ACCESS TO PRESCRIPTION DRUGS IN CANADA:

A Guide

August 2004

The Arthritis Society
The Lung Association

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Introduction

Prescription drugs are an essential component of our health care system. In Canada, various governmental agencies - both federal and provincial - are responsible for different aspects of the approval and delivery of prescription drugs. In addition, private health care plans play an important role in providing prescription drug coverage for a great many Canadians. For this reason, it can be hard to understand the 'big picture' of access to prescription drugs in Canada.

According to the Canadian Institute of Health Information (CIHI), in 2001, $13.2 billion was spent in Canada by public and private sources on prescribed drugs. They forecast that this amount would increase to almost $16.0 billion by 2003. Of the $13.1 billion that was spent in 2001 on prescription drugs, almost half (46.3%) was paid for by the public sector (by federal or provincial governments), while private health insurance paid for another 34% of the costs. The final 18% of prescription drug costs, or about $2.35 billion dollars, was paid for from out-of-pocket spending by Canadian households.

This document is intended to help Canadians to understand the process by which drugs are approved for sale in Canada, how decisions are made on what drugs are covered under health and insurance plans, what options are available if a Canadian cannot afford the cost of a prescribed medication and what happens if a drug or medication has an unintended side-effect or consequence from its use. It is hoped that by providing the information that Canadians need to understand the process for accessing prescription drugs, that Canadian citizens and landed immigrants will be able to access the full ranges of programs and services that are available to them. This document is as accurate as possible, as of August 2004. It is important to bear in mind, however, that the area of access to pharmaceuticals is complex and subject to rapid change.

Guide to the Document

This document has been arranged into six sections:

At the end of this document, there is also a list of federal and provincial formularies along with other groups and agencies that may be contacted for further information.

What subjects are not covered in this document?

In addition to **prescription drugs** there are many products available to Canadians that claim or are known to provide health benefits. These products include:

- *Natural Health Products* - vitamin pills, protein and other nutritional supplements.
- *Over-the-counter Medications/Non-prescription Drugs* – products like cold medicines or aspirin.
- *Agri-Foods and Genetically Modified Organisms* – new food products which are genetically engineered to provide health benefits.

Although it is important for Canadians to understand how these products are reviewed for safety and effectiveness and how they are approved for sale in Canada, the focus of this paper is only on **prescription drugs**.

Definitions and Acronyms

This section provides a brief description of some of the words and terms that are used throughout this paper in describing access to, and the approval of, drugs in Canada.

BGTD – The Biologics and Genetic Therapies Directorate at Health Canada.

Bioequivalent – A product is bioequivalent if it acts on the body with the same strength and is available to the target tissues to a similar degree as an identical amount of a different substance. (The American Heritage® Dictionary of the English Language: Fourth Edition. 2000)

Brand Name Drug – A brand name drug is a drug that is protected by a patent. This means that only the company which holds the patent for that drug can produce and sell it or license it for sale to another company in Canada for the duration of the patent.

CDR – The Common Drug Review program.

Co-payment – A co-payment is a fixed amount of money that an individual who is covered by a drug benefit plan pays for each drug that they purchase (for example, an individual might pay $10 ever time that they fill a prescription and their drug benefit plan will pay the rest of the cost of the medication).

DIN – Drug Identification Number.

Deductible – A deductible is the total cost of prescription drugs that an individual will pay for out of pocket before their drug benefit plan begins to cover part of the remainder of their costs (for example, if an individual has a $700 deductible on their drug benefit plan they will have to pay for the first $700 of prescription drugs that they purchase in a year, before their drug benefit plan will pay for a percentage of the rest of their drug costs).

Efficacy – The efficacy of a product is the degree to which it provides a definite health benefit for patients who are taking the drug, in comparison with those patients who are not taking the drug.

Generic Drug – A generic drug is a drug that is not covered by a Canadian patent, generally because another comparable brand name drug has already been approved for sale in Canada. Health Canada approves both generic and brand name drugs. Generic drugs must demonstrate *bioequivalence* with the comparable brand name drug.

HPFB – The Health Products and Food Branch of Health Canada.

IFHP – Interim Federal Health Program

NDS – New Drug Submission

NIHBP – Non-Insured Health Benefits Program

NOC – Notice of Compliance.

Pharmacoeconomics - The application of the methods of economic evaluation of health care programs to interventions involving pharmaceutical products. (hta.uvic.ca/glossary)

PMPRB – Patented Medicine Prices Review Board

Reference-based Pricing – A reference based pricing system is a benefit plan or formulary that will only reimburse the costs of a drug covered by their plan up to the cost of a particular 'reference drug'. This practice can impact on the affordability of those drugs that are more expensive than their reference drugs, for beneficiaries of these plans.

Reference Drug – The least expensive drug in a drug class.

Safety – No prescription drug will ever be 100% free of unanticipated health impacts and it is impossible for a regulatory system to test a new drug for every possible reaction and interaction with other substances. With this reality in mind, the term 'safety' in the context of a prescription drug in Canada means that there is an appropriate balance between the potential benefits of the new drug and its potential health risks to Canadians. Before a drug can be authorized for sale in Canada it goes through a rigorous approval process which is described in greater detail in the first section of this document.

SAP – Special Access Program

Side Effect – A side effect is any unwanted reaction caused by the use of a drug (for example, if you take a drug to treat your high-blood pressure but the drug also gives you a headache - the headache would be a side effect.)

TPD – The Therapeutic Products Directorate at Health Canada.

Section 1: An Overview of Access to Prescription Drugs in Canada

The federal and provincial governments, and private insurance plans all play a role in helping Canadians to access prescription drugs. This section will provide an overview of the key stakeholders that impact on access to prescription drugs for Canadians by answering the following questions:

Section 1.1: Responsibilities

1.1.1 What is the federal government's role in providing access to prescription drugs?

The federal government is responsible for setting and administering national principles or standards for the health care system through the *Canada Health Act.* This involves approving prescription drugs for market in Canada, and the ongoing monitoring of the safety, effectiveness, and the quality of drugs that are marketed in Canada.

In addition, the federal government provides direct health services to specific groups including: veterans, First Nations on reserves, Inuit, military personnel, inmates of federal penitentiaries and the Royal Canadian Mounted Police. As of 2004, the federal government will pay out approximately $2.2 billion per year for prescription drugs through various programs that reach about one million Canadians.

1.1.2 What is the role of provincial governments in providing access to prescription drugs?

The Provinces have primary constitutional jurisdiction for the provision of health care to Canadians, under the *Canada Health Act*. Within the parameters established by the Act, however, each province tailors its health care plan to meet the specific needs of its residents. For this reason, health care coverage, in general, and prescription drug coverage, more specifically, varies greatly from province to province. Provincial governments also decide which drugs will be covered under their provincial drug benefit plans, as discussed in greater detail in **Section 2.2** of this document.

All provinces provide drug coverage for low-income seniors and recipients of social assistance (welfare and disability among others) according to their formulary lists. Some provinces provide universal coverage to all seniors, and one province (Quebec) provides universal coverage to all residents who do not have any form of private insurance to cover prescription drug costs. For a complete listing of the types and eligibility for coverage by province, please see the table entitled **A Comparison of Provincial Health Benefits** in the Section 3.1.3 of this document.

1.1.3 What is the role of private health insurance in providing access to prescription drugs in Canada?

Some Canadians have drug coverage under some form of private health insurance, such as a work sponsored drug benefits plan.

1.1.4 How do private insurance plans determine which prescription drugs are covered?

Just like individual provinces, different private insurance companies have their own formularies and coverage plans. Each plan has their own process for deciding which drugs and how much of the cost of each drug will be covered by the plan so it is important for individuals to know and understand the particulars of their drug benefit plan.

1.1.5 What is a generic drug and how do they differ from brand name drugs?

A brand name drug is a drug that is protected, in Canada, by a patent. This means that only the company which holds the Canadian patent for that drug can produce and sell it or license it to another company for sale in Canada for the duration of the patent. A generic drug is a drug that cannot be covered by a Canadian patent because of the availability of an existing similar, brand name drug. Once the patent on the similar brand name drug has expired, any company that wants to can produce and sell the equivalent generic drug in Canada. Health Canada approves both generic and brand name drugs, and both are subject to similar standards of quality and production.

Before a generic drug is authorized for sale in Canada, its manufacturer must prove to Health Canada that the active ingredients in the generic drug are bioequivalent to those in the comparable brand name drug. This means that the active ingredients must be as pure, must dissolve at the same rate and must be absorbed in the same manner as those in the equivalent brand name drug.

Pharmacists have the option of switching a brand name drug for its generic equivalent, so if a consumer has been using a brand name drug and wants to make sure that they keep taking the same brand name version of that medicine, they need to specify to their pharmacist “no generic substitutions” when they are getting their prescriptions filled.

Section 1.2: Pricing

1.2.1 Who pays for prescription drugs in Canada?

The cost of prescription drugs in Canada is shared between Canadians themselves and coverage that is provided either through a government (federal or provincial) or private (typically provided through a drug benefit plan at work) drug benefit plan.

1.2.2 Do all drug benefit plans cover the entire cost of a prescription drug?

While almost half of the private drug benefit plans in Canada cover the entire cost of prescription drugs, many drug benefit plans (including all federal, territorial and provincial plans) will only cover a part of the total cost. There are three common types of drug benefit plans in this latter category:

- Those that pay for a percentage (generally ranging from 50% to 100%) of a recipient's prescription drug costs minus an annual deductible, and
- Those that pay for the entire cost of the drug(s), minus a co-payment.
- Those that use a system of reference-based pricing where the benefit plan will only pay an amount up to that of the reference drug in the class.

1.2.3 What is a formulary?

A formulary is a listing of:

a) The prescription (and non-prescription) drugs for which a particular health plan will pay all or part of the cost, and
b) The circumstances under which these costs will be paid.

There are two types of formularies, **open** and **closed**. An open formulary will cover the costs associated with any drug that is approved for sale in Canada, while a closed formulary only covers a specific list of drugs. Every provincial and federal health plan has its own closed formulary. Although it is still common for private insurance plans in Canada to use an open formulary, an increasing number of employers (about 20% as of 2000) are moving to a closed formulary structure, also known as a "managed formulary", and are paying only for a specific list of drugs (Health Canada, 2000). The federal government and each individual province has a committee to review any new drug that has been approved for sale in Canada and decide if that drug will be listed on their formulary.

Most provincial and federal drug benefit plans list the price that they will pay for the drugs listed on their own formularies. It may be all or a portion of the cost of a particular drug to Canadians. The maximum prices that will be paid for brand name drugs in Canada are set by the Patented Medicine Prices Review Board Canada. If a generic version of a drug is available, a benefit plan or formulary may specify that they will only pay an amount equal to price of the generic equivalent instead of the full price of the brand-name drug.

Most formularies have two kinds of listings for prescription drugs: **full** and **restricted**. A fully listed drug can be prescribed by any doctor and will be paid for by the drug benefit plan. In order to prescribe a restricted drug, a doctor must first get special written permission from the drug benefit plan in question.

1.2.4 How is the retail price of a prescription drug established?

The prices for brand name drugs in Canada are reviewed by the Patented Medicines Prices Review Board (PMPRB), a federal, quasi-judicial board that regulates the prices that can be charged by manufacturers of patented medicines. The purpose of this body is not to set the price that Canadians will pay for a drug, but rather to ensure that the maximum price for a patented drug in Canada is not excessive. The evaluation process the board uses to set the maximum price is quite complex and is based on factors such as the price of other drugs in the same therapeutic class and the price of the drug in other countries.

Once the price for a drug has been set, the manufacturer can sell the drug for any price, up to the maximum set by the board, to drug wholesalers or directly to pharmacies and hospitals. The price that a consumer will pay for a particular drug is determined by whether that drug is listed under their drug benefit plan and the amount that the formulary for that benefit plan has determined they will pay for that particular drug. In addition, different retail outlets charge a fee for "filling" the prescription, an amount that varies from one pharmacy to another.

Generic drugs are not subject to the PMPRB and their price is set on the free market.

Section 2: The Approval Process for Prescription Drugs in Canada

This section of the document answers some common questions about how prescription drugs are authorized for sale in Canada, why some drugs that are available in the United States are not available in Canada and the role that doctors and pharmacists play in ensuring that Canadians have access to prescription drugs.

The topics that are covered in this section are:

Section 2.1: Safety and the Approval Process

2.1.1 How do I know that the prescription drugs that are for sale in Canada are safe?

Before a prescription drug can be sold in Canada it must first be authorized for sale by the Health Products and Food Branch (HPFB) of Health Canada, following a comprehensive approval process. In this approval process the safety and well-being of Canadians is the primary concern. Drugs that are approved for sale in Canada are considered 'safe'; however, all prescription drugs will have risks as well as benefits.

It is important for all Canadians who take prescription drugs to be aware that it is impossible for the approval process for new drugs to examine the impact of the use of new drugs in all possible situations and for all possible types of individuals. In a small number of cases, the use of a drug may produce an unexpected, negative side-effect. These side-effects are known as adverse events and should be reported to a doctor who will notify the drug manufacturer and Health Canada. Please see **Section 5** of this document for more information on adverse events.

2.1.2 What is the process for approving drugs in Canada?

Before a new drug can be authorized for sale in Canada, it must undergo a formal drug approval process. This process consists of gathering information on how the drug works in both pre-clinical (non-human) and clinical (human) trials. Before a company receives permission to test a new drug in humans it must first conduct pre-clinical trials consisting of laboratory and animal studies. These studies determine whether the drug works in treating the disease or disorder for which it is intended, other effects (side-effects) that the drug may have, and the optimal dosage of the drug to use in human trials. If the results of the pre-clinical trials are promising then the person or company that is developing the drug (the sponsor) can apply to Health Canada for approval to conduct clinical trials on humans.

In order for a drug to be approved for sale in Canada, it must be proven to provide a definite health benefit for patients who are taking the drug in comparison with a control group of patients who are not taking the drug. This is known as a drug's efficacy. The efficacy of a new drug is determined through three stages of clinical trials.

> **Phase I: Safety** – The first phase of clinical trial examines the impact of using a drug on a limited number of individuals (normally less than 100) to determine a recommended dosage and to test for any side-effects. These trials are fairly brief and usually last from a few days to a few weeks.

Phase II: Effectiveness – The second phase of clinical trial looks at the impact of using a drug in the context of a larger number of individuals (generally in the range of 100-500) to determine if the drug produces the desired results. The second phase of drug testing is also used to determine which dosages of the drug are the most effective at delivering the desired results. Phase II trials last, on average, from six months to one year, although they can take longer in some cases.

Phase III: Duration and Longer Term Impacts – The third and final phase of clinical trials looks at the impact of using a drug on a much larger group of individuals (ranging from 500-2 500). These trials can also gather more information about the safety and effectives of the use of a drug, in comparison to either a placebo or to other existing drugs or medications. The length of Phase III trials can vary, but generally ranges from two to four years.

If the clinical trials demonstrate that the potential value of a drug outweighs its associated risks then the drug's sponsor can choose to file a New Drug Submission with Health Canada. The review process for prescription drugs is conducted by the Therapeutic Products Directorate (TPD) and the Biologics and Genetic Therapies Directorate (BGTD) at HPFB. New Drug Submissions contain detailed information about a drug's safety (any anticipated side effects), efficacy (health benefits) and quality, and include results from both the pre-clinical and clinical trials. The submission also includes a number of other important pieces of information about the production of the drug, its packaging and its labelling.

When the TPD or BGTD receive a New Drug Submission, they conduct a careful review and examination of all the submitted information to evaluate the safety, efficacy and quality of the drug. If they think it is useful, they will sometimes use external advisors or committees to aid in this review process. If, at the end of the review, the conclusion is reached that the benefits of the drug outweigh its risks, then the drug is authorized for sale in Canada and is issued a Notice of Compliance (NOC) and a Drug Identification Number (DIN). The Notice of Compliance is a document that gives the sponsor permission to market the newly authorized drug in Canada. Every prescription drug that has been approved for sale in Canada has a DIN number that must be printed on every container in which that drug is sold.

Once a drug is approved for sale in Canada, the Marketed Products Directorate at Health Canada is responsible for any post-market issues (such as collecting information about unexpected side-effects or reactions in some individuals or in certain circumstances), including monitoring and acting on reports of adverse drug reactions**.** Health Canada also has a separate directorate within HPFB called the Inspectorate that is responsible for ensuring that the production facilities that manufacture the drugs that are offered for sale in Canada meet international standards.

2.1.3 What are the limits of the drug approval process?

Although safety is the number one priority throughout the approval process for new drugs, it is important for Canadian consumers to understand that it is impossible to test a new prescription drug for every possible reaction, in every possible circumstance and for every possible user. What Health Canada can do, however, is study all of the data in a New Drug Submission (NDS) and determine, based on that information, whether the submitted drug has adequate supporting data and studies to prove that it is **safe, efficacious** and of consistent **quality**. If there is insufficient evidence to prove a drug's claims in any of these areas, then Health Canada will not authorize that drug for sale in Canada. If a drug is not authorized for sale in Canada, the drug's sponsor can re-submit it for approval with new or additional information to address the deficiencies that were identified in the original review, or they can appeal the decision to the Minister of Health of the Government of Canada.

2.1.4 How long does it take for a drug to go through the approval process?

The length of time that it takes to review a drug once it has been submitted to Health Canada depends on a number of factors, including the quality and size of the submission, and the workload at the Therapeutic Products Directorate (TPD) and at the Biologics and Genetic Therapies Directorate (BGTD) at the time that the New Drug Submission (NDS) is submitted. As of 2002, the review process was taking an average of 18 to 24 months to complete, from the time that the NDS is submitted until TPD or BGTD makes a decision for or against the authorization of the drug for sale. Concern has been expressed that this review time is longer than that of most OECD (Organization for Economic Development and Cooperation) countries. In response to this concern, in 2003 the federal government launched the Therapeutic Access Strategy to consult with stakeholders and to determine ways in which to improve the efficiency and effectiveness of Canada's drug authorization system.

Health Canada also has a Priority Review Process which allows for faster reviews of promising drug products that impact on life-threatening or severely debilitating illnesses, for which there are few effective therapies already on the market. Each year TPD and BGTD publish a summary of their actual review times in a given calendar year. Table 2.1 on the following page provides a summary of this information for the year 2003, in comparison with target review times.

2.1.5 What happens once a drug is authorized for sale by Health Canada?

Once a drug has a Notice of Compliance (NOC) and a Drug Identification Number (DIN), the company can market the drug in Canada and any doctor in Canada can write a prescription for the drug and pharmacies may then sell the drug to the public. When a drug receives NOC and a DIN number, it does not mean that the cost of the drug will be

covered by a particular health plan or that the drug will be available immediately for sale in Canada.

Table 2.1: Target Times vs. Actual Performance Times in the Authorization Process for New Drugs (2003)

New Drug Submissions (NDS) Review Process	Number of Submissions	Target Times - 2002 *(days)*	Range of Actual Performance Times – 2002 (*days)*	Average Actual Performance Times - 2002
Priority NDS	4	180	259-445	351
Non-Priority NDS	29	300	269-1184	665
Total NDS	33		259-1184	627

Source: Health Canada, Therapeutic Products Directorate, 2004

For a drug to be covered by a health plan, it must be submitted to each of the separate health plan's formulary committees for review. Formulary committees decide which drugs will be 'listed' – in other words, which drugs will be paid for by the health plan and which drugs will either be restricted access or will not be covered at all. Once a NOC has been issued, the drug's sponsor or company is permitted to submit the drug to each provincial formulary and other formularies for listing consideration. Many private drug benefit plans will cover most drugs once they receive their NOC. For a more complete description of the roles and responsibilities of provincial formularies, please read the sub-section 1.2.3 of this document entitled '**What is a formulary?'**document.

2.1.6 Some prescription drugs that are available in other countries do not seem to be available in Canada. Why is this?

In order for a drug to be authorized for sale in Canada, it must first be submitted for approval by the sponsor that plans to sell and distribute it. If it is not available in Canada it may be because it has not been submitted, the drug may be in the review process and this process may take longer in Canada than it does in another country, or a drug may be marketed in Canada under a different brand name than it is in other countries. To determine if a particular drug that is available in a foreign country is available in Canada under a different name, consult a local pharmacist.

2.1.7 Can I gain access to prescription drugs that have not yet been approved for sale in Canada?

There is a program called the **Special Access Program** that permits Canadians, under certain circumstances, access to drugs that have not yet been approved for sale in Canada. There is a full discussion of this program in the Section 4.2 of this document.

Section 2.2: The Role of the Provinces

2.2.1 How do the provinces decide which drugs they will cover?

After a drug has received its Notice of Compliance (NOC), the drug's sponsor is allowed (but not required) to submit that drug for listing to public and private formularies in Canada. The requirements for listing differ from province to province, but some of the information that is usually requested includes:

- Information on the manufacture and quality of the drug;
- Evidence of regulatory approval and a Drug Identification Number; and
- A specification of the price that will be charged for the drug.

Each province has its own advisory committee, mandate and budget for drug costs within their health care budget, and each province is responsible for making their own pharmacoeconomic decisions. These advisory committees make recommendations to the provincial Minister of Health about whether a drug should be listed on the provincial formulary (see also **'What is a formulary'** in Section 1.2.3 of this document) for which they are responsible, and whether the drug should have a full listing in which any licensed doctor can write a prescription and the patient can receive the drug through the formulary coverage, or restricted listing which means that the drug will only be covered after certain criteria are met and doctor must fill out a special form to ensure the patient can have the drug covered by the formulary.

Due to the differences in advisory boards, mandates and budgets, the lists of drugs that are covered vary widely from province to province, between federal and provincial formularies, and between public and private drug benefit plans. The variations include the number of drugs that are listed overall, the number of new drugs that are added to the listing each year, who can access these drugs, and how much of the price of the drug will be paid for by the Province. In some cases, if a generic version of a brand name drug is available in Canada; provincial formularies can specify that they will only pay an amount equal to the price of the generic version of a drug (which tend to be priced lower than their brand name equivalents).

Times to Listing and Number of Products Listed by Provincial Formularies (September 2001 to August 2003)

Public Formulary	% Public Prescription Drug Spend	Average Time to Listing in Days (Sept 2001 to Aug 2003)	Product Listings (n = 107) - Sept 2001 to Aug 2003 -		
			Total	Full	Restricted
BC	10.7%	450	22%	38%	63%
AB	5.4%	406	31%	67%	33%
SASK	2.1%	346	38%	34%	66%
MT	5.6%	551	39%	52%	48%
ONT	39.7%	494	23%	48%	52%
QUE	31.0%	374	48%	55%	45%
NB	1.7%	592	15%	38%	63%
NS	2.1%	428	27%	34%	66%
PEI	0.3%	744	16%	71%	29%
NF	1.5%	352	12%	85%	15%
Total/Average	100%	444	28%	50%	50%

Source: IMS Health, Provincial Reimbursement Advisor (2003)

2.2.2 How long does it take for a newly approved drug to be covered by my health plan?

A study by CMR International found that, in general, it takes about three months before a drug that is authorized for sale in Canada is available to consumers. The length of time it takes for formularies to make listing decisions varies greatly between provinces (between 350 and 600 days). Provinces with very complex listing requirements (such as Ontario) can take much longer to list a drug than those with a more streamlined process. Individuals can check the listing status of a drug in their province by contacting their **Provincial formulary** using the contact information provided at the end of this document.

2.2.3 What is the Common Drug Review?

Canada has recently put in a place a system known as the Common Drug Review (CDR). The CDR is a single process for reviewing new drugs and providing formulary listing recommendations to participating publicly-funded federal, provincial and territorial (F/P/T) drug benefit plans in Canada. All jurisdictions take part in the CDR with the exception of Quebec. Prior to the establishment of the CDR, each plan conducted its own drug reviews and had its own committee of experts to provide listing recommendations. The CDR was introduced to reduce duplication between formularies and streamline the system for listing newly approved drugs.

Concerns have been expressed about the CDR process, with some stakeholders expressing the view that it has actually lengthened the amount of time that it takes for a new drug to be listed on a provincial formulary. If a drug is not recommended for listing by the CDR then it will not, in all likelihood, be listed by any publicly-funded drug benefit plan. At the same time, however, if the CDR decides that a drug should be listed, each drug benefit plan still makes its own formulary listing and benefit coverage decisions based on the CDR recommendation and on the plan's own mandate, priorities and financial resources. Concern has also been expressed at the lack of patient involvement in the CDR process.

2.2.4 What can I do if I need a drug that is not currently listed on my province's formulary?

Every Province has a form of special authorization that can allow a patient to access a drug that is not covered under the provincial formulary. In general, this process involves a doctor submitting a specific request for the patient indicating why the non-listed drug is required and asking the province to provide coverage. Each province requires that a particular form or set of forms be completed and each request is compared against a set of criteria. The table entitled **A Comparison of Provincial Health Benefits** in the Section 3.1.3 of this document lists the type of process that is in place for special authorization in each province. To determine the process that is in place for special authorization in a particular province, contact the appropriate provincial formulary directly (the last Section of this paper provides a list of contact information for the provincial formularies).

2.2.5 What can I do if I think that a drug should be added to my provincial formulary or if my special authorization request is turned down?

Ultimately, all provincial formulary listing decisions are made by the provincial Minister of Health. Individuals who are unhappy either with a listing decision or with the outcome of a special authorization request can appeal the decision by contacting their local Member of the Provincial Legislature and asking them to intervene with the provincial Minister of Health, or by contacting their provincial Minister of Health directly.

2.2.6 What happens if I move from one province to another - can I still get the prescription drug or drugs that I am used to taking?

When a Canadian who is covered under a provincial drug benefit plan becomes a resident of a new province, their drug benefit plan coverage will change and the new province's formulary will apply. Since the formularies differ from province to province, both in terms of their coverage and the numbers and types of drugs that they list, this may mean that some of the drugs that an individual has been prescribed may no longer be paid for at the same level, or may not be paid for at all under their new coverage. In addition, an individual's coverage eligibility for a drug benefit plan may change. The chart in the

Section 3.1.3 of this document entitled **A Comparison of Provincial Health Benefits** provides an overview of the types of individuals who are covered under each province's drug benefit plan and the eligibility criteria that are applied to those who are covered.

Some provinces, (British Columbia, Ontario, Quebec and New Brunswick) have a three month delay from the time an individual becomes a resident in the Province to the time they become eligible for prescription drug coverage.

Similarly, drug coverage may change if a person changes private benefit plans – a situation that is common when changing jobs. Again, different drugs may be available with different coverage amounts. There may also be a waiting period from the end of one period of coverage (typically the last day of employment at one job) until an individual is eligible under their new drug benefit plan (which can take as long as six months after the commencement of employment in a new position under a new drug benefit plan).

Section 3: Types of Coverage that are Available to Help Canadians Pay for Prescription Drugs

Overall, almost 90% of Canadians are covered by some kind of drug benefit plan. This coverage may be from a federal program, a provincial health plan or a private insurance plan. This section explores the issue of drug plan coverage more closely and answers the following questions:

Section 3.1: Overview

3.1.1 Who is covered under provincial and other drug plans?

In general, there are two kinds of drug benefit plans – **private** and **government**. The following chart outlines individuals who are likely to be covered under each type of plan.

Table 3.1: Coverage under Private and Government Drug Benefit Plans

Private Plans	Government Plans
• Employment Benefit Plans • Individual Insurance Policies • Affinity-related group plans (e.g. university students, professional associations)	**Federal** • Registered Indians living on a reserve, eligible Inuit and Innu • Veterans • Military Personnel • RCMP • Federal Inmates **Provincial** • Seniors • Social Assistance Recipients • Institutionalized populations (health related and corrections) • Universal programs (available to all residents) – *Saskatchewan, Manitoba and British Columbia only*

Source: Applied Management in Assoc. with Fraser Group, Tristat Resources, 2000

3.1.2 Who is not covered at all?

Overall, approximately 90% of Canadian residents are covered by some form of drug benefit plan. Of these Canadians, about 10% are covered only for unusually high drug costs (termed 'catastrophic' drug costs) which are covered by the following provincial plans:

Table 3.2: Provincial Drug Plans Providing Protection from Catastrophic Costs

Province	Catastrophic Drug Coverage Provided by:
Ontario	**Ontario Trillium Plan**
Manitoba	**Pharmacare Plan**
Saskatchewan	**Prescription Drug Plan**
British Columbia	**Universal Plan**

Source: Kapur and Basu, Health Canada, 2003

In some provinces, individuals who are not seniors, are not on social assistance and who do not have access to private insurance are not covered by any form of drug benefits plan. As many as 25% of residents in the Atlantic Provinces fall into this category, as do approximately 20% of Albertans. Only Quebec offers universal coverage to all residents for routine purchases of prescription medication.

When seniors or those on social assistance move from one province to another, there can be a three-month delay before they become eligible for benefits in their new province of residence. Similarly, when an individual changes jobs, there can be a delay of up to six months before they become eligible for drug benefits under their new employer's benefits packages.

3.1.3 What are the differences between my province's health coverage and other Provincial health coverage plans?

As mentioned previously, there are a wide range of programs, benefits, eligibility and coverage provided under each of the provincial formularies. In some provinces, individuals who do not have a private drug benefit plan are only covered for so-called 'catastrophic' drug costs, or total yearly drug costs above a certain threshold (such as $1500 per year). This means that there are a number of individuals in these provinces whose drug costs do not cross the provincial threshold and hence have no drug coverage at all.

The 2003 First Minister's Health Accord provides for federal support to ensure that all Canadians protected against financial hardship from catastrophic drug costs by the end of 2005/06, so that Canadians, wherever they live, will have reasonable access to catastrophic drug coverage. Governments also committed to expanded and accelerated collaboration in pharmaceuticals management, on a variety of fronts.

Table 3.3 below provides a comparison of the provincial formularies by:

Eligibility – there are six (6) categories of individuals who are eligible for drug benefits in some provinces and not all provinces cover the same categories of individuals.

The most common categories of eligibility are:

1. Social Assistance
2. Seniors
3. Widows
4. Children <18
5. All Residents
6. Others

Criteria – within each of the eligibility categories there are a number of possible criteria (such as age, income, marital status, etc) which are used to determine whether an individual qualifies for coverage.

Conventional Coverage – the percentage of individuals in a Province who have some form of insurance (either public or private) that covers the purchase of most if not all of their prescription medications.

Catastrophic Coverage – the percentage of individuals in a Province who are covered only for catastrophic drug costs (costs over a certain threshold, at a minimum $1 500/year). These individuals must cover all drug costs up to this threshold from their household income.

Residents with No Coverage – the percentage or residents in a Province who are not eligible for any drug coverage under any circumstance.

Special Authorization - the program through which some Provinces provide special authorization to cover the costs drugs that are not listed on their formularies.

3.1.4 For which groups does the federal government provide prescription drug coverage?

The federal government provides direct health services to specific groups, including: veterans, First Nations Canadians living on reserves and eligible Inuit and Innu, military personnel, inmates of federal penitentiaries and the Royal Canadian Mounted Police. Members of the Royal Canadian Mounted Police or the Canadian Forces who have questions about their drug benefit coverage should contact their human resources representative. Federal inmates who have similar questions should contact the authorities in the facility in which they are incarcerated.

Table 3.3: A Comparison of Provincial Drug Benefits (2000)

Province	Eligibility	Criteria	Conv. Coverage (%)	Catastrophic Coverage (%)	Residents With No Coverage	Special Authorization
Newfoundland and Labrador	1. 2.	1. Income 2. Age	67.8	0.0	32.2	Special Consideration
Prince Edward Island	1. 2. 4.	1. Income 2. Age 4. Age, Family Income	71.5	0.0	28.5	Special Authorization
Nova Scotia	1. 2.	1. Income 2. Age, GIS benefit, Public plan premium expenditure	78.1	0.0	21.9	Exception Status Drug
New Brunswick	1. 2.	1. Income 2. Age, GIS benefit	75.1	0.0	24.9	Special Authorization Part A and B
Quebec	5.	5. Age, Income, Public plan premium expense, All residents	100.0	0.0	0	Medicamments d'exception; patient d'exception
Ontario	1. 2.	1. Income 2. Age	83.3	16.7	***	Limited use formulary benefits and Section 8
Manitoba	1. 6.	1. Income 6. No private coverage	69.0	31.0	***	Exception Drug Status
Saskatchewan	1. 2. 6.	1. Income 2. Age, GIS benefit 6. No private coverage	67.3	22.7	***	Exception Drug Status
Alberta	1. 2. 3.	1. Income 2. Age 3. Age, Marital Status, Income	80.1	0.0	19.9	Special Authorization
British Columbia	1. 2. 6.	1. Income 2. Age 6. No private coverage	76.8	23.2	***	Special Authority

Sources: Kapur and Basu, Health Canada, 2003; Jacobs and Bachynsky, Institute of Health Economics, 2000

**** All residents of Ontario, Manitoba, Saskatchewan and British Columbia have access to coverage for catastrophic drug costs under their provincial drug benefit programs. For some residents of these provinces, however, the out of pocket expense of prescription medications up to the threshold for catastrophic coverage is prohibitive leaving them without any effective coverage.*

Section 3.2: Recent Immigrants

All permanent residents in Canada are eligible for coverage under their provincial health care plan, and immigrants to Canada are encouraged to apply for medical coverage in their province of residence immediately upon arrival. In some provinces, temporary workers, students and some others in Canada on a temporary basis are also eligible for health care benefits. Permanent residents in British Columbia, Ontario, Quebec and New Brunswick have a three-month waiting period before they become eligible for provincial drug benefits. During this time, individuals must pay for temporary private health insurance coverage.

3.2.1 Will prescription drugs be covered under my provincial health coverage?

In general, provincial health plans only pay for essential or medically necessary services. Prescription drugs do not fall into this category. Some provinces (Quebec, Manitoba, Ontario, Saskatchewan and British Columbia) do pay for some non-medical services such as prescription drugs, or will pay for a portion of their total cost. Individuals who live in one of these provinces should contact their provincial formulary to determine their eligibility to receive benefits (numbers and addresses are provided at the end of this document).

3.2.2 What is the Interim Federal Health Program?

Refugee claimants who are needy or who are living in a province with a three-month eligibility waiting period can get emergency or essential health-care services through the Interim Federal Health Program at Citizenship and Immigration Canada (CIC). The Interim Federal Health Program's coverage includes essential prescription medication.

3.2.3 How can I tell if I'm eligible for the Interim Federal Health Program?

Immigration officers determine whether new immigrants are eligible for the Interim Federal Health Program (IFHP). New immigrants will be asked if they are in a position to pay for health care or are eligible for private or public health insurance. If the immigration officer is satisfied that an individual qualifies for the IFHP, the document giving access to coverage will be issued immediately.

3.2.4 How do I get more information?

For further information, individuals should contact their immigration officer. Health information for newcomers to Canada is available online at:
http://www.cic.gc.ca/english/newcomer/fact_health.html

Section 3.3: First Nations, Innu, and Inuit

First Nations, Innu and Inuit may be eligible for supplementary prescription drug coverage under the **Non-insured Health Benefits Program**.

3.3.1 What is the Non-Insured Health Benefits Program?

The Non-Insured Health Benefits (NIHB) Program of Health Canada provides supplementary health benefits to eligible First Nations and Inuit throughout Canada to meet medical or dental needs not covered by provincial, territorial or other third-party health insurance. The benefits and services of the NIHB Program are in addition to provincial and territorial insured health care programs.

3.3.2 Who is eligible?

To be an eligible recipient you must be a resident of Canada and one of the following:

- A registered Indian according to the *Indian Act*,
- An Innu member of one of the two Innu communities in Labrador (Davis Inlet and Sheshatshiu),
- An Inuk recognized by one of the Inuit Land Claim organizations, or
- An infant less than one (1) year of age, whose parent is an eligible recipient.

3.3.3 Which drugs and pharmaceutical services are covered under the NIHB program?

There are two types of medication which are covered under this program:

- Prescription drugs listed on the NIHB Drug Benefit List
- Approved over-the-counter medication

3.3.4 How do I access these drug benefits?

There are two simple steps to accessing the drug benefits plan:

- Visit a doctor, or any other licensed practitioner who will provide a prescription, and
- Bring the prescription to a pharmacy or to a nursing station or health center to be filled.

To obtain benefits the eligible individual will need to complete a Consent Form for themselves and any dependents. With consent, their benefits can be processed without delay and they will not have to pay for their prescription drugs up-front.

To talk to someone about consent, or to obtain the Consent Document and Consent Form call the NIHB Consent Information Centre, toll-free **at 1-888-751-5011**, or visit the website at:

www.healthcanada.ca/nihb-consent

3.3.5 I'm also covered under another health care plan. What does this mean for me?

For those individuals who are covered by another public or private health care plan, claims must first be submitted to these additional plans before they are submitted to the NIHB program.

3.3.6 How do I get more information on the Non-Insured Health Benefits Program?

For more information phone the NIHB Toll-Free Inquiry Centre at: **1-888-511-4666**

Contact the First Nations and Inuit Health Branch (FNIHB) Regional Office, or visit the Health Canada web site at:

www.hc-sc.gc.ca/fnihb/nihb/index.htm

Section 3.4: Veterans

The federal government provides a number of benefits for veterans with pensioned conditions.

3.4.1 What drug coverage benefits are available for veterans?

Eligible veterans are entitled to coverage from Veterans' Affairs Canada for drug benefits related to a pensioned (a condition that results from active service) condition. For treatments unrelated to a pensioned condition, veterans are required to access the provincial programs that are available to them. Clients eligible for health care benefits or services as veterans are provided with a **VAC Health Care Identification Card.**

Disability pensioners have access to treatment benefits, such as prescription drugs directly related to their pensioned conditions. Treatment benefits may also be provided to clients for non-pensioned conditions when these are not covered by a provincial health plan and the VAC client is receiving services under the Veterans Independence Program. Treatment benefits may also be provided when the veteran is within the income limits defined by the War Veterans Allowance Act.

3.4.2 What kind of drug coverage is available to eligible veterans?

Coverage includes most prescription drugs, some over-the-counter medications and some medical supplies. Most benefits can be readily accessed by eligible clients who have a prescription from their doctor or dentist. To better safeguard client health, however, some benefits may have to be pre-authorized by the Department. It is important to note that access to Veterans' Affairs Canada drug benefits will vary depending upon an individual's eligibility and specific health needs.

3.4.3 How do I obtain benefits?

Veterans must present their VAC Health Care Identification Card when filling their prescription from a provider who is a participant of the program. The provider will fill the order and send the bill to Blue Cross (who administers the system) for payment. Some benefits must be pre-authorized by Veterans' Affairs Canada before they can be issued by the provider. Information on participating providers can be obtained by calling the client information number printed on the VAC health care identification card where it says CLIENT INFO.

When prescriptions are filled by a provider who is not a participant of the VAC/Blue Cross System, veterans are required to pay for the prescription and will be reimbursed at a later time. If this is the case, veterans should call the client information number before obtaining the benefit to ensure that it is a benefit that is in fact covered by Veteran's Affairs Canada.

3.4.4 How do I get more information on prescription drug coverage for veterans?

Information on the health care program of Veterans' Affairs Canada can be found at:

http://www.vac-acc.gc.ca/clients/sub.cfm?source=services/healthcare

A **document** in pdf format called "**A Guide to Access VAC Health Benefits and The Veterans Independence Program**" is also available at this address.

Information is also available by telephone at:

1-866-522-2122 (English)
1-866-522-2022 (French)

Section 4: Accessing drugs that are Unavailable in Canada or that are not Covered by Insurance

Canadians may need access to prescription drugs that are either not yet approved for sale and/or are not yet available in Canada. At other times, Canadians may also need access to expensive prescription drugs that are not covered under their insurance plan's drug benefits. This section answers some questions about what individuals can do if they find themselves in either of these situations.

Section 4.1: Affordability

4.1.1 What options do I have if my doctor says that I could benefit from a drug that I cannot afford?

If a doctor indicates that an individual would benefit from a drug that is not listed on their provincial formulary, and if that individual is not eligible for drug benefits under any other insurance plan, they can apply to their provincial formulary for Special Authorization (as described in Table 3.3 of the previous section of this document). Individuals may also want to contact a disease support group that deals specifically with the illness or condition that requires the use of the medication (for examples of some disease support groups and their contact information please see the list of **Sponsoring Organizations** at the end of this document). These organizations may be able to help to identify additional sources of funding and they can serve as an invaluable resource in helping to address the challenges associated with these conditions. Local charity or social service groups may also be able to direct individuals to additional sources of funding to offset the costs of prescription drugs. A final option that may be available under certain circumstances is for individuals to apply to participate in clinical trials of new drugs.

4.1.2 How can I get involved in clinical trials for new drugs?

Eligibility for participation in clinical trials varies with each trial depending on the type of drug that is being tested and the types of individuals that are required for the trial. Potential benefits from volunteering for these trials include gaining access to medications that are not yet available on the market and gaining access to greater medical attention during the trial period. The negative aspects of volunteering can include the possible ineffectiveness of the new treatments beyond that of existing drugs that are already approved for sale, unintended side-effects of the new drug and/or receiving no benefit at all from the medication (since a certain number of participants in any clinical trial will be given a placebo in order to compare their results with participants who received the actual medication).

Lists of some ongoing and upcoming clinical trials can be found at:

www.myhealthcanada.com

4.1.3 What are my options if my doctor feels I require a particular drug that is not yet available in Canada?

If a doctor feels very strongly that a particular prescription drug is required that is not currently approved for sale in Canada, they can ask Health Canada in writing to allow individuals to have access to that particular drug. This type of request is known as Special Access and is part of the Special Access Program.

Section 4.2: The Special Access Program

4.2.1 What is the Special Access Program (SAP)?

The Special Access Program is designed to allow medical practitioners access to drugs that are not approved or offered for sale in Canada. Requests for special access are limited to patients with serious or life-threatening conditions in the event that conventional therapies have failed, are unsuitable, or are unavailable. Access is granted on a compassionate or emergency basis. Under these conditions, the Special Access Program can authorize the sale of a drug that would not otherwise be sold in Canada.

The Special Access Program is not intended to promote the early use of drugs, or to circumvent the new drug approval process. It is intended to provide compassionate access to drugs on an individual patient basis.

4.2.2 Who makes a request to the SAP – the patient or doctor?

An individual's doctor is responsible for initiating a request on their behalf and for ensuring that the decision to prescribe the drug in question is supported by credible evidence. Credible evidence may be found in the medical literature, or may be supplied by the manufacturer. The doctor is also responsible for ensuring that the patient is thoroughly informed of the possible risks and benefits of the drug being requested.

4.2.3 What types of drugs are typically authorized for use under the SAP?

Most of the drugs that are authorized under the Special Access Program treat patients with life threatening diseases or serious conditions such as intractable depression, epilepsy, transplant rejection, hemophilia and other blood disorders, terminal cancer, and AIDS. The Special Access Program can also respond to a specific health crisis, such as an outbreak of a communicable disease, by providing Canadians with access to non-marketed drugs.

4.2.4 If the SAP approves access to a drug, does that mean that it is safe?

No. Special Access Program authorization does not constitute an opinion or claim that a drug is either safe, effective, or of high quality. The SAP does not conduct comprehensive evaluations of the validity of drug information, nor of manufacturer's claims regarding safety, effectiveness or quality. It is the responsibility of an individual's doctor to carefully consider all the available information before making a submission to the SAP.

4.2.5 How long does it take to process a request to the SAP?

Every effort is made to process requests within 24 hours of receipt; however, requests for drugs for life-threatening conditions are given top priority. If a request is made for a drug that is new to the program it may take longer.

4.2.6 What conditions may be placed on the use of drugs accessed under the SAP?

The manufacturer has the right to impose restrictions on the use of their drug, typically to ensure compliance with the latest information regarding the safe use of the drug. Restrictions may include a limit on the amount of drug shipped, requests for further patient information, and conditions on shipping arrangements. Manufacturers also have the right to refuse to supply a drug.

Drugs accessed under the SAP may only be shipped to a doctor's office, or in-patient (hospital) pharmacies. Manufacturers are not permitted to ship directly to retail pharmacies under the SAP.

4.2.7 Who pays for the drugs being released though the SAP?

Manufacturers have the right to set the pricing of drugs accessed under the SAP. In practice, many release these drugs free of charge, although they are not required to do so. If there is charge, the cost must be covered by one of the following: the patient, the patient's family, the hospital, or a public and/or private insurance plan.

Section 5: What to do if a prescription drug is causing an unanticipated side-effect

Ideally, every prescription drug that is taken in Canada would do exactly what it is intended to do without any harmful side effects. In reality, however, every drug reacts a little differently with every person. Although drug companies undertake extensive testing to make sure that the drugs they sell are safe and effective, it is not possible for a company to test a drug under all possible circumstances. This section addresses the issue of what Canadians should do if they think that a drug that they are taking is having an unexpected side-effect or consequence, by answering the following questions:

Note: much of the information in this section is sourced from the Therapeutic Products Directorate Web Site at Health Canada.

5.1 Adverse Drug Reactions

5.1.1 What is an Adverse Drug Reaction?

When a drug has an unintended side-effect (a side effect being any unwanted reaction caused by taking the drug; for example, if an individual is taking a drug to treat high blood pressure and it also gives them a headache, the headache would be a side effect.), this is known as an adverse drug reaction.

A *serious* adverse drug reaction occurs when the side-effect happens at any dose and requires in-patient hospitalization or prolongation of existing hospitalization, causes congenital malformation, results in persistent or significant disability or incapacity, is life-threatening or results in death.

All prescription drugs will have both benefits and risks. An adverse reaction can occur even when the drug is being used as prescribed, and under normal conditions. Adverse reactions can range in severity from minor, such as a skin rash, to life threatening, such as a heart attack or liver damage.

5.1.2 Aren't prescription drugs supposed to be safe before they are approved for sale to Canadians?

Before a drug is approved for sale, safety and efficacy testing is done through clinical trials. These clinical trials mostly detect common and frequent adverse reactions. Adverse reactions, however, may develop over a longer period of time or may occur infrequently and are therefore not detected during these trials. In addition, clinical trials do not always mirror the real world conditions in which a particular drug may be used. For example, someone taking many different drugs might have an adverse reaction caused by the combination of the different drugs being taken together.

5.2 Reporting Adverse Drug Reactions

5.2.1 How is information on adverse reactions collected in Canada?

In Canada, the federal government is responsible for collecting and analyzing information on adverse reactions. The federal government relies heavily on voluntary reporting of suspected reactions by patients and health care professionals as well as reporting by the companies that are selling the drug in Canada.

Adverse reaction monitoring is coordinated nationally by the Marketed Health Products Directorate of Health Canada. Reports are collected by five regional Adverse Reaction Centres, in addition to the National Office in Ottawa. (For an Adverse Reaction Centre

in your area, please see the **Important Numbers and Other Contact Information** at the end of this document). Regional centres review incoming adverse reaction reports for quality and completeness, and then the reports are processed and analyzed by the National Office.

5.2.2 Aside from voluntary reporting, how else is information on adverse reactions being collected?

The Marketed Health Products Directorate collects additional information on adverse reactions from the following sources:

- Post-marketing studies conducted by manufacturers or health care institutions;
- Active surveillance activities which include the regular periodic collection of case reports from health professionals and health facilities;
- Publications in scientific journals;
- Collaboration with patient groups, academic institutions, professional associations in Canada and internationally; and
- Risk-communications from regulatory agencies in other countries.

In addition, manufacturers are legally responsible for providing Health Canada with any significant safety information for health products they sell in Canada.

5.2.3 What types of information are collected in adverse reaction reports?

If an individuals wishes to report an adverse reaction**,** they should first talk with their doctor, nurse or other health care professional. These health care professionals can help to make sure that reports contain all the information that Health Canada needs. If an individual is unable to speak with a health care professional of any kind then they can make a report by themselves to any of the Adverse Reaction Centres. Reports should contain the following information:

- A description of who is making they report and why they are taking the drug,
- Details about the reaction(s) that are suspected to have occurred as a result of the use of the drug, and
- The treatment and any final outcome(s) for the adverse reaction.

5.2.4 What if I put personal information in a report?

The identity and personal information about the individual making a report, along with the identity of their doctor, will be kept confidential.

5.2.5 How are adverse reaction reports used by the federal government?

Adverse reaction reports are analyzed to discover indications of possible safety issues with a drug. These possible indications are called *signals*. Once a signal is discovered, it is analyzed by experts to determine how likely it is that the reported adverse reaction was in fact related to the drug in question. In doing this analysis, these experts take into account factors such as the:

- Frequency, severity, plausibility, and quality of the information contained in the reports;
- Amount of the drug used;
- Time needed for the appearance of the reaction;
- Presence of any underlying diseases;
- Simultaneous use of other medications; and
- Evidence of disappearance or reappearance of the reaction once the drug was discontinued or reintroduced.

Additional studies and consultations with other regulatory agencies are often necessary to confirm the drug - adverse reaction relationship. Active international collaboration is essential in Canada's efforts to monitor adverse reactions, as we benefit greatly from the findings of countries with much larger populations.

5.2.6 How many reports does it take to trigger action?

Each single case is considered unique and is examined on its own merits. There is no set formula or specific number of reports that trigger an action, however; there is a general consensus among experts that more than one report is usually needed.

5.2.7 What sort of actions may be taken?

Health Canada and/or the company that makes and distributes a drug can take many types of action in response to analysis of adverse reaction reports, including:

- Canceling the marketing authorization (NOC) in Canada (so the drug can no longer be sold in Canada),
- Conducting studies to try to get a better idea of why a reaction is happening and how common it might be,
- Altering the packaging to clearly identify potential risks and providing instructions on the proper use of the drug,
- Issuing public alerts, and
- A variety of other activities depending on the number of reports and the types of reactions that are being reported in Canada and in the rest of the world.

5.2.8 How can I make an adverse reaction report?

Adverse reactions can be reported toll free to Health Canada at:

Tel: (866) 234-2345
Fax: (866) 678-6789

Calls will be directed to the appropriate Adverse Reaction Regional Centre.

5.2.9 Where can I get more information on adverse reactions and adverse reaction reporting?

The Canadian Adverse Reaction Newsletter is a quarterly publication that alerts health professionals and consumers to emerging patterns detected in the reviews of reports submitted to Health Canada. In addition, Health Canada and/or manufacturers can put out health product advisories as a result of the information which they get from adverse reaction reports. Advisories, warnings and fact sheets can also be found at:

http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_advisories_e.html

Section 6: Changes that could Impact on Access to Prescription Drugs in Canada

Because of concerns which have been expressed both by doctors and the public about the large discrepancies in drug benefit plan coverage between provinces, federal government programs and private insurance plans, the process for accessing prescription drugs in Canada has been the subject of many studies and reviews. This last section provides a glimpse of some possible (or likely) developments in how prescription drugs will be handled in Canada in the future.

6.0.1 What changes can Canadians expect that will impact on their access to prescription drugs?

Over the years, many recommendations have been made to address the differences in formulary coverage for prescription drugs in Canada. The 2002 Romanow Commission on the Future of Health Care in Canada recommended the establishment of a national formulary to ensure that the same prescription drugs are available to Canadians equally in every province.

To date, some progress has been made in this regard. Federal, provincial and territorial Health Ministers have agreed to establish a single common process for reviewing drugs for potential coverage under drug benefit plans in Canada and in March 2002, an interim Common Drug Review (CDR) body was set up at the Canadian Coordinating Office for Health Technology Assessment. This interim office is responsible for sharing drug reviews among participating jurisdictions. Despite this common review process, decisions to list drugs on provincial formularies remain with each participating province. Although Quebec does not formally participate in this process, it does share information and best practices.

Various groups and individuals have suggested that the creation of a drug review agency in Canada would have a beneficial impact on some issues relating to access to prescription drugs in Canada. Whether drugs are reviewed by a Branch of Health Canada (as they are now) or by a separate agency (like they are in the United States), there will not be any difference in terms of the responsibility of this body to ensure the safety, efficacy and quality of the drugs that are approved for Canadians. Some claims have been made, however, that the move to a drug review agency would act as a driver to reduce the review times for new drug submissions. Whether or not a change is made and an agency is formed, the federal government is striving to make the review process more transparent. This means that consumers will have more access to information on newly approved drugs and comments from the approval process by the reviewers.

Annex 1: Important Numbers and Other Contact Information

This Annex provides important contact information for federal and provincial government agencies that play an important role in accessing prescription drugs in Canada, and for the organizations that sponsored the production of this document.

Health Canada

Health Products and Food Branch

- Questions and concerns can be directed to: hpfb-dgpsa@hc-sc.gc.ca

Therapeutic Products Directorate

- Questions can be directed to: sipdmail@hc-sc.gc.ca.

Marketed Health Products

- Adverse reactions can be reported toll free to Health Canada at:

  Tel: 866 234-2345
  Fax: 866 678-6789

The Special Access Program

- Requests to the Special Access Program should be made through your doctor or other health care professional at:

  Special Access Programme
  Therapeutic Products Directorate
  Finance Building, 2nd Floor
  PL 0202C1, Tunney's Pasture
  Ottawa, ON, K1A 1B9

  TEL: (613) 941-2108 FAX: (613) 941-3194

  E-MAIL: SAPdrugs@hc-sc.gc.ca
  WEB SITE: http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/index_sap_e.html

Provincial Drug Formularies

Note: while all formularies list a contact phone number, some formularies list contact e-mails while others list contact addresses. Every formulary will respond to enquiries by telephone, fax, e-mail or letter.

Alberta Health Care Insurance Plan

1-780-427-1432
health.ahcipmail@gov.ab.ca

British Columbia Pharmacare Program

1-800-554-0250

BC PharmaCare
PO Box 9655 Stn Prov Govt
Victoria, British Columbia
V8W 9P2

Manitoba Pharmacare

1-800-297-8099
pharmacare@gov.mb.ca

New Brunswick Prescription Drug Program

1-506-453-2536
bc_nbpdp@atl.bluecross.ca

Department of Health and Wellness
P.O. Box 5100
Fredericton, N.B. CANADA E3B 5G8
fax: (506) 444-4697

Newfoundland and Labrador Prescription Drug Program

1-709-753-3615
nlpdp@mail.nf.ca

Nova Scotia Senior's Pharmacare Program

1-800-544-6191
http://www.gov.ns.ca/health/pharmacare/seniors_pharmacare_faq.htm

Ontario Drug Benefits Program

1-866-811-9893
DrugPrograms@moh.gov.on.ca

Drug Programs Branch
5700 Yonge Street, 3rd Floor
Toronto, Ontario
M2M 4K5
Canada

Ontario Trillium Plan
(*coverage for catastrophic drug costs in Ontario*)
1-800-575-5386
TrilliumDrugProgram@moh.gov.on.ca

Prince Edward Island Drug Cost Assistance Programs Formulary
1-902-368-6711

Second Floor, Jones Building
11 Kent Street
PO Box 2000,
Charlottetown, PE
C1A 7N8

Quebec Basic Prescription Drug Insurance Plan
1 800 561-9749
http://www.ramq.gouv.qc.ca/en/courrier/citoyencourriel.shtml

Québec
1125, chemin Saint-Louis
Sillery (Québec) G1S 1E7

Montréal
425, boul. de Maisonneuve Ouest, 3rd floor
Suite 303
Montréal (Québec) H3A 3G5

Saskatchewan Drug Plan and Extended Benefits Branch
1-800-667-7766
dpebweb@health.gov.sk.ca

T.C. Douglas Building
3475 Albert Street
Regina, Saskatchewan
CANADA
S4S 6X6

Regional Adverse Drug Reaction Centres in Canada

British Columbia
British Columbia Regional AR Centre
c/o BC Drug and Poison Information Centre
1081 Burrard Street
Vancouver BC V6Z 1Y6
Tel: (604) 806-8625 Fax: (604) 806-8262
adr@dpic.ca

Ontario
Ontario Regional AR Centre
c/o LonDIS Drug Information Centre
London Health Sciences Centre
339 Windermere Rd.
London ON N6A 5A5
Tel: (519) 663-8801 Fax: (519) 663-2968
adr@lhsc.on.ca

Atlantic
Atlantic Regional AR Centre
For New Brunswick, Nova Scotia, Prince Edward Island
and Newfoundland
c/o Queen Elizabeth II Health Sciences Centre
Drug Information Centre
1796 Summer Street, Rm 2421
Halifax NS B3H 3A7
Tel: (902) 473-7171 Fax: (902) 473-8612
adr@cdha.nshealth.ca

Saskatchewan
Saskatchewan Regional AR Centre
c/o Saskatchewan Drug Information Service
College of Pharmacy and Nutrition
University of Saskatchewan
110 Science Place
Saskatoon SK S7N 5C9
Tel: (306) 966-6329 Fax: (306) 966-2286
Sask.AR@usask.ca

Québec
Québec Regional AR Centre
c/o Drug Information Centre
Hôpital du Sacré-Coeur de Montréal
5400, boul. Gouin ouest
Montréal (QC) H4J 1C5
Tel: (514) 338-2961 Fax: (514) 338-3670
cip.hscm@sympatico.ca

All other provinces and territories
National AR Centre
Marketed Health Products Safety and Effectiveness Information Division
Marketed Health Products Directorate
Finance Building, Tunney's Pasture
AL 0201C2
Ottawa ON K1A 1B9
Tel: (613) 957-0337 Fax: (613) 957-0335
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www.diabetes.ca

Heart and Stroke Foundation of Canada
222 Queen Street, Suite 1402
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Telephone: (613)569-4361
Fax: (613)569-3278
www.heartandstroke.ca

The Arthritis Society
The Arthritis Society (National Office)
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Fax: 416-979-8366
E-mail: info@arthritis.ca
www.arthritis.ca

The Lung Association
1-888-566-5864
www.lung.ca
For a listing of provincial offices, see the website listed above.

The Lung Association (National Office)
3 Raymond Street, Suite 300
Ottawa, ON K1R 1A3
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Phone: 613-569-6411
Fax: 613-569-8860
E-mail: info@lung.ca

Annex 2: References and Website of Interest

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Websites

AARP, www.aarp.org

The Arthritis Society, www.arthritis.ca

Best Medicines Coalition, www.bestmedicines.ca

Canadian Diabetes Association, www.diabetes.ca

Canadian Institutes for Health Research, www.cihi.ca

The Canadian Journal of Clinical Pharmacology, www.pulsus.com

Canadian Pharmacists Association, www.pharmacists.ca

Consumer Advocare Network, www.consumeradvocare.org

The General Medical Journal, www.bmj.com

Health Canada, www.hc-sc.gc.ca
Health Products and Food Branch, www.hc-sc.gc.ca/hpfb-dgpsa
Therapeutic Products Directorate, www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt

Heart and Stroke Foundation of Canada, www.heartandstroke.ca

Hewitt Associates – Canada, was4.hewitt.com

Institute of Health Economics, www.ihe.ca

National Library of Medicine, www.ncbi.nlm.nih.gov

The Lung Association, www.lung.ca

Rx&D, www.canadapharma.org

University of British Columbia, www.publicaffairs.ubc.ca,
www.pharmacoeconomics.ubc.ca

Ward Health Strategies, www.wardhealth.com

The Whitehouse, www.whitehouse.org

Websites for Provincial Formularies as listed above

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