliance would clearly be a significant cost for health care in our Province.

We found that the ministry has done limited work in this area. Identifying the extent of non-compliance, the reasons for it and the solutions to reduce it are not easy tasks and to our knowledge no other jurisdictions have made significant progress in this area.

The ministry recognizes that information on non-compliance would help ensure drug programs address this issue. However, taking steps in this direction cannot be accomplished by the ministry alone. A joint effort with the medical and pharmacy professions, the pharmaceutical industry and the patients is needed.

Recommendation

The ministry should encourage and support the medical and pharmacy professions and the pharmaceutical industry to do more to determine the extent of, and reasons for, patients' non-compliance with drug therapies, so that it can ensure programs exist to address this issue.

Non-compliance is not totally the fault of the patient, but patient health education may improve the rate of compliance. For these reasons, there is a growing expectation for the ministry to have an increased role in providing information to patients about appropriate drug use. It is doing this through the initiatives described below:

B.C. Seniors Medication Information Line

To provide information to the Province's seniors, the Science Council of British Columbia operates the Seniors Medication Information Line (B.C. SMILE), a toll-free telephone line. This program is operated from the Faculty of Pharmaceutical Sciences at the University of British Columbia, and is funded primarily by the pharmaceutical industry with financial support from Pharmacare.

A pharmacist answers all calls, providing information on prescription and non-prescription medications and answering questions about adverse drug reactions, interactions, and misuses of medications. This service supplements information provided by the patient's own pharmacist and physician.

We did not find any indication that Pharmacare was using information from the program (e.g. what issues concern callers) to help focus ministry efforts at informing patients about the medications they are taking. To avoid a missed opportunity, we encourage the ministry to review the questions and concerns raised by callers to the Seniors Medication Information Line to help focus ministry efforts at informing patient groups across the Province.

Therapeutics Initiative

Recently, the ministry has contracted with the Therapeutics Initiative to provide training to patients. In a recent presentation at a seniors' centre, seniors were informed about heart medications so they could better interpret the claims made by drug manufacturers. A small survey of patients who attended the session indicated that the information provided had improved their use of drugs. Other stakeholders we interviewed, however, questioned whether instructing patients—the traditional domain of physicians and pharmacists—is an appropriate role for the

Therapeutics Initiative. They suggested that its role should remain that of scientific advisor, assessing the therapeutic advantage of drugs.

In our opinion, Pharmacare, together with physicians and pharmacists, needs to review this method of informing patients so that efforts are coordinated to provide maximum benefit.

Focusing on Specific Medical Conditions

In some instances, the ministry believes that focusing information at a specific group is the best way to improve drug use by patients. For example, in the case of asthma drugs, several studies have shown that a significant number of individuals do not use these medications properly, and therefore waste much of the benefit—even to the point, in some cases, of requiring emergency room and hospital visits. As a result, the ministry is planning a specific information campaign directed at asthma patients. We encourage the ministry to increase such efforts, but suggest that it be done in a coordinated manner with physicians and pharmacists.

The PharmaNet System

PharmaNet, the computer network implemented in 1995, connects the ministry and all community pharmacies in the Province. It is accessed each time a pharmacist processes a prescription. The College of Pharmacists oversees the management of the highly confidential drug and patient information contained in the PharmaNet system. Although Pharmacare has unlimited access only to the PharmaNet information for those drugs that it pays for, requests can be made for broader access to certain types of information.

In our opinion, this system fosters appropriate drug use by identifying drug interactions and possible cases of drug fraud and abuse for review by pharmacists. However, we think that more can be done to improve the system and increase its usefulness.

From the pharmacist's perspective, PharmaNet aids in reducing the inappropriate use of prescription medication by providing a comprehensive drug profile of an individual. If a patient is taking more than one prescription drug, the system shows this and the pharmacist can determine if an undesirable drug interaction could result when a new drug is added to the existing regimen. This feature addresses a concern identified by the 1991 Royal Commission on Health Care Costs, which recognized inappropriate drug use as one of the five most important quality-of-care issues for the elderly.

Courtesy: Ministry of Health and Ministry Responsible for Seniors

PharmaNet helps identify drug interactions for review by pharmacists

In countering drug fraud and abuse, PharmaNet also helps detect identical or similar prescriptions obtained from different doctors or a prescription that has been copied and submitted to more than one pharmacy. Individuals who are abusing the system are placed in the Restricted Client Program and are restricted to the use of one doctor and one pharmacy.

According to ministry monitoring since the inception of PharmaNet until March 31, 1997, the automated drug-checking features have flagged the following for pharmacists' attention:

- 347,668 potentially serious drug interaction or dosage warnings for prescription combinations that could have had severe implications for the patient;
- 2,676,090 other significant warnings to alert pharmacists of drug usage situations which could have been dangerous to the patient; and
- 525,486 possibly significant warnings to alert pharmacists to use conservative measures until more information is known.

In the six-month period ending March 31, 1997, the following pharmacist interventions occurred:

- 3,162 consulted the prescriber and changed the dose; and
- 1,851 consulted the prescriber and changed the instructions for use.

The system also identified:

- 1,024 prior adverse reactions;
- 794 therapeutic duplications;
- 583 significant drug interactions;
- 414 sub-therapeutic doses;
- 286 dangerously high doses; and
- 216 previous treatment failures.

While many of these occurrences may have been detected by pharmacists even without the use of PharmaNet, it is generally acknowledged that the system is playing an important role in detecting potential problems. The information captured in the PharmaNet system has also been crucial in the conduct of prescription and other reviews that identify unusual prescribing and dispensing patterns.

The ministry recognizes the benefits of expanding the PharmaNet system into hospital emergency rooms and physicians' offices as it would provide better access to a patient's drug profile, which can thus aid in diagnoses and prescribing decisions. It has already started a pilot project in one of the hospital emergency departments and five more sites were expected to be added in the spring of 1998. The College of Physicians and Surgeons has selected 14 sites in total.

We agree with the expansion of the PharmaNet system into hospital emergency room departments and we encourage the ministry to carry out the planned pilots. We also encourage the ministry to further develop plans to expand the PharmaNet system into physicians offices, allowing direct access to patient drug profiles.

Despite these current applications however, we think the system is very underused as a resource for improving drug use. At the PharmaNet Benefits Analysis Workshop held by the ministry in April 1997, many participants expressed a similar view. They suggested, for example, that the ministry develop a standard set of reports and produce them on a periodic basis. They also came up with a number of ways the information could be used to promote good drug use such as, analyzing patient consumption of specified drugs to identify trends which could aid in policy development and targeting patient groups for educational materials.

Recommendation

The ministry should implement the recommendations of the PharmaNet Benefits Analysis Workshop that call for the information now collected by the PharmaNet system to be used to evaluate the effects of health policies already implemented and to develop policies to promote appropriate drug use.

We also think that the PharmaNet system should include prescription drugs from sources outside of the community pharmacy. In cancer clinics, medical day care in hospitals, and HIV/AIDS clinics, drugs may be administered to patients without being entered in the PharmaNet system. The same is true when patients undergo kidney dialysis or receive drug samples from their physicians. The reason is that these drugs are not dispensed through a community pharmacy.

In our opinion, excluding these drugs from the patient profile reduces the effectiveness of the PharmaNet system in detecting potentially dangerous drug interactions and/or interactions of drugs which, when combined, result in ineffective drug therapy. We believe Pharmacare should identify all sources of drugs taken by patients—not just those dispensed at community pharmacies—and determine whether there are practical solutions for including them in the PharmaNet system.

Recommendation

The ministry should identify all sources of prescription drugs, other than community pharmacies, and determine whether to include the drug information from these sources in the patient profiles contained in the PharmaNet system.

Controlling the Use of High-Cost/Limited-Use Drugs

Appropriate drug therapies ensure that the right drug is used to treat the right symptoms. Some drugs present a special risk to the ministry because they are unusually costly and are often meant for only specific conditions.

In our opinion, the ministry ensures that high-cost/limited-use drugs are used appropriately. This includes using the PharmaNet system to restrict some drugs from being generally available as benefits, and providing reimbursement for some drugs only when they are prescribed by a specialist. The ministry also employs agencies that have special expertise in treating patients with specific illnesses that require high-cost/limited-use drugs.

Restricting Benefits

One approach used by Pharmacare to control the use of high-cost/limited-use drugs is to restrict them as benefits. We believe this helps to ensure that such drugs are used appropriately.

When approving drugs as benefits under its programs, Pharmacare makes a decision about whether a drug will be available generally or only for specific conditions—that is, a "restricted benefit." Physicians wishing to prescribe the drug to a patient must first obtain special authority from Pharmacare. This involves having ministry pharmacists review the special authority request to ensure that the drug will be used to treat the right medical condition, the treatments attempted to date, and other contributing factors. As well, a ministry physician is available to review appeals and difficult requests. If special authority is granted, the PharmaNet system is updated to indicate the approval and level of coverage the patient is entitled to from Pharmacare.

Using Expert Agencies

Pharmacare also controls the use of several high-cost/limited-use drugs by having other agencies administer programs on the ministry's behalf. We believe that this helps to control the use of those drugs because these agencies have specialized knowledge of certain illnesses and can therefore make the decisions as to which patients are suitable candidates to use the drugs, and can ensure that the drugs are used appropriately.

AIDS Medications

Pharmacare works with the Centre for Excellence in HIV/AIDS at St. Paul's Hospital to deliver medications for the illness. In 1996, the centre was granted Pharmacare funding for several new AIDS medications such as 3TC and protease inhibitors. The Pharmacare grant to St. Paul's for the fiscal year ended March 31, 1998 was $22.6 million (1997: $12.9 million).

Betaseron

Pharmacare works with neurologists of the Multiple Sclerosis Clinic at the University of British Columbia to deliver the Betaseron Distribution Program. The program was developed in 1996 to ensure the appropriate use of Betaseron, developed to alleviate the illnesses associated with multiple sclerosis. The program was established to respond to Pharmacare's concerns about the broad and unrestricted use of the medication.

Betaseron has a very narrow application. Only those multiple sclerosis patients referred to as "relapse-remitting" have been shown to derive any benefit from the drug. These individuals make up to 50% of the general multiple sclerosis population. The drug is also extremely expensive, costing about $17,000 per patient per year.

According to the ministry, 350 British Columbia multiple sclerosis patients were eligible for Betaseron treatment, with an additional 30 to 40 individuals expected to qualify in each new year. As of December, 1997 there were 157 patients actually taking the drug. The ministry has negotiated to have the manufacturer of Betaseron provide a portion of the funding to support patient services.

Under the program, the Multiple Sclerosis Clinic:

- assesses patient eligibility for the drug through predetermined criteria reviewed on an individual basis by the neurologists at the Multiple Sclerosis Clinic and forwards the results to the Multiple Sclerosis Expert Panel for review and approval;
- educates patients before treatment; and
- measures neutralizing antibodies in patients.

Other Drugs

Other high-cost/limited-use drugs for which expert agencies are used to assess eligibility and ensure appropriate use include:

- Dornase Alpha Recombinant (Pulmozyme)—assessed by the three provincial cystic fibrosis clinics at Children's Hospital, St. Paul's Hospital, and Victoria General Hospital.
- Human Growth Hormone—assessed by the Endocrine Department at Childrens' Hospital for children with severely stunted growth.
- Cyclosporine (Sandimmune IV and Neoral)—assessed by rheumatologists for patients with severely debilitating arthritic conditions.
- Clozapine (Clozaril)—assessed by Riverview Hospital for patients with severe schizophrenia.

Requiring Specialist Prescription

For a number of drugs, the ministry exercises control, via the PharmaNet System, by only providing full reimbursement if the prescribing physician belongs to a certain specialty group. Some of those groups include:

- Dermatology
- Endoscopy
- Gastroenterology
- Haematology
- Immunology
- Neurology
- Oncology
- Opthamology
- Pediatrics
- Physical Rehabilitation
- Radiology
- Respiratory Medicine
- Rheumatology

In general, we think that this helps to ensure that certain high-cost/limited-use drugs are used appropriately, as long as there is some monitoring of prescribing patterns to ensure that the drugs are used appropriately. In this regard, the ministry should consider consulting with the College of Physicians and Surgeons about including the prescribing practices of specialists in their reviews.

ensuring cost-effective drug therapies

Several drugs are frequently available at differing costs to treat a particular illness. Prescribing the highest-cost drug when a lower-cost alternative is as effective can unnecessarily add to the cost of Pharmacare. We expected the ministry to ensure that, where alternative drugs are available to treat the same conditions, the most cost-effective drug is prescribed. In addition, we expected the ministry to allow flexibility in the application of its policies based on medical need and to prevent the waste of drug products as a cost control measure.

Conclusion

The ministry ensures that cost-effective drugs are prescribed and waste is prevented through the Low-Cost Alternative and Trial Prescription programs as well as the 30 Day Supply Limit policy. The Reference Drug Program, also helps ensure cost-effective drugs are prescribed, but, it needs to be independently evaluated to determine whether the health of patients is negatively affected and whether savings are eroded by increased costs in other parts of the health care system. The ministry is committed to having the program independently evaluated and is encouraging independent evaluations to be carried out. In applying its cost control policies, the ministry is appropriately flexible, responding on the basis of medical need.

Findings

Prescribing Medications That Are Not Cost-Effective

For many years now, “generic” products have existed that provide the same therapeutic effectiveness (using the same active ingredients) as “name brand” alternatives, but at a lower cost. In addition, many drugs available by prescription, and whose daily costs may vary significantly, can be grouped into classes used to treat a particular illness.

In most cases, physicians prescribe a specific drug because of previous positive results attained when the drug was used with other patients to treat similar symptoms. It is possible, however, that the product chosen is not the most cost-effective alternative. For example, a physician may prescribe the most costly product without knowing that a lower-cost alternative is as effective. This is understandable, given the vast number of drug products on the market and more added each year. It can

be very difficult for a busy physician to remain current with all the drug products available and to know which drug should be tried first and which is the most cost-effective.

Ministry Initiatives to Help Ensure Cost-Effective Drugs Are Prescribed

The ministry has introduced two programs to help ensure that cost-effective drugs are prescribed:

- the Low-Cost Alternative Program; and
- the Reference Drug Program.

Low-Cost Alternative Program

The Low-Cost Alternative Program came into effect in British Columbia on April 21, 1994. It involves using lower-cost generic products rather than the higher-cost brand-name product. This is referred to as "level 1" substitution and most provincial plans use comparable programs.

The Low-Cost Alternative Program helps to ensure that, when available, lower-cost generic products are prescribed. This is achieved by limiting Pharmacare's reimbursement for patient drug costs to the actual acquisition cost of the average of the lower-cost alternatives. For some categories, this means that only the generic products will be eligible and, in some cases, only one brand-name product. If a patient makes the choice to purchase a product for which a lower-cost alternative exists, the patient pays the difference.

We found that the ministry is making adequate use of the Low-Cost Alternative Program as a cost control measure. A January 1997 study commissioned by Health Canada to examine the impact of recent federal legislation changes on the health system found that British Columbia's generic share of all prescriptions is higher than the national average. It also noted that Ontario has consistently encouraged mandatory substitution, such that its generic share of prescriptions rose from about 34% in 1993 to over 40% in 1996. Similarly, British Columbia's generic share of prescriptions increased from about 36% in 1993 to about 44% in 1996. According to ministry estimates, the program saves Pharmacare about $20 million annually.

In some situations patient's may have medical problems associated with the low-cost alternative drug (usually intolerance to the additives or binding agents used in the drug). In our opinion, the ministry has adequately addressed this risk by implementing a process that allows a patient's physician to make a written medical request to allow the

Courtesy: Ministry of Health and Ministry Responsible for Seniors

The ministry has programs to help ensure that cost-effective drugs are prescribed

patient to receive full coverage ("special authority") for the higher-priced product. Ministry medical staff review physician requests for special authority and approve those deemed to be based on medical necessity. Overall, the ministry has found that requests for special authorization are decreasing as the public becomes accustomed to the use of generic medications.

Reference Drug Program

The Reference Drug Program (formerly called "Reference Based Pricing") was introduced by the ministry to address its concerns that some classes of drugs were not being prescribed cost-effectively. The program is referred to by some as "level 2" drug substitution—switching medications that fall within the same class of drugs, are chemically similar, and are used to treat similar medical conditions. The concept is used in other countries including New Zealand, Denmark, Netherlands and Germany. No other jurisdiction in North America has adopted the policy in the same way. Key stakeholder groups in British Columbia including medical and pharmacy associations and their members, hospitals, consumer groups, and industry have polarized views of the program. Some support the program while others strongly oppose it. Supporters believe that the program is effective in controlling costs without causing any negative health outcomes, while opponents believe that the program has caused severe problems for patients and has shifted costs to other parts of the health care system.

In our opinion, the Reference Drug Program helps to ensure that cost-effective drugs are prescribed. This is achieved by making the cost of the reference drug the level of coverage that the ministry will establish for any medication in that class used to treat that condition. As a result, patients eligible for Pharmacare benefits have three options:

- to receive full coverage for the "reference" drug;
- to choose a more expensive drug and pay the difference out of pocket; or
- to have their physician apply for full coverage for a non-reference drug if there is a medical reason to do so.

Evidence of Uneconomical Prescribing

In the first three-quarters of 1995, before the program was implemented, prescriptions for the lower priced H2-Antagonist, Cimetidine (used to treat upper gastrointestinal complaints and non-ulcer dyspepsia), amounted to about 22,000. Prescriptions for the higher cost Ranitidine, Famotidine and Nizatidine (other drugs in the same class used to treat acid-related gastrointestinal disorders) together totaled about 95,000. Research in both British Columbia and Ontario indicated that, in terms of efficacy and safety, only subtle differences existed among these drugs. Costs, however, varied considerably, with daily prices ranging from a low of $0.14 to a high of $0.94. While the cost differences appear to be small, numerous prescriptions for these medications add up to a substantial total cost to Pharmacare. During the same time period, similar circumstances existed for Nitrates (used to treat certain heart conditions) and non-steroidal anti-inflammatory drugs (NSAIDs are used, for example, to treat arthritis and chronic lower back pain). As a result, the first class of drugs brought under the Reference Drug Program on October 1, 1995 were H2-Antagonists. On November 1, 1995, all Nitrate prescriptions were subject to the program, while on November 27, 1995, NSAIDs were added. ACE inhibitors and calcium channel blockers (used to treat heart attack and stroke) were added in January 1997.

Impact on Costs

An independent Ottawa-based consultant evaluated the Reference Drug Program using data from the PharmaNet system. The study considered data up to December 1996.

The report concluded that the shifts in use to the reference drug products appeared to be permanent, and that an increase of between 85% and 350% in prescriptions for reference drugs

had occurred, compared to a decrease of 60% in prescriptions for the non-reference drugs in the categories. The report went on to say that these changes in drug use resulted in real savings of about $20 million during 1996. This compares to the ministry's projected savings of about $25 million. The study also reported that the difference between its estimate of savings and that of the ministry lies in the fact that it did not evaluate the impacts on Plan E, and that the ministry's estimate includes factors for population growth, inflation, and increased use. The ministry concurs with these explanations.

Addressing the Risk of Negative Health Outcomes

Implementing a drug substitution program involves the risk that patients' health may be negatively affected. In our opinion, the ministry has minimized this risk but, to fully address this issue, the program should be independently evaluated.

First, to ensure that the reference drug is as safe as other drugs in the same class and the most cost-effective, the ministry sought the independent, expert advice of organizations such as the Therapeutics Initiative, the Canadian Medical Association, and the Centre for Evaluation of Medicines at McMaster University.

Second, the ministry identified patient groups who were at risk if their medications were changed. As a result, children and patients with certain medical conditions are exempt from the policy. In addition, certain physician groups are exempt from the policy on the basis of their specialty and expertise (NSAID prescriptions by rheumatologists, for instance, are not subject to the program).

We noted an article in the *Canadian Medical Journal* (April 1996) that questions the decision to exempt specialists, since they are precisely the physicians who will be most heavily targeted by the pharmaceutical industry's marketing. The article concludes that specialists would benefit from the feedback through the special authority process, and this would also enhance the educational feature of the program. Some of the stakeholders we interviewed also questioned exempting specialists and children from the program. We believe it would be useful for the ministry to revisit this issue and consider whether these exemptions continue to be appropriate.

Third, to ensure that a patient has access to a more expensive non-reference drug when their physician thinks it is in their best interest, his or her doctor may obtain special authorization from the ministry.

The special authorization form is a simple one-page document made up mostly of check boxes. It requires the physician to certify that the patient meets one of the exemptions, such as:

- being frail and elderly, with a complex, multi-drug therapy;
- being cognitively impaired, such that changing medications may represent a threat to compliance; or
- having tried the reference product without success.

The ministry continues to streamline the process for obtaining this "special authority" and several options are available to simplify communication of the special authority request to Pharmacare—mail, fax, and telephone call. Provided the special authority form has been properly completed, Pharmacare's policy is typically to approve it. The ministry received about 50,000 requests during 1997 and estimates that it approved about 98%, most within 24 to 48 hours.

Monitoring the Impacts of the Reference Drug Program

The ministry does not expect the program to have any major impact on health outcomes. It believes that there is little pharmacologic difference between the reference and non-reference drugs in the same class, and therefore patient response to the former should be about the same. It also believes that the special authority process, which allows patients to be exempted from the program where medically necessary, is being adequately utilized.

In our opinion, however, it is important that the ministry monitor the program to ensure that it is not causing significant negative effects on the health outcomes of citizens impacted by the program and that significant cost shifting to other parts of the health care system is not occurring.

The ministry has carried out some monitoring of administrative data collected before and after introduction of the Reference Drug Program to assess the impact on health outcomes. The monitoring included data from hospitals on admissions and from the Medical Services Commission on services provided in hospital and for certain illnesses. Monitoring was centred on seniors because they tend to use more medications than other groups and they are the largest and most stable group of clients.

The ministry concluded that the program is not having a negative impact on health outcomes. The ministry also concluded that, because there has been no significant increase

in either hospitalizations or use of physician services, cost shifting to other parts of the health care system has been insignificant.

We found the ministry's monitoring described above useful, although it does not answer a few questions that some stakeholders may have. For example, to what extent:

- did those who were previously stabilized on a non-reference drug experience non-life-threatening side effects after switching to a reference drug product;
- did the ministry achieve its expected use of the referenced drugs and have these changed patterns been sustained over time; and
- did the ministry incur additional costs associated with the program. For example, what is the cost associated with additional physician and hospital visits, administering the program and special authorities?

The ministry recognizes that some may perceive its monitoring of the Reference Drug Program as being biased. To address this issue, the ministry encourages independent groups to conduct controlled scientific studies of the program. To date, the ministry has agreed to provide seed funding for three projects and about $150,000 for an evaluation involving several respected researchers. The results are expected to be available in about 2 years.

Recommendation

The ministry should encourage independent reviews of the Reference Drug Program and report the results to key stakeholders.

Expanding the Reference Drug Program

Given preliminary evidence that the Reference Drug Program saves drug costs without negatively affecting health outcomes and costs in other parts of the health care system, one might expect the ministry to expand the program.

Pharmacare acknowledges that it is considering other drug classes that might be added to the Reference Drug Program. For example, there has already been some public discussion about expanding the program to two of the remaining top 10 prescribed drug classes—those used to treat cholesterol and asthma. However, Pharmacare has indicated that it plans to move cautiously in these areas.

Results of Monitoring Health Outcomes after Implementing the Reference Drug Program

The ministry concluded that seniors who switched medications after the Reference Drug Program was implemented in 1995 had no significant change in the rate of hospitalization. The results were as follows:

H2-Antagonists

The rate of hospitalization for gastrointestinal bleeding was almost unchanged. The average rate was 60.0 hospitalizations per week in the period before the Reference Drug Program started, versus 60.6 hospitalizations per week during the first six months of the program.

Nitrates

The rates of hospitalization for fainting and heart attack were almost unchanged. For fainting, the average rate was 73.5 hospitalizations per week in the period before the program started, and 72.2 hospitalizations per week during the first five months of the program. For heart attack, the average rate was 73.1 hospitalizations per week in the period before the program started, versus 68.8 during the first five months of the program.

NSAIDS

The rate of hospitalization for gastrointestinal bleeding was almost unchanged. The average rate was 49.9 hospitalizations per week during the period before the program started, versus 49.8 per week during the first four months of the program.

ACE Inhibitors and Calcium Channel Blockers

Data is more limited than the above drug categories because hospital separation data are not complete until one year after the dates of treatment. As a result, evaluation in the interim is based only on Medical Services Plan data.

The number of seniors who received medical services for heart attack or stroke was not significant. The average incidence of services for a heart attack suffered for the first time was 12.2 patients per week during the nine months before the program started, versus 9.4 patients per week during the first two months of the program. The average incidence of first services for stroke was 16.9 patients per week during the nine months before the program started, and 16.1 patients per week in first two months of the program.

Pharmacare also states that it does not foresee the Reference Drug Program being expanded greatly. We think this is reasonable, since some research indicates that about 90% of what is possible to cover in a truly cost-effective way has already been reference-priced in British Columbia.

Ministry Initiatives to Prevent Waste

Cost-effective prescribing includes minimizing waste. Drug waste is a potentially significant cost to both Pharmacare and the overall health care system. A 1996 study by the Auditor General of Alberta states that 70 tonnes of unused drugs were collected in Alberta during a one-year period and destroyed. The British Columbia Pharmacy Association has suggested that as much as half of all drugs dispensed in British Columbia are only partially used.

Prescribed drugs may not be used for a variety of reasons. Patients may, for example, find a drug ineffective, be unable to tolerate a drug's side effects, or die before a prescription is fully used. Waste is compounded by the tendency of individuals to buy large quantities of prescription drugs to reduce the amount paid for pharmacists' dispensing fees.

To help minimize drug waste, the ministry has implemented two initiatives:

- the Trial Prescription program; and
- the 30 Day Supply Limit policy.

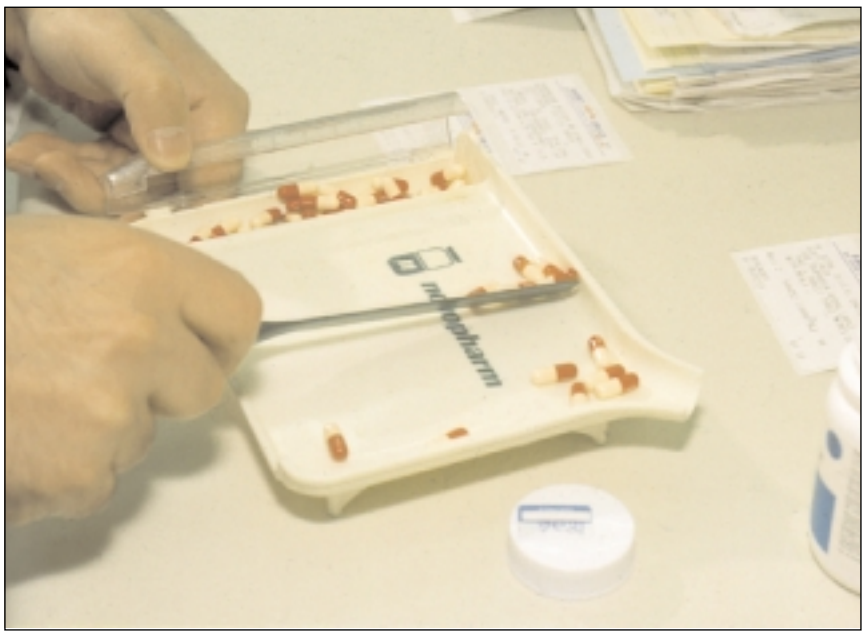
Trial Prescription Program

Evidence shows that drug waste amongst patients trying a drug for the first time is a significant and costly problem. To address this concern, the ministry introduced the Trial Prescription Program on February 1, 1993. Under the program, when new prescriptions are presented to a pharmacist, an initial 7 to 14 day supply is dispensed to determine whether it is effective and/or tolerated by the patient. The ministry pays the initial dispensing fee. If therapy is to continue, the patient returns to the pharmacy for the balance of the prescription. Key stakeholders support the program.

In our opinion, the Trial Prescription Program helps to minimize drug waste. In a pilot leading up to the introduction of the program, it was found that almost one-third of the prescriptions were discontinued. In addition, the cost of the additional dispensing fees paid by Pharmacare was found to be considerably less than the savings in unused drugs.

The program was initially implemented for a group of eight medications that—being expensive, hard to tolerate, and generally used chronically—were dispensed in large quantities. After initial success, the program was expanded in January 1995 (in cooperation with the BC Pharmacy Association), to include more drugs. In April 1996, the program was again expanded to include all reference drug medications, and the trial period was extended to 14 days (from 10 days) to better reflect the period of potential reaction associated with the new drugs.

We found that support exists for expanding the program. The B.C. Pharmacy Association recommended that the use of trial quantities of medication be encouraged for all new prescriptions and that the list of trial drugs identify medications excluded, rather than those medications eligible, for the Trial Prescription Program. The association also noted that expanding



Courtesy: Ministry of Health and Ministry Responsible for Seniors

Ministry programs exist to address drug waste

the program would preclude the need for drug sampling—a controversial practice whereby manufacturers provide free samples of new drug products to physicians to promote their use by patients. Under the program, the patient would be allowed to try a small quantity of a drug product without paying the initial dispensing fee.

Recommendation

The ministry should consider expanding the Trial Prescription Program to help minimize drug waste.

30 Day Supply Limit

Evidence shows that providing a patient with an excessive supply of a drug product results in significant waste. The 30 Day Supply Limit addresses this concern by providing patients a limited supply of drugs when filling short-term and first-time prescriptions. This helps to minimize drug waste.

Since November 1996, the maximum supply that Pharmacare covers for short-term drugs and first-time prescriptions for maintenance drugs has been limited to 30 days' supply. Maintenance drugs are medications used for long-term conditions such as diabetes and Parkinson's disease. Short-term drugs include antibiotics, sedatives, sleeping pills and barbiturates, some of which are addictive or become ineffective if used for a long time.

The 30 Day Supply Limit applies to all Pharmacare plans except Plan B, which covers residents of long-term care homes. Exemptions are available for residents of rural or remote areas without a pharmacy nearby.

All other prescriptions and repeat prescriptions of maintenance drugs are covered for a maximum of 100 days' supply. Prescriptions for quantities in excess of 100 days receive no Pharmacare coverage. Reimbursement is limited to a 100 day supply to prevent waste if therapy is discontinued, and to ensure appropriate monitoring of patient compliance with the physician's prescribed therapy.

We found that pharmacists promote the cost savings and health benefits resulting from the 30 Day Supply Limit. Other provinces have also found that the approach helps to reduce waste and have therefore employed similar programs with some variation. Most limit quantities to 28–35 days' supply for treatment drugs, and to 100–180 days' supply for maintenance drugs.

paying the right price for drugs dispensed

The most significant component of Pharmacare's annual budget is payments to pharmacists for the cost of drugs dispensed. Pharmacists purchase drugs and, in turn, charge the ministry at the time the drugs are dispensed. We expected the ministry to ensure that it pays the right prices for drugs and only for drugs dispensed.

Conclusion

The ministry ensures that it pays reasonable prices for drugs dispensed by pharmacies by basing the amount it pays on the pharmacies' actual acquisition costs up to a maximum of 7% above the manufacturers' list prices and through controls in the PharmaNet system. However, to obtain additional assurance a pharmacy audit program is needed. The ministry is aware of this deficiency and is currently developing such a program.

Findings

Ministry Initiatives to Ensure It Pays Reasonable Drug Prices

Canada imposes price controls on individual drug products through the Patented Medicine Prices Review Board. The principal mandate of the board is to ensure that prices of patented medicines in Canada are not "excessive." Prices of new drugs are based on international price indices. Price increases for existing drugs are limited to changes in the consumer price index for Canada, though the process controls only the manufacturers' prices for drug products.

Under Pharmacare, pharmacies purchase the drugs needed to fill prescriptions and bill Pharmacare when the drugs are dispensed. Pharmacies can purchase drugs in a variety of ways. For example, a manufacturer may sell its products to a wholesaler, who adds a mark-up to the price and then sells the products to pharmacies. The average mark-up by British Columbia's seven wholesalers has been approximately 12%. Alternatively, wholesalers may sell drug products to distributors who add an additional mark-up and then sell the drugs to the pharmacies. Because these drug distribution methods can unnecessarily add to Pharmacare's costs, it is important for the ministry to ensure that it pays reasonable prices for drugs dispensed.

In our opinion, the ministry ensures that it pays reasonable prices for drugs dispensed, however, additional assurance could be provided if the ministry conducted pharmacy audits.

The ministry states that it will pay pharmacies no more than the actual acquisition cost of a drug up to a maximum of 7% above the manufacturer's list price. The ministry checks that it pays the correct prices for drugs by regularly obtaining manufacturer price lists and updating the PharmaNet system with the new prices. As prescriptions are filled, the system checks the prices entered by pharmacists throughout British Columbia against the manufacturers' price lists. Pharmacists are contacted to confirm errors detected and corrections are made.

We also found that most other provinces with programs similar to Pharmacare apply some form of control over the price they pay for drugs. Some provinces reimburse on a "best available price" basis; the other provinces reimburse on variations of "actual acquisition cost" or "maximum allowable cost."

A weakness, however, is that the ministry has not carried out field audits of pharmacies for some time. As a result, there is a risk that pharmacies could be paying lower prices for drug products than the allowed price, and not passing these savings along to the ministry. The ministry is aware of this weakness and is currently developing a pharmacy audit program.

Ministry Initiatives to Ensure It Pays Only For Drugs Prescribed and Dispensed

Under the present system, physicians prescribe drugs to patients and pharmacists dispense the drugs and charge the ministry for those products. This system presents a number of risks for the ministry. For example:

- patients could copy prescriptions and submit them to a number of pharmacies;
- physicians could issue prescriptions for drugs that are not needed but are used for drug abuse or sold on the street; and
- pharmacists could submit transactions for drugs that have not been dispensed.

In our opinion, the PharmaNet system helps to address these risks, but the ministry can do more to ensure that valid prescriptions exist for all drugs dispensed.

The PharmaNet system helps pharmacists detect drugs being obtained fraudulently by providing drug histories for each patient no matter where the patient made his or her drug purchases. According to ministry reports, in the six-month period ending March 31, 1997, the PharmaNet system helped to detect many cases of potential fraud. Pharmacists, using the information on the system, did not dispense prescriptions presented by patients for the following reasons:

- in 133 cases, because the patient presented a falsified / altered prescription;
- in 598 cases, because the patient was suspected of "multi-doctoring"; and
- in 515 cases, because the patient was suspected to be overusing / abusing prescription medications.

As we noted above, however, regular field audits of pharmacies are not conducted. As a result, the ministry cannot be sure that valid prescriptions exist for all drugs dispensed. The ministry indicated to us that the proposed pharmacy audit procedures will include a prescription verification component. This, along with its current process of confirming with a sample of patients that they actually filled a prescription at a pharmacy, will address the risk of possible non-existent prescriptions.

Recommendation

The ministry should conduct field audits of pharmacies to ensure that it pays the right amounts for drugs dispensed.

evaluating and reporting program results

An important element in the management of a program is evaluating the extent to which intended results have been achieved. We expected management to carry out evaluations of its major programs for managing the cost of drug therapies and fostering appropriate drug use, and to report the results to key stakeholders.

Conclusion

The ministry has not developed a comprehensive performance evaluation framework or fully evaluated several programs. Reporting to key stakeholders on the extent to which the ministry has managed the cost of drug therapies and fostered appropriate drug use has also been limited.

Findings

Performance Evaluation Framework

As called for in the April 1996 joint report of the Auditor General of British Columbia and Deputy Ministers' Council on Enhancing Accountability for Performance, government managers are expected to have a program performance evaluation framework in place. In this model, managers identify key program activities that they control and are accountable for. They then measure the results of these activities by using a range of indicators, and compare the results to established targets to determine whether performance is meeting expectations and if not, why. We believe this is the only way managers can objectively assess whether government programs are achieving their intended effects.

In this audit, we have discussed several programs introduced by the ministry to manage the cost of drug therapies and foster appropriate drug use. We found parts of a framework to evaluate these programs—for example, some estimates of expected cost savings associated with various programs (Exhibit 8)—but not a complete framework, such as assessments of the extent to which the savings were actually achieved.

When we looked at spending for Pharmacare, it was not apparent that the ministry's estimated cost savings had actually been achieved, because actual spending for the program between the 1995 and 1997 fiscal years continued to increase (Exhibit 9). The ministry did not have a reconciliation of its expected savings with actual program spending, although it

Exhibit 8

Ministry's Estimated Savings from Cost Control Programs

Cost Control Program	Implementation Date	Estimated Annual Savings ($millions)
Low-cost alternative	April 1994	20
Reference drug		
▪ H_2-Antagonists	October 1995	
▪ Nitrates	November 1995	25
▪ NSAIDs	November 1995	
▪ Calcium channel blockers	January 1997	10
▪ ACE Inhibitors	January 1997	4
Drug delisting	November 1996	1
Maximum 7% up-charge[1]	1996	8
Waste control		
▪ Trial Prescription[2]	February 1993	No estimate available
▪ 30 Day Supply Limit	November 1996	4
Fraud Reduction	1995	13
Therapeutics Initiative[2]	1995	No estimate available
Pharmacoeconomics Initiative[2]	1996	No estimate available

[1]Initial estimate of savings for limiting the up-charge on manufacturer prices for drugs was $6 million and an additional estimated savings of $2 million for lowering it from 9% to 7%.

[2]We found no overall estimate of savings for these programs.

Source: Ministry of Health

Exhibit 9

Financial Results and Drug Use, 1993/94–1996/97

Fiscal Year	Annual Budget ($000)	Annual Expenditures ($000)	Change (%)	Annual Pharmacare Surplus/(Deficit) ($)	Annual Use (No. Rx)	Change (%)
1993/94	357,392	389,750	10.2	(32,358)	10,682,417	-.3
1994/95	364,787	370,483	-4.9	(5,696)	10,917,231	2.2
1995/96	406,573	391,780	5.7	14,793	11,732,020	7.5
1996/97	396,324	424,846	8.4	(31,382)	11,330,834	-3.4

Source: Ministry of Health

did provide some explanations for the differences, which included the introduction of a variety of new and costly programs. For example, the ministry introduced the HIV/AIDS program at a cost of about $23 million for the fiscal year ending March 31, 1998 (1997: $12.9 million). Similarly, Plan D for Cystic Fibrosis patients was introduced in 1995 and costs about $2 million per year. Another significant program, Betaseron for multiple sclerosis patients, was introduced in 1996 at a cost of about $6 million per year. Introduction of the PharmaNet system resulted in additional costs of about $13 million per year because patients are no longer required to submit claims for reimbursement—the system does it automatically.

We believe that stakeholders would find it useful to have an analysis prepared by the ministry reconciling estimated savings from cost control programs with actual savings along with information that identifies how those savings have been used.

Some stakeholders are interested in whether the ministry's cost control programs are shifting costs to other parts of the health care system (e.g., increasing hospitalizations and physician visits). The ministry has done some work in this area, but not a comprehensive evaluation of the issue. Similarly, we found that the ministry did carry out some assessments of its programs on health outcomes, but these were not as refined as we expected.

Ministry initiatives to foster appropriate drug use frequently involve having the work performed by independent organizations (Exhibit 10). We found that the ministry had

Exhibit 10

Ministry-funded Programs That Foster Appropriate Drug Use

Program	Annual Ministry Funding ($)
Therapeutics Initiative	525,000
Prescribing Pattern Reviews	200,000
Dial-A-Dietician	162,000
North Shore Community Drug Utilization Review Program	143,000
Prevention Resource Centre	50,000
Seniors Medication Line	20,000
Total annual spending	**1,100,000**

Source: Ministry of Health

not received recent reports from some of the organizations describing their activities. We also found only limited evaluation of the work performed and the results achieved. For example, we found evaluations of the work done by the Therapeutics Initiative, but nothing for the other five programs: Prescribing Pattern Reviews, Dial-A-Dietician, North Shore Community Drug Utilization Review, the Prevention Resource Centre, and the Seniors Medication Line.

Recommendation

The ministry should develop a framework of performance indicators that measures the results of its programs for managing the cost of drug therapies and fostering appropriate drug use.

Reporting to Key Stakeholders

It is not enough for the ministry to develop an evaluation framework and measure and evaluate results. Also important is providing stakeholders with timely performance information so that they can see that a program is working as intended or, if it is not, that they can offer their suggestions for improvement. Management principles affirm that optimal practice and quality performance can be most consistently achieved across a system by providing meaningful feedback on performance to those involved in implementing the changes—in this case, pharmacists and physicians.

We found that the ministry periodically publishes a booklet called “Pharmacare Trends” which describes its various programs and analyzes program costs over several years. Missing, however, is any analysis of the results of its programs for managing the cost of drug therapies and fostering appropriate drug use (as discussed above). Once this information is developed, we believe that this document offers an appropriate means of providing stakeholders with that performance information.

Recommendation

The ministry should periodically measure, evaluate and report to key stakeholders on the performance of its programs for managing the cost of drug therapies and fostering appropriate drug use.

ministry response

The Ministry of Health and the Ministry Responsible for Seniors appreciates the opportunity to respond to the report on Managing the Cost of Drug Therapies and Fostering Appropriate Drug Use *issued by the Office of the Auditor General of British Columbia. We were pleased to note that the Auditor General concluded that we have introduced several programs to manage drug costs, and that we have made significant progress in fostering appropriate drug use.*

We value this external review of the program. The Pharmacare staff are proud of the work that we do, and view the Auditor General's report as a valuable tool for Pharmacare to use in strengthening the program.

Drugs are an essential element in the provision of contemporary health care. Governments, consumers and health professionals share responsibility for their effective utilization at different levels. The federal government is responsible for ensuring the safety and efficacy of any drug approved for marketing in Canada. Provincial governments are responsible for funding these drugs through drug plans designed to meet the needs of their citizens. Through their drug approval process and formulary listing decisions, both levels of government can encourage the pharmaceutical industry to develop better drugs that enhance compliance by minimizing adverse reactions, while maximizing therapeutic benefit.

While the Pharmacare program can introduce measures to influence drug use, it is the physicians' prescribing behaviour that has the greatest impact on drug utilization.

The professional Colleges of Pharmacists and Physicians are responsible for ensuring that their members provide the necessary information to consumers in order to optimize their drug therapy. In addition, they monitor patient compliance and response to therapy. The Pharmacare program is one player in a complex field.

British Columbia is recognized as a leader for its Pharmacare program. Pharmacare is designed to improve the health status of British Columbians by ensuring reasonable access to, and appropriate use of prescription drugs and related benefit services.

Pharmacare provides outstanding drug coverage for British Columbians, despite the increasing cost pressures facing the program. The report of the Auditor General confirms the success of the Pharmacare program in meeting both its health care and fiscal responsibilities. Many of the actions recommended had already been undertaken prior to the tabling of the report.

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

Recommendation 1:
Review currently listed drugs periodically to ensure they continue to provide good value for money.

Pharmacare has developed a rigorous process that brings together medical and economic experts to review all applications for new drugs added to the list of drug benefits. All new drugs undergo a detailed rigorous review, whereby, pharmaceutical companies submit product information to Pharmacare. This information, as well as independently gathered information, is reviewed by expert medical and economic committees that operate at arms length from government, pharmaceutical industry and other vested interest groups.

The committees review a new drug to assess its therapeutic benefit, based on the evaluation of the best scientific evidence, and its cost effectiveness and pharmacoeconomic advantage. This information is brought together at the Drug Benefit Committee that makes the decision on whether to add a new drug to the benefit list.

We will be asking the Drug Benefit Committee to undertake a similar review of the drug benefit list by therapeutic drug class.

Recommendation 2:
Obtain appropriate and timely information from organizations receiving ministry funding that describes the activities carried out and the accomplishments achieved.

The report specifically cites the lack of a written report from two groups, the North Shore Community Drug Utilization Program, and the College of Physicians and Surgeons of B.C. The report of the North Shore program has subsequently been received. We have yet to receive any information from the College of Physicians and Surgeons.

Pharmacare is addressing the issue of accountability and reporting through the project management activities and the assignment of Pharmacare contacts to administer contracts with organizations and individuals who receive ministry funding. We will ensure that appropriate and timely information and services are received.

Recommendation 3:
Encourage and support the medical and pharmacy professions and the pharmaceutical industry to do more to determine the extent of, and reasons for, patients' non-compliance with drug therapies, so that the ministry can ensure programs exist to address this issue.

As noted in the introductory section, Pharmacare is one of many partners involved in the provision of effective pharmaceutical care. Patient compliance with prescribed regimens is important in order to ensure optimal therapeutic outcomes.

We recognize that an inherent role of the physician and pharmacist is to encourage patient compliance as part of their day to day practice. It is also integral that patient involvement in discussions about medication use occur to achieve success in this area. Pharmacare supports programs which establish dialogue and communication with the medical and pharmacy professions, industry and consumer groups.

The ministry supports programs that address the issue of patient compliance with drug therapies. The British Columbia Seniors Medication Information Line (BCSMILE) provides information on prescription and non-prescription medications and clarifies issues of adverse reactions, interactions, and misuse of medications; issues which relate to patient non-compliance with drug therapies.

In addition, the ministry supports the White Rock Seniors Project-Excellence in Health Community Pilot Project. This pilot project is comprised of an education component, staffed by volunteer seniors and designed to increase the medication knowledge of seniors; and, an intervention component, staffed by a pharmacist and nurse, targeting seniors at high-risk for medication-related problems.

Pharmacare has also implemented policies aimed at improving patient compliance, such as our Trial Prescription Program and a Maximum Days Supply policy. These initiatives promote good medical practice, provide physicians with the opportunity to monitor patient compliance with prescribed therapies, ensure medications are working satisfactorily, prevent undesired side effects from developing unnoticed and reduces waste.

Finally, the ministry participates on a Federal/Provincial/Territorial Task Force created to address issues of pharmaceutical utilization, prescribing practices, consumer education and patient compliance. These initiatives will enhance the ability to better understand the state of drug utilization in Canada.

***Recommendation 4*:**
Implement the recommendations of the PharmaNet Benefits Analysis Workshop that call for the information now collected by the PharmaNet system to be used to evaluate the effects of health policies already implemented and to develop policies to promote appropriate drug use.

Access to the PharmaNet database is controlled by the College of Pharmacists of B.C.. Working with the College, Pharmacare will review the observations and recommendations of the PharmaNet Benefits Analysis Workshop and determine strategies to implement the recommendations. Some of the recommendations have already been implemented and others are currently being addressed.

The ministry is also working with Health Canada on a national Health Transition Fund initiative to investigate the feasibility of a national approach to prescription drug information for analysis of drug costs, utilization and outcomes.

Recommendation 5:
Identify all sources of prescription drugs, other than community pharmacies, and determine whether to include the drug information from these sources in the patient profiles contained in the PharmaNet system.

Pharmacare recognizes the need for comprehensive drug profiles and will be working closely with the College of Pharmacists of British Columbia and other stakeholder groups to address the issue of adding other drug categories to patient profiles.

Recommendation 6:
Encourage independent reviews of the Reference Drug Program and report the results to key stakeholders.

Pharmacare's Reference Drug Program (RDP) is designed to encourage cost-effective prescribing of medications. Under RDP, Pharmacare coverage is based on the cost of the reference drug or drugs in a therapeutic category. This is the drug considered to be medically effective and the most cost-effective in that category.

Pharmacare has initiated an Independent Scientific Evaluation of the Reference Drug Program (RDP) to fulfil Pharmacare's commitment to evidence-based policy. Pharmacare has encouraged independent groups to initiate controlled scientific studies of health care utilization before and after RDP.

- *The Pharmaceutical Outcomes Research and Policy Program at University of Washington, Seattle is evaluating RDP Gastric Acid Suppression Drugs and Non Steroidal Anti Inflammatory Drugs.*
- *The Centre for Evaluation of Medicines at McMaster University, Hamilton, is evaluating nitrates.*
- *Dr. Steven Soumerai of Harvard Medical School, Boston is conducting a scientific evaluation of RDP of antihypertensives, joined by Sebastian Schneeweiss, MD, of Ludwig Maximilian University of Munich, Germany, and Harvard School of Public Health, Boston.*
- *A prospective evaluation of future RDP is being designed. The principal investigator is Dr. Bruce Carleton, Director, Pharmaceutical Outcomes program. This research is to be funded from the Pharmacare Health Transition Fund.*

Recommendation 7:
Consider expanding the Trial Prescription Program to help minimize drug waste.

Reducing unnecessary costs to the Pharmacare program due to excessive drug wastage is an important objective for Pharmacare. Pharmacare continues to support the Trial Prescription Program and is currently working with the British Columbia Pharmacy Association and the College of Pharmacists of British Columbia to evaluate the program and investigate expansion to help minimize drug waste.

Recommendation 8:
Conduct field audits of pharmacies to ensure that the ministry pays the right amounts for drugs dispensed.

The ministry agrees with the need to audit pharmacies to ensure that the goods and services are provided as outlined in Pharmacare's Pharmacy Participation Agreement. Recently a Pharmacare Audit Section has been established within the ministry to actively address the issue of pharmacy audits.

In addition, Pharmacare is considering an audit of the special authority process for limited use and Reference Drug Program medications. This process would verify and ensure that special authority guidelines are being met.

Recommendation 9:
Develop a framework of performance indicators that measures the results of Pharmacare programs for managing the cost of drug therapies and fostering appropriate drug use.

In reviewing the effectiveness of the Pharmacare program, there are two major considerations, the impact on health, and cost. Both of these need to be considered in a broad context, extending beyond the cost and direct effect of the drug alone. Pharmacare has undertaken a number of steps to measure the impact of various programs for managing the cost of drug therapies and fostering appropriate drug use. All projects developed to measure the results of Pharmacare programs embody rigorous international standards of scientific evaluation.

Under the Reference Drug Program, monitoring of rates of medical services and hospitalizations for sentinel diagnoses before and after the introduction of RDP indicates that RDP has had no detectable impact on health care use. The rates have been monitored using both hospital separation data and data from the Medical Services Commission on the services provided in hospital and for certain illness diagnostic codes.

In addition, monitoring of the expenditures on the therapeutic classes of the drugs under RDP is ongoing. Finally, a RDP Evaluation Sub-Committee, chaired by Dr. Bruce Carleton, meets regularly to discuss the evaluation of outcomes of the RDP.

Recommendation 10:
Periodically measure, evaluate and report to key stakeholders on the performance of Pharmacare programs for managing the cost of drug therapies and fostering appropriate drug use.

Pharmacare produces a report, titled Pharmacare Trends, *which reports on the performance of Pharmacare programs, focussing on the financial costs of Pharmacare, operations, drug utilization, and inter-provincial comparison and a look ahead to the future of Pharmacare.*

Pharmacare is committed to the periodic production of this and other measurement, evaluation and reporting activities to key stakeholders.

appendices

appendix a

Provincial Prescription Drug Programs in Canada

Province	Have a universal plan?	Separate senior's coverage?	Any groups treated separately?	Co-payment or deductible?
British Columbia	Yes	Yes: 100% of drugs; 100% of dispensing fees up to $200	Cystic Fibrosis patients and medically dependent children	Plan E: $600 deductible and 30% of fee copay up to $2000/year. Plan A: 100% of dispensing fee up to $200/year
Alberta	No	Yes: do not pay premium or $50 deductible on non-drugs	Dependents of seniors, widow's pension recipients	No deductible; copay 30% up to $25 maximum
Saskatchewan	Yes	Yes	Cystic Fibrosis, diabetes, cancer, transplant, and AIDS patients	$850 semiannually; seniors vary with income and place of residence ($100-200/ year); Social Assistance adults $2/Rx; copay 35%
Manitoba	Yes	Yes: lower deductible	Lifesaving Drug Program	3% of adjusted family income >$15000 per year, 2% of adjusted family income <$15000
Ontario	Yes	Yes: Drug Benefit Act (not eligible for Trillium Drug Plan)	Cystic Fibrosis patients	$2/Rx copay for most seniors; deductible for Trillium Drug Plan varies with income and family size
Quebec	No	Yes	Sexually transmitted disease patients	25% of cost up to maximum which varies by age and income
New Brunswick	No	Yes, if they meet an income test	Transplant, AIDS, and Human Growth Hormone Deficiency patients	Seniors copay $9.05/Rx; GIS recipients max $250/ year; Social Services adults $4/Rx; children $2/Rx to max $250/year; Cystic Fibrosis, transplant, AIDS, HGHD patients $50/ year registration fee and 20%, max. $20, up to $500/year
Nova Scotia	No	Yes: $215 premium, possible credit of $30 depending on income	Cystic Fibrosis, AIDS, Human Growth Hormone Deficiency, hemophiliac with HIV, and diabetes insipidus patients	No deductible; max. copay $3 or 20%/Rx, max. $200/year for seniors or $150/year for family benefit recipients; income assistance $3/Rx
Prince Edward Island	No	Yes	Cystic Fibrosis, diabetes, and organ transplant patients	Seniors copay $7 + fee; others copay $14.85/Rx; Welfare Assistance $2/Rx if filled at community pharmacy; $5/vial for insulin
Newfoundland and Labrador	No	Yes, if GIS received	Cystic Fibrosis patients	Seniors pay professional fee + 10% of ingredient cost if >$30

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Province	Apply "ability to pay" criteria for coverage?	Pay pharmacies for actual acquisition cost of drugs or another method?	Use a formulary?	Claimants pay a premium?	Private insurance integrated with any other schemes?
British Columbia	No	Actual acquisition cost + max. 7% on wholesale sourced drugs	No	Yes (for MSP)	Yes
Alberta	No	Yes	Yes	Yes	No
Saskatchewan	Yes	Actual acquisition cost + varying markup	Yes	No	No
Manitoba	Yes	Yes, for care home patients only	Yes	Yes	No
Ontario	Yes	Best available price + 10%	Yes + some exceptions	Yes	Yes
Quebec	Yes	Yes	Yes	Yes	No
New Brunswick	Yes	Yes	Yes	Yes	Yes
Nova Scotia	No	Yes	Yes	Yes	No
Prince Edward Island	No	Direct catalogue price + 13% for wholesale sourced drugs	Yes	No	No
Newfoundland and Labrador	Yes	Direct catalogue price + 15% for wholesale sourced drugs	Yes	No	No

Source: Provincial Drug Benefit Programs, Canadian Pharmaceutical Association, 15th Edition, June 1996
BC information supplied by the Ministry of Health

appendix b

1998/99 Reports Issued to Date

Report 1

Follow-up of 1996 Performance Audits/Studies

Report 2

Managing the Cost of Drug Therapies
and Fostering Appropriate Drug Use

appendix c

Office of the Auditor General: Performance Auditing Objectives and Methodology

Audit work performed by the Office of the Auditor General falls into three broad categories:

- Financial auditing;
- Performance auditing; and
- Compliance auditing.

Each of these categories has 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 performance auditing.

Performance Auditing

Purpose of Performance Audits

Performance audits look at how organizations have given attention to economy, efficiency and effectiveness.

The concept of performance auditing, also known as value-for-money auditing, is based on two principles. The first is that public business should be conducted in a way that makes the best possible use of public funds. The second is that people who conduct public business should be held accountable for the prudent and effective management of the resources entrusted to them.

The Nature of Performance Audits

An audit has been defined as:

> *…the independent, objective assessment of the fairness of management's representations on performance, or the assessment of management systems and practices, against criteria, reported to a governing body or others with similar responsibilities.*

This definition recognizes that there are two primary forms of reporting used in performance auditing. The first—referred to as attestation reporting—is the provision of audit opinions on reports that contain representations by management on matters of economy, efficiency and effectiveness.

The second—referred to as direct reporting—is the provision of more than just auditor's opinions. In the absence of representations by management on matters of economy, efficiency and effectiveness, auditors, to fulfill their mandates, gather essential information with respect to management's regard for value for money and include it in their own reports along with their opinions. In effect, the audit report becomes a partial substitute for information that might otherwise be provided by management on how they have discharged their essential value-for-money responsibilities.

The attestation reporting approach to performance auditing has not been used yet in British Columbia because the organizations we audit have not been providing comprehensive management representations on their performance. Indeed, until recently, the management representations approach to value for money was not practicable. The need to account for the prudent use of taxpayers' money had not been recognized as a significant issue and, consequently, there was neither legislation nor established tradition that required public sector managers to report on a systematic basis as to whether they had spent taxpayers' money wisely. In addition, there was no generally accepted way of reporting on the value-for-money aspects of performance.

Recently, however, considerable effort has been devoted to developing acceptable frameworks to underlie management reports on value-for- money performance, and public sector organizations have begun to explore ways of reporting on value-for-money performance through management representations. We believe that management representations and attestation reporting are the preferred way of meeting accountability responsibilities and are actively encouraging the use of this model in the British Columbia public sector.

Presently, though, all of our performance audits are conducted using the direct reporting model; therefore, the description that follows explains that model.

Our performance audits are not designed to question government policies. Nor do they assess program effectiveness. The Auditor General Act directs the Auditor General to assess whether the programs implemented to achieve government policies are being administered economically and efficiently. Our performance audits also evaluate whether members of the Legislative Assembly and the public are provided with appropriate accountability information about government programs.

When undertaking performance audits, auditors can look either at results, to determine whether value for money is actually achieved, or at management processes, to determine whether those processes should ensure that value is received for money spent.

Neither approach alone can answer all the legitimate questions of legislators and the public, particularly if problems are found during the audit. If the auditor assesses results and finds value for money has not been achieved, the natural questions are "Why did this happen?" and "How can we prevent it from happening in future?" These are questions that can only be answered by looking at the process. On the other hand, if the auditor looks at the process and finds weaknesses, the question that arises is "Do these weaknesses result in less than best value being achieved?" This can only be answered by looking at results.

We try, therefore, to combine both approaches wherever we can. However, as acceptable results information and criteria are often not available, our performance audit work frequently concentrates on managements' processes for achieving value for money.

We seek to provide fair, independent assessments of the quality of government administration. We conduct our audits in a way that enables us to provide positive assessments where they are warranted. Where we cannot provide such assessments, we report the reasons for our reservations. Throughout our audits, we look for opportunities to improve government administration.

Audit Selection

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

We believe that performance audits conducted 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. Because of limited resources, we have not been able to achieve this schedule.

Our Audit Process

We carry out these audits in accordance with the value-for-money auditing standards established by the Canadian Institute of Chartered Accountants.

One of these standards requires that the "person or persons carrying out the examination possess the knowledge and competence necessary to fulfill the requirements of the particular audit." In order to meet this standard, we employ professionals with training and experience in a variety of fields. These professionals are engaged full-time in the conduct of performance audits. In addition, we often supplement the knowledge and competence of our own staff by engaging one or more consultants, who have expertise in the subject of that particular audit, to be part of the audit team.

As performance audits, like all audits, involve a comparison of actual performance against a standard of performance, the CICA prescribes standards as to the setting of appropriate performance standards or audit criteria. In establishing the criteria, we do not demand theoretical perfection from public sector managers. Rather, we seek to reflect what we believe to be the reasonable expectations of legislators and the public. The CICA standards also cover the nature and extent of evidence that should be obtained to support the content of the auditor's report, and, as well, address the reporting of the results of the audit.

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