

COUNTRY PROFILE CANADA

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Legal System

Canada is a federal parliamentary democracy and constitutional monarchy based on the British common law system, except for Quebec, which has a civil law system based on the French Code Napoleon. Canada has a bi-jurisdictional system as the responsibilities of public and private law are separated and exercised exclusively by the Parliament and provinces/territories respectively.

Health Care System

Canada has a publicly funded health care system. Publicly funded health care is financed with general revenue raised through federal, provincial and territorial taxation. [1] Roles and responsibilities for Canada's health care system are shared between the federal and provincial-territorial governments. The roles of the federal government in health care include:

1. Setting and administering national policies for the system under the *Canada Health Act*
2. Provide financial support to the provinces and territories by means of cash and tax transfers through the Canada Health Transfer.
3. Funding and delivering of primary and supplementary services to certain groups of people such as Inuit, serving members of the Canadian forces, inmates and refugees. [2]

The provinces and territories administer and deliver most of Canada's health care services, with all provincial and territorial health insurance plans expected to meet national principles set out under the *Canada Health Act*. [3] Each provincial and territorial health insurance plan covers medically necessary hospital and doctors' services that are provided on a pre-paid basis, without direct charges at the point of service. [4] Provinces and territories provide coverage to certain people (e.g. seniors, children and low-income residents) for health services that are not generally covered under the publicly funded health care system (supplementary services). [5] The level of coverage varies across the country. Those who do not qualify for supplementary benefits under government plans pay for these services through out-of-pocket payments or through private health insurance plans. [6]

Treaty Ratifications

	Signed	Ratified	Acceded
International Convention on Economic, Social and Cultural Rights (ICESCR)	-	-	19 May 1976

Convention on the Elimination of All Forms of Discrimination against Women (CEDAW)	17 July 1980	10 December 1981	-
Convention of the Rights of the Child (CRC)	28 May 1990	13 December 1991	-
ILO Convention 169 (Indigenous and Tribal People Convention)	-	-	-
International Convention on the Protection of the Rights of All Migrant Workers and Members of their Families	-	-	-

Constitution

The Constitution Act does not establish a right to health. However, it does refer to the right to life, a health-related right.

Paragraph 7 Canadian Charter of Rights and Freedoms (Part I of the Constitution Act, 1982):
“Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice”

Overview of Relevant Provisions

Indicator	National Legislation	National Regulation
Government Commitment Mandatory language	One of the primary objectives of Canadian health care policy is to facilitate reasonable access to health services without financial or other barriers. [7]	
Sustainable Financing State reimbursement scheme	<p>The Canada Health Act sets out criteria which health care insurance plans, established by the law of the provinces and territories, must satisfy. [8]</p> <p>Paragraph 12 of this Act expatiates on the accessibility criterion. The provincial and territorial plans must provide all insured persons reasonable access to medically necessary hospital and physician services without financial or other</p>	

	barriers.	
Sustainable Financing State subsidy		
Rational Selection Essential medicines framework	<p>The Minister of Health may establish a list that sets out prescription drugs, classes of prescription drugs or both. [9]</p> <p>In the light of the Canadian Access to Medicines Regime (CAMR), schedule 1 of the Patent Act elaborates a list of patented pharmaceutical products. [10]</p>	<p>The Prescription Drugs List replaces Schedule F to the Food and Drugs Regulations. The Minister of Health directs the authority to a senior official within the Health Products and Food Branch of Health Canada, who makes a decision following a recommendation from a Health Canada committee of scientific experts. [11]</p>
Affordable Prices Availability of generics	<p>Establishes a Patent Medicines Prices Review Board, which has the power to direct the patentee, by order, to cause the maximum price of patented medicines to be reduced to such a level the Board considers non excessive. [12]</p> <p>The purpose of sections 21.02 to 21.1 Patent Act, as a part of the CAMR, is to give effect to Canada's and Jean Chretien's pledge to Africa Act by facilitating access to pharmaceutical products to address public health problems afflicting many developing and the least-developed countries. [13] It represents the first implementation of the TRIPS flexibilities declared in the August 30, 2003 General Council decision of the World Trade Organization (WTO).</p>	<p>The application for authorization under section 21.04 Patent Act is elaborated in the Use of Patented Products for International Humanitarian Purposed Regulations.</p>

Observations

- The right to health or, more specifically, the right to essential medicines, is not explicitly stated in the Canadian Constitution.
- Canada acceded to the International Covenant on Economic, Social and Cultural Rights and ratified the Convention on the Elimination of All Forms of Discrimination against Women and the Convention of the Rights of the Child.
- Although the Minister of Health established a list of prescription drugs, the list could not be considered as an essential medicine list because it is only a list of medicinal ingredients that when found in a drug, require a prescription.
- With the introduction of the Canadian Access to Medicine Regime, a framework is provided in order to address the problem of unaffordability of medicines in many developing countries and the least-developed countries.

Government Commitment Overview

Canada Health Act

3. It is hereby declared that the primary objective of Canadian health care policy is to protect, promote and restore the physical and mental well-being of residents of Canada and to facilitate reasonable access to health services without financial or other barriers.

Sustainable Financing (State Reimbursement scheme) Overview

Canada Health Act

12. (1) In order to satisfy the criterion respecting accessibility, the health care insurance plan of a province

- (a) must provide for insured health services on uniform terms and conditions and on a basis that does not impede or preclude, either directly or indirectly whether by charges made to insured persons or otherwise, reasonable access to those services by insured persons;
- (b) must provide for payment for insured health services in accordance with a tariff or system of payment authorized by the law of the province;
- (c) must provide for reasonable compensation for all insured health services rendered by medical practitioners or dentists; and
- (d) must provide for the payment of amounts to hospitals, including hospitals owned or operated by Canada, in respect of the cost of insured health services.

Rational Selection Overview

Food and Drugs Act

29.1 (1) The Minister of Health delegates the authority to a senior official within the Health Products and Food Branch of Health Canada, who makes a decision following a recommendation from a Health Canada committee of scientific experts.

(2) The list is not a regulation within the meaning of the Statutory Instruments Act.

Patent Act

21.02 (...) "pharmaceutical product" means any patented product listed in Schedule 1 in, if applicable, the dosage form, the strength and the route of administration specified in that Schedule in relation to the product.

21.03 (1) The Governor in Council may, by order,

(a) on the recommendation of the Minister and the Minister of Health, amend Schedule 1

(i) by adding the name of any patented product that may be used to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics and, if the Governor in Council considers it appropriate to do so, by adding one or more of the following in respect of the patented product, namely, a dosage form, a strength and a route of administration
(...)

Affordable prices Overview

Patent Act

21.01 The purpose of sections 21.02 to 21.2 is to give effect to Canada's and Jean Chrétien's pledge to Africa by facilitating access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

83. (1) Where the Board finds that a patentee of an invention pertaining to a medicine is selling the medicine in any market in Canada at a price that, in the Board's opinion, is excessive, the Board may, by order, direct the patentee to cause the maximum price at which the patentee sells the medicine in that market to be reduced to such level as the Board considers not to be excessive and as is specified in the order.

(2) Subject to subsection (4), where the Board finds that a patentee of an invention pertaining to a medicine has, while a patentee, sold the medicine in any market in Canada at a price that, in the Board's opinion, was excessive, the Board may, by order, direct the patentee to do any one or more of the following things as will, in the Board's opinion, offset the amount of the excess revenues estimated by it to have been derived by the patentee from the sale of the medicine at an excessive price:

- (a) reduce the price at which the patentee sells the medicine in any market in Canada, to such extent and for such period as is specified in the order;
- (b) reduce the price at which the patentee sells one other medicine to which a patented invention of the patentee pertains in any market in Canada, to such extent and for such period as is specified in the order;
or
- (c) pay to Her Majesty in right of Canada an amount specified in the order.

(3) Subject to subsection (4), where the Board finds that a former patentee of an invention pertaining to a medicine had, while a patentee, sold the medicine in any market in Canada at a price that, in the Board's opinion, was excessive, the Board may, by order, direct the former patentee to do any one or more of the following things as will, in the Board's opinion, offset the amount of the excess revenues estimated by it to have been derived by the former patentee from the sale of the medicine at an excessive price:

- (a) reduce the price at which the former patentee sells a medicine to which a patented invention of the former patentee pertains in any market in Canada, to such extent and for such period as is specified in the order; or
- (b) pay to Her Majesty in right of Canada an amount specified in the order.

(4) Where the Board, having regard to the extent and duration of the sales of the medicine at an excessive price, is of the opinion that the patentee or former patentee has engaged in a policy of selling the medicine at an excessive price, the Board may, by order, in lieu of any order it may make under subsection (2) or (3), as the case may be, direct the patentee or former patentee to do any one or more of the things referred to in that subsection as will, in the Board's opinion, offset not more than twice the amount of the excess revenues

estimated by it to have been derived by the patentee or former patentee from the sale of the medicine at an excessive price. (5) In estimating the amount of excess revenues under subsection (2), (3) or (4), the Board shall not consider any revenues derived by a patentee or former patentee before December 20, 1991 or any revenues derived by a former patentee after the former patentee ceased to be entitled to the benefit of the patent or to exercise any rights in relation to the patent.

(6) Before the Board makes an order under this section, it shall provide the patentee or former patentee with a reasonable opportunity to be heard.

(7) No order may be made under this section in respect of a former patentee who, more than three years before the day on which the proceedings in the matter commenced, ceased to be entitled to the benefit of the patent or to exercise any rights in relation to the patent.

Provincial Legislation – Saskatchewan

Health Care System Saskatchewan

The Saskatchewan health care system is made up of many provincial, regional and local organizations working together. The Minister of Health oversees the strategic direction of the system and Saskatchewan Health oversees and coordinates the delivery of health services in the province. It is the responsibility of the province to establish a health care insurance plan, which meets the conditions and criteria set out in the Canada Health Act. The Prescription Drugs Regulations provide, in the light of the Medical Insurance Act and the Canada Health Act, financial assistance to a variety of groups such as children, elderly, low income families and residents in need of special assistance. Indigenous people, such as the Inuit, receive financial support from the federal government.

Drug Plan and Extended Benefit Branch

The Minister of Health compiled, with advice of the Drug Advisory Committee, the Saskatchewan Formulary. The formulary is a list of therapeutically effective drugs of proven high quality that have been approved for coverage under the Drug Plan. However, some drugs are reviewed and recommended for coverage under the Exception Drugs Status (EDS). [14] Examples are drugs that have potential use in other than the approved indications (off-label use), drugs that are more expensive than listed alternatives and offers an advantage in only a limited number of indications or drugs that are ordinarily administered only to hospital in-patients but are being administered outside the hospital because of unusual circumstances. [15] Drugs approved for EDS coverage are subject to the same deductible and co-payment as formulary drugs. The criteria for coverage under EDS are listed in appendix A of the formulary.

Only the accepted tendered drug can be used to fill a prescription in a Standing Offer Contract (SOC) interchangeable group. If a prescription is ordered as “no substitution” for any brand other than the SOC brand listed, the Drug Plan will cover the actual acquisition cost to the listed SOC unit price. [16] However, in extremely rare cases where a person is not able to use a particular brand or product, the physician may request exemption from full payment of incremental cost when a specific brand or drug in an interchangeable category is found to be essential for a particular patient. [17]

In the field of health care, the province of Saskatchewan is cooperating with the other provinces and territories through the Council of the Federation. On 18th January 2013, the Council made an announcement regarding generic drug prices; the participating provinces and territories have agreed to establish a price point for six of the most common generic

drugs at 18 percent of the equivalent brand name drug. [18]

Overview of Relevant Provisions

Indicator	Provincial Legislation	Provincial Regulation
Provincial Government Commitment Mandatory language		
Sustainable Financing State reimbursement scheme	<p>The Minister of Health is responsible for the establishment and administration of a medical care insurance plan for the residents of Saskatchewan. [19]</p> <p>Services that are medically required services provided in Saskatchewan by a physician are insured services. [20]</p> <p>Furthermore, the Minister of Health may establish a program within the department of health to provide financial assistance to residents in the purchase of drugs. [21]</p>	<p>The Prescription Drugs Regulations provide different types of Drug Plan coverage:</p> <ol style="list-style-type: none"> 1. Residents receiving benefits pursued through the Saskatchewan Assistance Plan are entitled to Drug Plan benefits at a reduced charge, or at no charge depending on their level of coverage. A difference is made between plan one, two and three beneficiaries. [22] 2. Special assistance is provided to residents with cystic fibrosis, end-stage renal disease or any other illness or condition designated by the Minister of Health and residents under palliative care. They only have to pay the incremental drug price difference and prescription charge. [23] 3. The Special Support Program helps families whose annual drugs costs exceed 3.4% of the family adjusted income. [24] 4. Single seniors and senior families receiving the Seniors Income Plan or Guaranteed Income Supplement have a \$100 or \$200 semi-annual deductible. [25] 5. Under Seniors' Drug Plan, eligible seniors of 65 years and older pay up to \$15 plus the incremental drug price difference per prescription. [26] 6. The Children's Drug Plan is

		<p>available for all children under the age of 14. Families will only pay a total of \$15 plus the incremental drug price difference per prescription. [27]</p>
<p>Sustainable Financing State subsidy</p>	<p>The Minister of Health may assign grants or pay subsidies to The University of Saskatchewan or any other body or person for the purpose of furnishing information with respect to drugs to physicians, pharmacists or any other person. [28]</p>	
<p>Rational Selection Essential medicines framework</p>	<p>The Minister of Health shall prepare a formulary, which list those drugs for which payment may be made by the minister. [29]</p> <p>But: the Minister of Health may make a payment, in any amount and in accordance with any terms and conditions that the minister considers appropriate, to or on behalf of any resident who has received a drug whether or not the drug is listed in the formulary. [30]</p>	<p>The Prescription Drugs Regulations apply only to drugs that are listed in the formulary; however, a reference is made to the Exception Drug Status drugs in Appendix A of the formulary. [31]</p>
<p>Affordable Prices Availability of generics</p>		<p>The Minister of Health may designate groups of drugs in the formulary as maximum allowable cost (MAC) groups if each of the drugs in the group are of similar therapeutic effect. The Minister shall also designate a maximum allowable cost per unit for drugs in a MAC group. [32]</p> <p>The Prescription Drugs Regulations provide drug price calculations for drugs not part of an interchangeable group or a maximum allowable cost group, for drugs part of an interchangeable group and for drugs part of a MAC group. [33]</p> <p>In the case where more than one interchangeable product is available, the Recognized Drug Price is</p>

¹ Id., para. 4.

		calculated on the price of the lowest cost interchangeable drug. ² [34]
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Observations

- The Prescription Drugs Regulations provide Drug Plan coverage for many different groups such as children, seniors and low-income families. Indigenous people, such as the Inuit, are receiving financial support from the federal government.
- In most cases there is a co-payment arrangement, people have to pay up to a specific price or have to pay up to a specific percentage of their income.
- An essential medicines framework is present in the form of a Formulary compiled by the Minister. However, the Prescription Drugs Act provides a discretionary power to the Minister of Health to make payments to and on behalf of a resident who has received a drug that is not listed in the Formulary. See also the Exception Drugs Status Program.
- Provincial regulations provide clear drug price calculations.
- Provincial legislation and regulations do not specifically mention generics. However, the drug price calculations in the Prescription Drugs Regulations are based on the lowest drug price within interchangeable groups/maximum allowable cost groups.
- In order to ensure the viability of the Drug Plan, the provincial government of Saskatchewan uses different policies:
 - o The Low Alternative Cost Policy: In the case where more than one interchangeable product is available, the Drug Plan reimbursement is calculated on the price of the lowest cost interchangeable drug.
 - o Maximum Allowable Cost (MAC) Policy: The price of the most cost-effective drugs are used as a guide to set the maximum price the Drug Plan will cover for other similar drugs used to treat the same condition. (Currently this policy only applies to proton-pump inhibitors).

Sustainable Financing (State Reimbursement Scheme) Overview

The Saskatchewan Medical Insurance Act

8 The minister shall be responsible for establishing and administering pursuant to the provisions of this Act a plan of medical care insurance for the residents of Saskatchewan.

14(1) Subject to sections 15 and 24, services that are medically required services provided in Saskatchewan by a physician are insured services.

The Prescription Drugs Act

3 The minister may establish a program within the department for providing financial assistance to residents in purchasing drugs they require for preventative, diagnostic or therapeutic purposes and for doing any other things the minister considers advisable to assist residents in purchasing such drugs and without limiting the generality of the foregoing, the minister may:

² Id., para. 4 (2).

- (a) acquire and package drugs and make arrangements for the distribution of drugs by such means as he considers advisable;
- (b) contract, negotiate or enter into arrangements with manufacturers, wholesalers, pharmacists, hospitals or other persons for any of the purposes mentioned in clause (a) or any purpose related thereto;
- (c) subject to the approval of the Lieutenant Governor in Council, participate or enter into an agreement with the Government of Canada or the government of any other province, or any agency of the Government of Canada or any other provinces for any of the purposes mentioned in clause (a) or any purpose related thereto;
- (d) do such other things as may be prescribed by the Lieutenant Governor in Council; and
- (e) exercise any other power connected with or incidental to the powers herein mentioned.

The Prescription Drugs Regulations 1993

7(9) Subject to section 7.1, for any benefit period commencing on or after July 1, 1993, a family unit that includes at least one member:

- (a) who is receiving the Guaranteed Income Supplement; and
- (b) to whom section 6 and clause 10(2)(e) do not apply;

is eligible with respect to each benefit period to receive reimbursement from the minister, or to have payment made on the family unit's behalf by the minister to participating pharmacies from which drugs are obtained by the family unit, in the amount B calculated in accordance with the formula prescribed in subsection (10).

(10) For the purposes of subsection (9):

$B = 0.65(\text{ARDP} - \$200)$ where ARDP is the sum of all recognized drug prices for:

- (a) drugs obtained by a family unit during a benefit period from participating pharmacies; and
- (b) drugs obtained by the family unit during a benefit period for which the family unit is entitled to reimbursement pursuant to section 13.

(11) Subject to section 7.2, for any benefit period commencing on or after July 1, 1993, a family unit that includes at least one member:

- (a) who resides in a special-care home for which a license is issued pursuant to The Housing and Special-care Homes Act ;

- (b) who is receiving the Guaranteed Income Supplement; and
- (c) to whom section 6 and clause 10(2)(e) do not apply;

is eligible with respect to each benefit period to receive reimbursement from the minister, or to have payment made on the family unit's behalf by the minister to participating pharmacies from which drugs are obtained by the family unit, in the amount B calculated in accordance with the formula prescribed in subsection (12).

(12) For the purposes of subsection (11):

$B = 0.65(\text{ARDP} - \$100)$

where ARDP is the sum of all recognized drug prices for:

- (a) drugs obtained by a family unit during a benefit period from participating pharmacies; and
- (b) drugs obtained by the family unit during a benefit period for which the family unit is entitled to reimbursement pursuant to section 13.

9(1) For the purposes of subsection (2), "family unit" does not include those persons who meet the criteria in subclause 2(1)(e)(iii).

(2) Subject to subsection (3), a family unit that is receiving benefits pursuant to The Saskatchewan Assistance Plan Supplementary Health Benefits Regulations, being Saskatchewan Regulation 65/66, is eligible:

- (a) subject to clause (b), to obtain a drug from a participating pharmacy on payment to the pharmacy of \$2 plus the incremental drug price difference, if any; and
- (b) to obtain from a participating pharmacy any insulin, oral hypoglycaemic, urine testing

agent, injectable vitamin B-12 or birth control pill, that is a drug listed in the formulary, on payment to the pharmacy of only any incremental drug price difference and without payment of a prescription charge.

(3) A family unit described in section 5 is not eligible to receive any benefits pursuant to this section.

10(2) The following persons are entitled to obtain a drug from participating pharmacies on payment to the pharmacy of only any incremental drug price difference and without payment of a prescription charge:

(a) a person who is receiving benefits pursuant to The Saskatchewan Assistance Plan Supplementary Health Benefits Regulations, being Saskatchewan Regulation 65/66, and who:

- (i) is a resident and is a member of a family unit that obtains five or more drugs per month on a continuing basis, as verified by a duly qualified medical practitioner, and is required to pay a corresponding number of prescription charges per month; or
- (ii) is not a resident;

(b) Repealed. 3 Jly 98 SR 60/98 s6.

(c) a dependent child of a family unit mentioned in subsection 9(2);

(c.1) a dependent child who is a member of a family unit mentioned in section 5;

(d) a resident who is receiving benefits pursuant to The Saskatchewan Assistance Plan Supplementary Health Benefits Regulations, being Saskatchewan Regulation 65/66, and who resides in:

- (i) a special-care home for which a licence is issued pursuant to The Housing and Special-care Homes Act ;
- (ii) a private-service home or a residential-service facility for which a licence or certificate of approval is issued pursuant to The Residential Services Act ; or
- (iii) an approved home as defined in The Mental Health Services Act ;

(e) a resident who resides in a special-care home for which a licence is issued pursuant to The Housing and Special-care Homes Act and who:

- (i) requires:
 - (A) limited personal care;
 - (B) intensive personal care and limited nursing care; or
 - (C) long-term care;

(ii) either:

- (A) is receiving benefits pursuant to The Saskatchewan Income Plan Act ; or
 - (B) has no income or has income in an amount that would make the resident eligible to receive benefits pursuant to The Saskatchewan Income Plan Act ;
- and

(iii) in the opinion of the minister, requires the benefit described in this subsection;

(f) a resident who:

- (i) is the subject of an agreement made pursuant to section 9 or 10 of The Child and Family Services Act ;
- (ii) has been voluntarily committed to the Minister of Social Services pursuant to section 46 of The Child and Family Services Act ; or
- (iii) is described in subsection 52(1) of The Child and Family Services Act ;

(g) a resident who is:

- (i) a person who is being provided with services pursuant to section 56 of The Child and Family Services Act ;
- (ii) a person in relation to whom assistance is being provided pursuant to The Adoption Assistance Regulations ; or
- (iii) an inmate of a correctional facility within the meaning of The Corrections Act .

10.1(1) In this section:

- (a) “drug” includes designated medical supplies as defined in The Drug Plan Medical Supplies Regulations;
- (b) “senior co-payment amount” means, with respect to each instance in which a drug is dispensed to a senior, the total of \$15 plus the incremental drug price difference, if any, with respect to the drug dispensed.
- (2) Subject to subsections (2.1), (3) and (4) and sections 10.11 to 10.2, for any benefit period commencing on or after July 1, 2007, a senior is eligible to receive reimbursement from the minister, or to have payment made on the senior’s behalf by the minister to participating pharmacies from which drugs are obtained by the senior, in the amount SB calculated in accordance with the following formula:
SB = ARDP – (SCA – AIDP) where: ARDP is the sum of all recognized drug prices for:
(a) drugs obtained by the senior during a benefit period from participating pharmacies; and
(b) drugs obtained by the senior during a benefit period for which the senior is entitled to reimbursement pursuant to section 13;
SCA is the sum of all senior co-payment amounts paid by the senior in the benefit period; and AIDP is the sum of all incremental drug price differences paid by the senior in the benefit period.
- (2.1) On and from July 1, 2008, a senior is entitled to receive reimbursement from the minister, or to have payment made on the senior’s behalf by the minister to participating pharmacies from which drugs are obtained by the senior, only with respect to any period for which the senior is determined to be eligible in accordance with section 10.11.
- (3) Subject to subsections (4) and (5), if the senior benefit calculated pursuant to subsection (2) for a benefit period with respect to a senior is less than any of the benefits to which the senior would be entitled pursuant to section 5, 5.1, 6, 6.1, 7, 7.1 or 7.2 or pursuant to sections 12 to 12.7, the senior is entitled to receive the greatest benefit to which the senior would be entitled for that benefit period.
- (4) If a family unit includes one or more members who are seniors and one or more members who are not seniors:
- (a) the members who are not seniors are not entitled to the senior benefit; but
- (b) the members who are seniors shall be included in the number of members of the family unit for the purpose of calculating the benefits to which the family unit is entitled.
- (5) A senior or a family unit that includes a senior shall provide the minister with any information that the minister considers necessary for the purposes of calculating the benefits to which the senior or the family unit is entitled.

10.3(1) In this section:

- (a) “child” means a resident who is less than 15 years of age;
- (b) “child co-payment amount” means, with respect to each instance in which a drug is dispensed to a child, the total of \$15 plus the incremental drug price difference, if any, with respect to the drug dispensed;
- (c) “drug” includes designated medical supplies as defined in The Drug Plan Medical Supplies Regulations.
- (2) Subject to subsection (3), and section 10.4, for any benefit period commencing on or after July 1, 2008, a child’s family unit is eligible to receive reimbursement from the minister, or to have payment made on the child’s behalf by the minister to participating pharmacies from which drugs are obtained on the child’s behalf, in the amount CDB calculated in accordance with the following formula:
CDB = ARDP – (CCA – AIDP) where: ARDP is the sum of all recognized drug prices for:

(a) drugs obtained on the child's behalf during a benefit period from participating pharmacies; and

(b) drugs obtained on the child's behalf during a benefit period for which the child's family unit is entitled to reimbursement pursuant to section 13;

CCA is the sum of all child co-payment amounts paid by the child's family unit in the benefit period; and

AIDP is the sum of all incremental drug price differences paid by the child's family unit in the benefit period.

(3) If the children's drug benefit calculated pursuant to subsection (2) for a benefit period with respect to a child is less than any of the benefits to which the child's family unit would be entitled pursuant to section 5, 5.1, 9 or 10 or pursuant to sections 12 to 12.7, the child's family unit is entitled to receive the greatest benefit to which the child's family unit would be entitled for that benefit period.

11 A resident is entitled to obtain a drug from participating pharmacies on payment to the pharmacy of only any incremental drug price difference and without payment of a prescription charge where that resident:

(a) has cystic fibrosis, end-stage renal disease, a condition of paraplegia or any other illness or condition designated by the minister and possesses a written statement signed by an official of the department indicating that the resident has one of those illnesses or conditions; or

(b) is under active palliative care and has been designated by the minister as a person who is entitled to have payment for drugs made on his or her behalf.

12.4 The threshold co-payment of a family unit for a benefit period is the amount TC calculated in accordance with the following formula:

$TC = 0.034 \times \text{FUI}$ where FUI is the family unit income for the applicable taxation year.

Sustainable Financing (State Subsidy) Overview

The Prescription Drugs Act

3.1 The minister may:

(a) make grants or pay subsidies to, or make agreements with, The University of Saskatchewan or any other body or person for the purpose of furnishing information with respect to drugs to physicians, pharmacists or any other person;

(b) enter into arrangements with a laboratory or any other body or person for the purpose of conducting tests or studies to assist in determining whether a payment should be made under this Act for a certain drug.

Rational Selection Overview

The Prescription Drugs Act

4(1) The minister shall cause to be prepared a formulary which shall list those drugs for which payment may be made by the minister.

(2) The minister may make such provision as he considers advisable for distributing and publishing the formulary.

5.1 Notwithstanding any other provision of this Act or the regulations, the minister may make a payment, in any amount and in accordance with any terms and conditions that the minister considers appropriate, to or on behalf of any resident who has received a drug whether or not the drug is listed in the formulary.

The Prescription Drugs Regulations 1993

2.1(1) Subject to subsections (2) and (3), these regulations apply only to drugs that are listed in the formulary.

(2) With respect to drugs listed in Appendix A of the formulary, these regulations apply if:

(a) a practitioner who is authorized pursuant to an Act to prescribe the drug or a pharmacist applies, on behalf of a person who is a member of a family unit, for coverage for that drug pursuant to the Exception Drug Status Program; and

(b) the person on whose behalf an application mentioned in clause (a) is made is approved for coverage for that drug by the minister applying the criteria set pursuant to section 5.1 of the Act.

(3) Section 13.2 and Tables 1 and 2 of the Appendix apply to all drugs that are prescribed or dispensed for a person in Saskatchewan.

Affordable prices Overview

The Prescription Drugs Regulations 1993

3.2 (1) The minister may, from time to time, in the formulary designate groups of drugs as maximum allowable cost groups if, on the advice of persons with relevant expert knowledge, the minister is satisfied that each of the drugs in the group is of similar therapeutic effect.

(2) The minister shall, in the formulary, designate a maximum allowable cost per unit for drugs in a maximum allowable cost group designated pursuant to subsection (1).

4(1) If a drug dispensed is not part of an interchangeable group or a maximum allowable cost group, the recognized drug price for the drug dispensed is the amount RDP calculated in accordance with the following formula:

$RDP = (N \times AP) + M + ADF$ where:

N is the number of units of the drug dispensed;

AP is the actual price per unit charged by the person operating the participating pharmacy for the brand of drug dispensed, to a maximum of the price per unit indicated for that drug in the formulary;

M is the maximum mark-up that a person operating a participating pharmacy may charge, in accordance with an agreement mentioned in section 5 of the Act, on the number of units of the brand of drug dispensed; and ADF is the actual dispensing fee charged by the person operating the participating pharmacy for the brand of drug dispensed, to a maximum of the maximum dispensing fee that may be charged in accordance with an agreement mentioned in section 5 of the Act.

(2) If a drug dispensed is part of an interchangeable group and is not part of a maximum allowable cost group, the recognized drug price for the drug dispensed is the amount RDP calculated in accordance with the following formula:

$$\text{RDP} = (\text{N} \times \text{APB}) + \text{MIC} + \text{ADF}$$

where:

N is the number of units of the drug dispensed; APB is the actual price per unit charged by the person operating the participating pharmacy for the brand of drug dispensed, to a maximum of the price per unit for the lowest priced brand of drug in the same interchangeable group as the drug dispensed; MIC is the maximum mark-up that could be charged by a person operating a participating pharmacy, in accordance with an agreement mentioned in section 5 of the Act, if, rather than dispensing the brand of drug dispensed, the person operating the pharmacy had dispensed the lowest priced brand of drug in the same interchangeable group as the drug prescribed in the same number of units as the drug prescribed; and ADF is the actual dispensing fee charged by the person operating the participating pharmacy, for the brand of drug dispensed, to a maximum of the maximum dispensing fee that may be charged in accordance with an agreement mentioned in section 5 of the Act.

(3) If a drug dispensed is part of a maximum allowable cost group, the recognized drug price for the drug dispensed is the amount RDP calculated in accordance with the following formula:

$$\text{RDP} = (\text{N} \times \text{APC}) + \text{MMAC} + \text{ADF}$$

where: N is the number of units of the drug dispensed; APC is the actual price per unit charged by the person operating the participating pharmacy for the brand of drug dispensed, to a maximum

determined in accordance with subsection (4); MMAC is the maximum mark-up that could be charged by a person operating a participating pharmacy, in accordance with an agreement mentioned in section 5 of the Act, if, rather than dispensing the brand of drug dispensed, the person operating the pharmacy had dispensed, in a quantity having the same therapeutic effect as the number of units of the drug prescribed, a drug that did not exceed the maximum allowable cost per unit for the maximum

allowable cost group to which the drug prescribed belongs; and ADF is the actual dispensing fee charged by the person operating the participating pharmacy, for the brand of drug dispensed, to a maximum of the

maximum dispensing fee that may be charged in accordance with an agreement mentioned in section 5 of the Act.

(4) For the purposes of subsection (3), the maximum value of APC is the lowest of the following values, as of the date on which the drug was dispensed:

- (a) the maximum allowable cost per unit for drugs in the maximum allowable cost group to which the drug dispensed belongs;
- (b) the maximum price per unit indicated in the formulary for the drug dispensed;
- (c) if the drug dispensed is also a member of an interchangeable group, the maximum price per unit for the lowest priced brand of drug in the interchangeable group to which the drug dispensed belongs.

References

[1] Health Canada 'Canada's Health Care System' <http://www.hc-sc.gc.ca/hcs-sss/pubs/system-regime/2011-hcs-sss/index-eng.php> accessed on 28 February 2014.

[2] Ibid.

[3] Health Canada 'Canada Health Act' <http://www.hc-sc.gc.ca/hcs-sss/medi-assur/cha-lcs/index-eng.php> accessed on 15 April 2014.

[4] See note 1.

[5] Ibid.

[6] Ibid.

[7] Canada Health Act, para. 3.

[8] Id., para 7.

[9] Food and Drugs Act, para 29.1.

[10] Patent Act, section 21.02 and paragraph 21.03(1)(a).

[11] Health Canada, 'Questions and answers – Prescription DrugList' http://www.hc-sc.gc.ca/dhp-mps/prodpharma/pdl-ord/pdl_list_fin_ord-eng.php accessed 28 February 2014.

[12] Patent Act, para. 83.

[13] In October 2003, under pressure from the Canadian society, Medecins Sans Frontieres (MSF) and the UN Special Envoy on HIV/Aids in Africa, the Canadian government committed itself to implement the WTO decision from August 2003. The Jean Chrétien Pledge to Africa Act (JCPA) was presented as a legislative priority of the then Prime Minister, Jean Chrétien. The JCPA is a important piece of legislation implementing the Canadian Access to Medicines Regime (CAMR). Medecins Sans Frontieres, 'The Jean Chrétien Pledge to Africa Act or Canada's attempt to provide medicines for the poor, Questions & Answers' http://www.msf.ca/sites/canada/files/BRIEF_jcpa.pdf accessed on 25 April 2014.

[14] Government of Saskatchewan, 'About the Saskatchewan Formulary' <http://formulary.drugplan.health.gov.sk.ca/About.aspx> accessed 28 February 2014.

[15] Ibid.

[16] Ibid.

[17] Ibid

[18] Council of the Federation 'Provinces and Territories Seek Significant Cost Savings for Canadians on Generic Drugs' (18 January 2013) <http://www.councilofthefederation.ca/en/latest-news/13-2013/122-territories-seek-significant-cost-savings-on-generic-drugs> accessed 28 February 2014.

[19] The Saskatchewan Medical Insurance Act, para. 8.

[20] Id., para 14.

[21] The Prescription Drugs Act, para 3.

[22] The Prescription Drugs Regulations 1993, para. 9 and 10.

[23] Id., para. 11.

[24] Id., para. 12.

[25] Id., para. 7.

[26] Id., para 10.1.

[27] Id., para 10.3.

[28] The Prescription Drugs Act, para. 3.1 (a).

[29] Id., para. 4.

[30] Id., para 5.1.

[31] Prescription Drugs Regulations, para. 2.1 (1).

[32] Id., para. 3.2.

[33] Id., para 4

[34] Id., para. 4 (2).