
PREFACE

OBJECTIVES

The Drug Plan has been established to:

- provide coverage to Saskatchewan residents for quality pharmaceutical products of proven therapeutic effectiveness;
- reduce the direct cost of prescription drugs to Saskatchewan residents;
- reduce the cost of drug materials;
- encourage the rational use of prescription drugs.

THE FORMULARY

The Saskatchewan Formulary is a listing of the therapeutically effective drugs of proven high quality that have been approved for coverage under the Drug Plan. It is compiled by the Minister of Health with the advice of the Drug Advisory Committee of Saskatchewan (DACS) and is published annually, with regular updates.

The members of the DACS are appointed by the Minister of Health and provide independent, specialized advice on drug-related matters. The membership on the DACS is composed of two public representatives as well as clinical specialists in the areas of medicine, pharmacology, pharmacy, and economics.

The ongoing work of the DACS includes the evaluation of new products, as well as the re-evaluation of products as required. The goal is to list a range and variety of drugs that will enable prescribers to select an effective course of therapy for most patients.

THE DRUG REVIEW PROCESS

Saskatchewan is participating in the Common Drug Review (CDR).

The CDR helps support and inform drug plan decisions about drugs by providing:

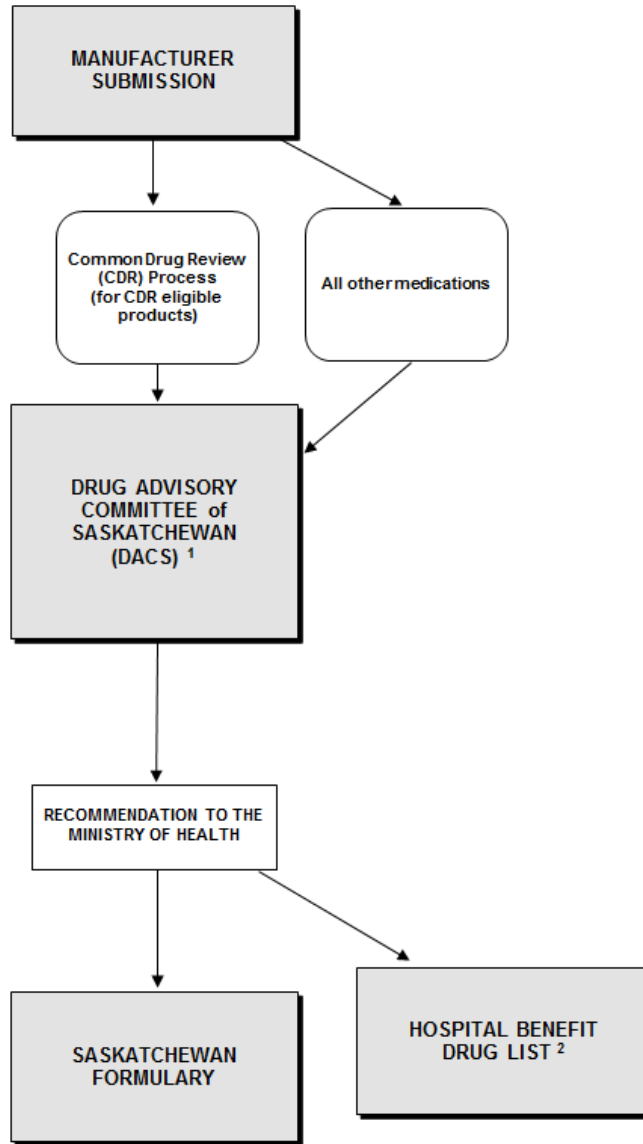
- systematic reviews of the clinical evidence
- reviews of the pharmacoeconomic information
- detailed recommendations by the Canadian Drug Expert Committee (CDEC).

The Drug Plan continues to make final benefit-listing and coverage decisions, based on CDEC recommendations, and jurisdictional factors, such as plan mandates, priorities, and resources.

For more information about the CDR and CDEC, visit: <http://www.cadth.ca>.

Upon receipt of the CDEC recommendation, the DACS will begin Saskatchewan's review. Using this information, along with additional details of anticipated cost and impact on patterns of practice, the DACS makes a recommendation to the Minister of Health. These recommendations reflect the "Policy for Inclusion of Products in the Saskatchewan Formulary" (see pages ix - xi).

SASKATCHEWAN FORMULARY PRODUCT SUBMISSION PROCESS*



¹ The DACS provides independent, specialized advice on drug-related matters to the Minister of Health.

² All products listed in the Saskatchewan Formulary are benefits when used in the hospital setting.

* The majority of submissions for interchangeable generic drugs do not require committee review as the Executive Director of the Drug Plan has the authority to approve these products for coverage. More complex interchangeable drug submissions are reviewed by the drug review committee.

REQUEST FOR PRODUCT ASSESSMENT

Submission Process

Any supplier wishing to have products listed in the Saskatchewan Formulary or the Hospital Benefit Drug List may submit requests for product assessment. The route a submission follows is determined by the indication of the products. There is no deadline date for submissions for listing in the Formulary. In general, submissions are reviewed in order of receipt.

Clinical Documentation (please submit electronically)

Single-Supplier Product Submissions

New Chemical Entities, New Combination Products and New Indications for Listed Products.

Saskatchewan is participating in the Common Drug Review (CDR) process. As a consequence, submissions for new chemical entities, new combination products and new indications for listed products should be made directly to CDR Directorate in accordance to the CDR Submission Guidelines as posted on the Canadian Agency for Drugs and Technologies in Health website <http://www.cadth.ca>.

Single Source Products That Do Not Contain New Chemical Entities

Saskatchewan Health will accept submissions of single source products that do not contain new chemical entities or new combinations and that will not fall under the jurisdiction of the CDR process; however, the same submission requirements as per CDR guidelines will apply to this category of products.

Line Extension Products

The following submission requirements pertain to new strengths and formulations or reformulations of drug products that are currently listed in the Saskatchewan Formulary.

1. Copy of NOC
2. Copy of completed Drug Identification Number (DIN) notification form
3. Copy of approved Product Monograph
4. Justification of the need for the Line Extension
5. Copy of Comprehensive Summary ("Clinical Studies" section only) or other document accepted by Health Canada and copies of critical studies that address key clinical issues relevant to the new strength, formulation or reformulation or evidence of formulation proportionality or bioequivalence data; and evidence of a similar dissolution profile.

Clinical documentation in support of products to be reviewed may be submitted at any time. The committee meets on a regular basis and will review submissions as quickly as possible upon receipt. Details of the criteria for product listings are published in each edition of the Formulary and in regular updates to the Formulary.

Notification is required whenever there is a change in formulation or in the clinical information published in the product monograph, for any listed product as well as for any product under review.

Interchangeable Product Submissions

The following submission requirements pertain to multi-source products submitted for listing in an interchangeable grouping in the Saskatchewan Formulary.

- A. Drug products in solid oral dosage forms reviewed by the TPD according to the guidelines, "Conduct and Analysis of Bioavailability and Bioequivalence Studies - Part A and B" and have a Canadian Reference Product on the Notice of Compliance.
 - 1. Copy of NOC
 - 2. Copy of completed Drug Identification Number (DIN) notification form
 - 3. Copy of approved Product MonographNote: Comparative (Bio) studies may be requested on a case-by-case basis.

- B. Drug products in solid oral dosage forms reviewed by the TPD according to the guidelines "Conduct and Analysis of Bioavailability and Bioequivalence Studies - Report C".
 - 1. Copy of NOC
 - 2. Copy of completed Drug Identification Number (DIN) notification form
 - 3. Copy of approved Product MonographNote: Comparative (Bio) studies may be requested on a case-by-case basis.

- C. Drug Products that are cross-referenced
 - 1. Copy of NOC
 - 2. Copy of completed Drug Identification Number (DIN) notification form
 - 3. Copy of approved Product Monograph
 - 4. Letters from both the manufacturer of the submitted product and the manufacturer of the cross-licensed product, confirming that the two products are identical in all aspects, except for embossing and labelling.
 - 5. Price information including current pricing should be provided at the time of the generic product submission.

- D. Drug products in Aqueous Solutions (e.g. oral, ophthalmics, inhalation, injections) that have a Canadian Reference Product on the Notice of Compliance.
 - 1. Copy of NOC
 - 2. Copy of completed Drug Identification Number (DIN) notification form
 - 3. Copy of approved Product MonographNote: Comparative (Bio) studies may be requested on a case-by-case basis.

- E. Drug products in semi-solid formulations (e.g. creams, ointments)
 - 1. Copy of NOC
 - 2. Copy of completed Drug Identification Number (DIN) notification form
 - 3. Copy of approved Product MonographNote: Comparative (Bio) studies may be requested on a case-by-case basis.

Drug Products Without a Canadian Reference Product

The following submission requirements pertain to products submitted for listing in an interchangeable grouping where the active ingredient is designated as an “old drug” by the TPD and the drug product is approved on the basis of DIN application (i.e. an NOC is not issued) or is issued a Notice of Compliance without a Canadian Reference Product.

- A. Drug products in solid dosage forms
 1. Copy of completed Drug Identification Number (DIN) notification form
 2. Copy of approved Product Monograph or Prescribing Information
 3. Executive summary of comparative bioavailability study or pharmacodynamic study or studies conducted in accordance with the TPD guidelines, “Conduct and Analysis of Bioavailability and Bioequivalence studies - Part A and B and Report C.

- B. Drug Products Not in Solid Oral Dosage Form
 1. Copy of completed Drug Identification Number (DIN) notification form
 2. Copy of approved Product Monograph or Prescribing Information
 3. Executive summary of comparative Bioavailability study or pharmacodynamic study or studies conducted in accordance with the TPD guidelines or surrogate comparisons with the reference drug product (i.e. in vivo or vitro test methods or a pharmacodynamic or therapeutic equivalence study).

- C. Drug Products That Are Cross-Referenced
 1. Copy of completed Drug Identification Number (DIN) notification form
 2. Copy of approved Product Monograph or Prescribing Information
 3. Letters from both the manufacturer of the submitted product and the manufacturer of the cross-licensed product, confirming that the two products are identical in all aspects, except for embossing and labelling.

Manufacturing Documentation (please submit electronically)

A copy of completed and approved Certified Product Information Document (C.P.I.D.) should be submitted with the clinical documentation if possible, but will be accepted at a later date.

Economic Evaluation (please submit one electronic copy as well as one paper copy)

Price information including current price list and/or catalogue should be provided at the time of product submission. Submission of pharmacoeconomic analyses are encouraged. The National Pharmacoeconomic Guidelines serve as a guide. The Drug Advisory Committee of Saskatchewan will routinely consider direct “medical” costs such as:

- impact on laboratory tests for monitoring, evaluation or diagnosis
- impact on physician office visits
- impact on hospitalization or institutionalization

- impact on surgical procedures
- increased or decreased incidence and severity of side effects
- expected market share information is requested to allow for an accurate projection of the impact of a new product.
- product patent expiration date is requested to allow for consideration of the potential long-term economic impact of the product.
- copies of the initial product launch material, and any subsequent promotional material sent to physicians and pharmacists.

The availability of quality-of-life analyses is encouraged. Submission of a budget impact analyses for Saskatchewan Health is required.

Additional Documentation Required for Generic and Single Source Products:

- A letter authorizing unrestricted communication regarding the drug product between the Saskatchewan Prescription Drug Plan and:
 1. Participating federal/provincial/territorial (F/P/T) drug plans
 2. F/P/T governments, including their agencies and departments
 3. F/P/T health authorities (including regional authorities and related facilities)
 4. Health Canada
 5. Patented Medicine Prices Review Board (PMPRB)
 6. Canadian Agency for Drugs and Technology in Health (CADTH)
- A letter confirming the ability to supply product.

Submission Procedure

Requests for product assessment, together with complete documentation as noted above should be sent to:

Drug Review Manager
 Drug Plan and Extended Benefits Branch
 Ministry of Health
 2nd Floor, 3475 Albert Street
 Regina, Saskatchewan S4S 6X6

NOTES CONCERNING THE FORMULARY

Benefits

The Saskatchewan Formulary lists the drugs, which are covered by the Drug Plan. A prescription is required for all drugs dispensed under the Drug Plan with the exception of insulin, blood-testing agents, urine-testing agents, syringes, needles, lancets and swabs used by diabetic patients. Certain drugs are covered under the Exception Drug Status Program (EDS) and require that specific medical criteria are met before coverage is granted. See Exception Drug Status criteria (Appendix A) for more information regarding EDS.

Eligibility

With a few exceptions, all Saskatchewan residents with a valid Saskatchewan Health Services card are eligible for coverage under the Drug Plan. The exceptions include those who have prescription costs paid by another agency. For example:

- Health Canada; First Nations and Inuit Health Branch
- Workers' Compensation Board
- Veterans Affairs Canada
- members of the Canadian Forces
- inmates of Federal Penitentiaries

Policy for Inclusion of Products in the Saskatchewan Formulary

1. Only products produced by manufacturers approved by Health Canada will be considered.
2. Only drug products formulated and produced in accordance with sound manufacturing principles and found to comply with official standards will be considered.
3. Only drug products which are valid therapeutic agents, with proven clinical effectiveness, for the diagnosis, prevention or treatment of mental or physical disorders will be listed. The availability of suitable alternative agents, and potential for undesirable effects will be considered.

The medical literature and clinical studies are reviewed and evaluated to determine if the drug product is therapeutically effective for the treatment of the conditions for which the drug is indicated.

The clinical literature is also reviewed to determine the therapeutic advantages or disadvantages in relation to alternative agents, which may or may not be listed in the Saskatchewan Formulary.

The rate and severity of potential undesirable effects are reviewed and compared with those for alternative products.

In reviewing products for which suitable alternatives are listed in the Formulary, consideration will be given to the following additional criteria:

- clinical documentation must clearly demonstrate therapeutic advantages such as:
 - more effective for treatment of the condition(s) for which the drug is intended;
 - increased safety as shown by reduced toxicity and reduced incidence of adverse reactions and/or side effects;
 - improved dosing schedule;
 - reduced potential for abuse or inappropriate use;
 - OR
 - anticipated cost of a product of equivalent therapeutic effectiveness must offer a potential economic advantage over listed alternatives.
4. The cost of therapy relative to the clinical efficacy is reviewed and compared to the cost of therapy relative to the clinical efficacy of alternative agents.

An increased cost may be justified if the drug product produces better clinical results in a significant portion of the patient population, demonstrates fewer or less severe undesirable effects, or has a dosage regime which improves patient compliance.

The cost of oral combination products relative to the combined costs of the single entities, the cost of the various dosage strengths relative to therapeutic advantages, and the cost of additional dosage forms relative to the therapeutic advantages will be considered when reviewing such products.

5. Some drug products will not be listed as regular benefits, but may be made available on Exception Drug Status for treatment of approved clinical indications. (See Appendix A) for Exception Drug Status criteria.
6. Combination products are required to meet the following additional criteria:
 - each component must make a contribution to the claimed effect;
 - the dosage of each component (amount, frequency, duration of therapeutic effect) must be such that the combination is safe and effective for a significant patient population, requiring such concurrent therapy as defined in the labelling;

A component may be added to:

 - enhance safety or effectiveness of the principal active ingredient;
 - minimize the potential for abuse of the principal active ingredient.
 - combination fixed ratio must be "right" for:
 - significant portion of patients;
 - significant amount of natural history of disease.
7. Sustained, prolonged or delayed release dosage forms are required to meet the following additional criteria:
 - clinical studies have demonstrated the sustained, prolonged or delayed action of the active ingredient;
 - the dosage form possesses therapeutic advantages in the treatment of the disease entity for which the product is indicated.
8. The various strengths of one dosage form will be considered if they possess therapeutic advantages and meet the required standards for quality and cost.
9. The various dosage forms of a drug product will be evaluated individually.
10. Drug products not listed in the Schedules of the Food and Drugs Act, Narcotic Control Act or the Saskatchewan Pharmacy Act, but usually sold on prescription, will be considered for inclusion.
11. Products which contain the same amount of the same active ingredient in an equivalent dosage form and are of acceptable equivalent therapeutic effectiveness will be listed as interchangeable.
12. The following will not be listed:
 - fertility agents;

- drugs used in erectile dysfunction;
- certain over-the-counter preparations;
- drugs used primarily in hospitals;
- antineoplastic agents (these are provided to patients through the Saskatchewan Cancer Agency);
- anti-tuberculosis drugs;
- blood derivatives - immune serum globulin for prophylaxis against infectious hepatitis or measles or for treatment of immune deficiency disease is available from the Health Offices;
- vaccines and sera - most immunological agents are available from the Health Offices;
- safety engineered syringes.

13. Drug products identified by trade names deemed to be inappropriate, confusing and/or misleading may not be listed. Some examples include:

- products with similar or identical trade names but containing different active ingredients;
- products with a different strength of ingredient, manufactured by the same supplier, but with a different trade name.

Policy for Formulary Deletion

The Minister of Health may delete any product from the Saskatchewan Formulary under the following circumstances:

1. Upon the recommendation of the DACS:
 - where the standards of quality and/or production have altered and are not considered to meet accepted standards;
 - where new information demonstrates that the product does not have adequate therapeutic benefit;
 - where undesirable effects of the product make the continued listing of the product inappropriate;
 - where new products possessing clearly demonstrated therapeutic advantages have been listed, thereby making the continued listing of the product unnecessary.
2. Upon the recommendation of the Drug Plan where there are undesirable financial, supply or administrative implications to continued listing of a product, the Drug Plan will consult with the DACS prior to making a recommendation. The comments of the Committee will be brought to the attention of the Minister.
3. Where the Minister of Health believes a product should be deleted, the Minister will consult with the DACS before making a final decision.
4. Upon notification from the manufacturer that the product has been discontinued.

Exception Drug Status

Certain drug products may be considered for Exception Drug Status coverage under one or more of the following circumstances:

- the drug is ordinarily administered only to hospital inpatients and is being administered outside of a hospital because of unusual circumstances;

- the drug is not ordinarily prescribed or administered in Saskatchewan but is being prescribed because it is required in the diagnosis or treatment of a patient having an illness, disability or condition rarely found in this province;
- the drug is infrequently used since therapeutic alternatives listed in the Formulary are usually effective but are contraindicated or found to be ineffective because of the clinical condition of the patient;
- the drug has been deleted from the Formulary, but is required by patients who were previously stabilized on the drug;
- the drug has potential for use in other than approved indications;
- the drug has potential for the development of widespread inappropriate use;
- the drug is more expensive than listed alternatives and offers an advantage in only a limited number of indications.

The following information is required to process Exception Drug Status requests:

- * patient name
- * patient Health Services Number (9 digits)
- * name of drug
- * diagnosis relevant to use of drug
- * prescriber name
- * prescriber phone number

Saskatchewan Prescription Drug Plan policy does not allow a fee to be charged to clients for Exception Drug Status applications made to the Drug Plan on the client's behalf.

See Appendix A for further details regarding Exception Drug Status.

"No Substitution" Prescriptions

Drug Plan benefits will be based only on the lowest priced interchangeable brand as listed in the Formulary or sticker updates. Credit towards established deductibles or thresholds (for income based drug coverage under Special Support) will also be based on the lowest priced interchangeable brand. Although the Formulary will continue to list all approved brands, patients will, in addition to their normal share of cost, be responsible for any incremental cost associated with the selection of a higher cost brand.

It is important to note that both generic and brand name products are manufactured under the same standards of good manufacturing practice, and that only those brands, which meet the standards for bioequivalence, are accepted as interchangeable in Saskatchewan.

In cases where a patient experiences problems with a specific brand of a medication, a prescriber may make application for exemption from the cost of the "no sub" brand.

(See Special Coverages for details)

<http://formulary.drugplan.health.gov.sk.ca/publications/SpecialCoverages.pdf>

Adverse Drug Reactions

Health Canada encourages the reporting of suspected adverse reactions. Saskatchewan prescribers, pharmacists, and other health professionals are encouraged to participate in the **Canada Vigilance Program**; see Supplementary Information at the back of the book.

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Drug products are listed alphabetically by generic name and brand name at the back of the Formulary.

Pharmacologic-Therapeutic Classification of Drugs

The drugs are classified according to the pharmacologic-therapeutic classification developed by the American Society of Health System Pharmacists for the purpose of the American Hospital Formulary Service.

Permission to use this system has been granted by the American Society of Health System Pharmacists. The Society is not responsible for the accuracy of transpositions or excerpts from the original content.

Within each therapeutic classification the drugs are listed alphabetically according to their generic names. Under each drug, acceptable products are listed. Drugs with multiple uses may be listed in one or more classes.

Prescription Quantities

The Drug Plan places no limitation on the quantities of drugs that may be prescribed. Prescribers shall exercise their professional judgment in determining the course and duration of treatment for their patients. However, in most cases, the Drug Plan will not pay benefits or credit deductibles for more than a 3-month supply of a drug at one time.

The quantity dispensed for one dispensing fee shall be determined by the terms of the contract in force when the prescription was dispensed. For drugs listed on the *Two Month* and *100 Day* maintenance drug lists, refer to the Maintenance Drug Schedule. Because of possible waste and the potential danger of storing large quantities of potent drugs in the home, the Drug Plan does not encourage the dispensing of unreasonably large quantities of prescription drugs.