

SUBMISSIONS for DRUG REVIEWS

- 1) Only submissions satisfying all of the submission requirements of the applicable category of drug product that are deemed complete by the applicable submission deadline date will be put forward for review.
- 2) In addition to the submission requirements, the Expert Committee and/or Alberta Health and Wellness, at their sole discretion, reserve the right to request the drug product file from Health Canada's Therapeutic Products Directorate (TPD), or any additional information from the manufacturer, CEDAC, or any other entity that the Expert Committee and/or Alberta Health and Wellness consider necessary, which may result in a delay in the listing recommendation for the drug product.
- 3) There is no obligation or guarantee that every completed submission will be reviewed, and/or a recommendation made, by a specific date or at the next scheduled meeting of the Expert Committee.
- 4) Pre-NOC submissions may be made; however, the submission will only be reviewed once it is complete.
- 5) Any request by a manufacturer to hold a submission will result in a submission being deemed incomplete as of the date of the request. A submission on hold will only be considered complete once correspondence is received from a manufacturer to proceed with the submission.
- 6) Only one (1) copy of a submission for a drug product is required. A determination by Alberta Blue Cross that a submission is complete is preliminary and made only for the purposes of forwarding the submission for review.
- 7) Drug manufacturers are permitted to provide other information they feel may be important to the review of a submission e.g. selected references or additional studies completed after a drug product had been submitted to the Therapeutic Products Directorate, Health Canada. Comparative studies with other listed drug products are most relevant.
- 8) Information on submission deadlines are posted on the *Alberta Health and Wellness Drug Benefit List* website which can be accessed at <http://www.ab.bluecross.ca/dbl/manufacturers.html>.

Notice of Significant Changes - By making a submission, and if a drug product is listed on the *List*, manufacturers acknowledge and agree that they are required to notify the Senior Manager, Scientific and Research Services of any significant change to listed drug products. Significant changes are considered to be changes in NOC, DIN, product name, manufacturer or distributor, indication, product monograph, packaging, formulation, manufacturing specifications or any change that could potentially affect the bioavailability or bioequivalence of a drug product.

All submissions should be sent to the attention of:

Senior Manager
Scientific and Research Services
Alberta Blue Cross
10009 108 Street NW
Edmonton, Alberta T5J 3C5

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ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST

All inquiries should be directed to:

Coordinator

Scientific and Research Services

Alberta Blue Cross

10009 108 Street NW

Edmonton, Alberta T5J 3C5

Phone: (780) 498-8098

Fax: (780) 498-3534

Email: submissions@ab.bluecross.ca

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Interpretation Notices

From time to time, or as circumstances warrant, certain practices or procedures may be adopted by the Committee pertaining to the interpretation of the procedures and criteria published in the *AHWDBL Policies and Guidelines*. In order to assist manufacturers in preparing and submitting effective drug review submissions, the Expert Committee has determined that, where it deems appropriate, notice of these practices will be provided to manufacturers through "Interpretation Notices".

The Notices are intended to be a guide to assist manufacturers, but in situations where the Notices lead to inconsistencies or conflicts, the criteria in the Drug Review Procedure and Submission Requirements and Criteria, will apply.

Notices will be published electronically and it continues to be the responsibility of manufacturers to monitor amendments to the *AHWDBL*. For convenience only, hard copies of Notices may be provided with the *AHWDBL Interim Updates* where deemed appropriate by Alberta Blue Cross.

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INTERPRETATION NOTICE #1

INTERCHANGEABILITY and NON-CANADIAN REFERENCE PRODUCTS

The *Submission Requirements and Criteria* of the AHWDBL require manufacturers to provide the *Expert Committee on Drug Evaluation and Therapeutics* (“Expert Committee”) with data comparing the submitted drug product to the reference drug product. Under the *Interchangeable Drug Products Criteria*, manufacturers are also required to demonstrate bioequivalence with the reference drug product in accordance with the Criteria.

At various times, some manufacturers have submitted interchangeability submissions using a Non-Canadian Reference Product (NCRP). After reviewing several submissions, the Expert Committee has adopted the practice of permitting manufacturers to demonstrate bioequivalency by providing data comparing the submitted drug product to a NCRP that meets the *Criteria for use of a Non-Canadian Reference Product* as set out in Health Canada’s *Drugs Directorate Policy regarding the use of a Non-Canadian Reference Product under the provisions of Section C.08.002.1(c) of the Food and Drug Regulations* (the “NCRP Criteria”).

Important Note: Health Canada does not determine interchangeability and therefore, a determination by Health Canada that a product meets the NCRP Criteria *is not sufficient proof* for the Expert Committee’s purposes. The Expert Committee will continue to consider and assess all of the submission materials, and make its own determination whether the NCRP Criteria, the Submission Requirements and the Criteria are met, and whether the product may be designated as interchangeable.

The practice in these situations is that, after receipt of the submission, Alberta Blue Cross makes a request to Health Canada for a copy of the Therapeutic Products Directorate’s review (TPD File) for the submitted product(s). Manufacturers are advised that, in order to avoid a possible deferral, they may include a full copy of the TPD File in their submission. If necessary, submissions may be deferred until the TPD File is received. Product submissions may, at the discretion of Alberta Blue Cross, be scheduled for review if the TPD File is received 7 days prior to the meeting date.

As with all submissions, the Expert Committee retains the right to request additional materials from the manufacturer, Health Canada or any other entity it determines appropriate in order to conduct its review.

Issue Date: November 9, 2006

SUBMISSION REQUIREMENTS

The following Submission Requirements pertain to submissions not eligible for review under the CDR Procedure.

A) New Chemical Entities/Single Source Drug Products

The following submission requirements pertain to New Chemical Entities, New Combination Products where one or more of the active moieties have never been listed on the *List*, and other single source drug products that have never been listed on the *List*, and are not eligible for review under the CDR Procedure. Submissions for drug products in this category should first be directed to the CDR Directorate.

1. Consent Letter
 - an unrestricted letter authorizing Alberta Health and Wellness and its agent/designate to access, discuss, use, collect from, and disclose to its agents, consultants, Health Canada, the Canadian Agency for Drugs and Technologies in Health (CADTH) and all persons, parties or entities involved in the CDR Procedure, the Patented Medicine Price Review Board (PMPRB), Alberta Health Services and the government of any province or territory in Canada, all submission information and information in the possession of Health Canada, CADTH, PMPRB, Alberta Health Services and the government of any province or territory in Canada
2. Letter Confirming Ability to Supply
 - a letter signed by a senior official providing assurance that the manufacturer is able to supply the specific drug product and strength from the time of listing in a quantity sufficient to meet the anticipated demand in Alberta for a minimum of 6 months.
3. A hard copy and electronic (CD) copy of the following from the Common Technical Document:
 - a. Clinical Overview (Module 2.5), and
 - b. Clinical Summary (modules 2.7.1, 2.7.3, 2.7.4 and 2.7.6).Note: If a Common Technical Document was not prepared for Health Canada, a Comprehensive Summary may be acceptable in lieu.
4. Copy of completed Drug Identification Number (DIN) notification form
5. Copy of Notice of Compliance (NOC)
6. Current Patent Status
 - a signed statement from the manufacturer stating that the submitted product does not infringe any patents
 - expiry date(s) of all Canadian patent(s)
7. Price Information
 - The proposed price for Alberta (which must be in compliance with the Price Policy)
8. Product Monograph
 - in addition to a hard copy, an electronic (CD) copy of the TPD-approved Product Monograph compatible with Microsoft Word is required
9. Economic Information
 - a comprehensive pharmacoeconomic analysis in accordance with: the “*Guidelines for the economic evaluation of health technologies: Canada* [3rd Edition]”. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2006.; cost-effectiveness and cost-utility data and the impact on “direct” healthcare costs are most useful

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- a completed *Budget Impact Assessment for the Alberta Health and Wellness Drug Benefit List* form. Note: copies of the most recent version of this form can be obtained by accessing the *Alberta Health and Wellness Drug Benefit List* website at www.ab.bluecross.ca/dbl/manufacturers.html, or by contacting the Coordinator, Scientific and Research Services, Alberta Blue Cross at Phone: (780) 498-8098 or Fax: (780) 498-3534.
10. If requested, the manufacturer must provide written confirmation from the CDR Directorate that the drug product is not eligible for review under the CDR Procedure.

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B) Changes to Special Authorization or Restricted Benefit Status of Listed Single Source Drug Products Due to a New Indication

The following submission requirements pertain to single source drug products currently listed via special authorization or as restricted benefits that have received a new indication from Health Canada, where the manufacturer wishes to request expansion of the coverage criteria or change in benefit status due to the new indication and where the drug products are not eligible for review under the CDR Procedure. Submissions for drug products in this category that have been previously reviewed under the CDR Procedure should first be directed to the CDR Directorate.

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 - an unrestricted letter authorizing Alberta Health and Wellness and its agent/designate to access, discuss, use, collect from, and disclose to its agents, consultants, Health Canada, the Canadian Agency for Drugs and Technologies in Health (CADTH) and all persons, parties or entities involved in the CDR Procedure, the Patented Medicine Price Review Board (PMPRB), Alberta Health Services and the government of any province or territory in Canada, all submission information and information in the possession of Health Canada, CADTH, PMPRB, Alberta Health Services and the government of any province or territory in Canada
2. Letter Confirming Ability to Supply
 - a letter signed by a senior official providing assurance that the manufacturer is able to supply the specific drug product and strength from the time of listing in a quantity sufficient to meet the anticipated demand in Alberta for a minimum of 6 months.
3. Justification for the Expanded Coverage Criteria or Change in Benefit Status
 - a separate document indicating the reason for and evidence to justify the need for the expanded coverage criteria or change in benefit status due to the new indication
4. A hard copy and electronic (CD) copy of the following from the Common Technical Document:
 - Clinical Overview (Module 2.5), and
 - Clinical Summary (modules 2.7.1, 2.7.3, 2.7.4 and 2.7.6)
5. Note: If a Common Technical Document was not prepared for Health Canada, a Comprehensive Summary may be acceptable in lieu. Copy of Notice of Compliance (NOC) for the new indication.
6. Current Patent Status
 - a signed statement from the manufacturer stating that the submitted product does not infringe any patents
 - expiry date(s) of all Canadian patent(s)
7. Price Information
 - The proposed price for Alberta (which must be in compliance with the Price Policy)
8. Product Monograph (revised to include the new indication)
 - in addition to a hard copy, an electronic (CD) copy of the TPD-approved Product Monograph compatible with Microsoft Word is required

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9. Economic Information
 - a comprehensive pharmacoeconomic analysis **prepared with respect to the new indication only** in accordance with: the “*Guidelines for the economic evaluation of health technologies: Canada* [3rd Edition]”. Ottawa: Canadian Agency for Drugs and Technologies in Health; 2006.; cost-effectiveness and cost-utility data and the impact on “direct” healthcare costs are most useful
 - a completed Budget Impact Assessment for the *Alberta Health and Wellness Drug Benefit List* form **prepared with respect to the new indication only**. Note: copies of the most recent version of this form can be obtained by accessing the *Alberta Health and Wellness Drug Benefit List* website at www.ab.bluecross.ca/dbl/manufacturers.html, or by contacting the Coordinator, Scientific and Research Services, Alberta Blue Cross at Phone: (780) 498-8098 or Fax: (780) 498-3534.
10. If requested, the manufacturer must provide written confirmation from the CDR Directorate that the drug product is not eligible for review under the CDR Procedure.

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C) Line Extension Drug Products

The following submission requirements pertain to new strengths and formulations or reformulations of drug products that are currently listed or are under consideration for listing on the *List* and where products are not eligible for review under the CDR Procedure. Submissions for drug products in this category that have previously been reviewed under the CDR Procedure should first be directed to the CDR Directorate.

1. Consent Letter
 - an unrestricted letter authorizing Alberta Health and Wellness and its agent/designate to access, discuss, use, collect from, and disclose to its agents, consultants, Health Canada, the Canadian Agency for Drugs and Technologies in Health (CADTH) and all persons, parties or entities involved in the CDR Procedure, the Patented Medicine Price Review Board (PMPRB), Alberta Health Services and the government of any province or territory in Canada, all submission information and information in the possession of Health Canada, CADTH, PMPRB, Alberta Health Services and the government of any province or territory in Canada
2. Letter Confirming Ability to Supply
 - a letter signed by a senior official providing assurance that the manufacturer is able to supply the specific drug product and strength from the time of listing in a quantity sufficient to meet the anticipated demand in Alberta for a minimum of 6 months.
3. Justification for the Line Extension
 - a separate document indicating the reason for and evidence to justify the need for the new strength, formulation or reformulation of the drug product
4. A hard copy and electronic (CD) copy of the following from the Common Technical Document:
 - Clinical Overview (Module 2.5), and
 - Clinical Summary (modules 2.7.1, 2.7.3, 2.7.4 and 2.7.6).

Note: If a Common Technical Document was not prepared for Health Canada, a Comprehensive Summary may be acceptable in lieu.

In the event a Comprehensive Summary was not prepared for Health Canada (i.e. clinical studies have not been conducted on the new strength, formulation or reformulation) then the manufacturer must provide evidence establishing a clear linkage between the submitted product(s) and a currently listed product(s). This can be in the form of:

 - i. bioequivalence data; or
 - ii. evidence of formulation proportionality (i.e. a comparison of master formulae for all submitted strengths) and evidence of a similar dissolution profile.
5. Copy of completed Drug Identification Number (DIN) notification form
6. Copy of Notice of Compliance (NOC)
7. Current Patent Status
 - a signed statement from the manufacturer stating that the submitted product does not infringe any patents
 - expiry date(s) of all Canadian patent(s)
8. Copy of completed and approved Certified Product Information Document (CPID)
 - in lieu of the CPID, a Master Formula and Final Product Specifications must be provided
9. Price Information
 - The proposed price for Alberta (which must be in compliance with the Price Policy)

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10. Product Monograph (revised to include the line extension)
 - in addition to a hard copy, an electronic (CD) copy of the TPD-approved Product Monograph compatible with Microsoft Word
11. Economic Information
 - a completed *Budget Impact Assessment for the Alberta Health and Wellness Drug Benefit List* form. Note: copies of this form can be obtained by accessing the *Alberta Health and Wellness Drug Benefit List* website at www.ab.bluecross.ca/dbl/manufacturers.html, or by contacting the Coordinator, Scientific and Research Services, Alberta Blue Cross at Phone: (780) 498-8098 or Fax: (780) 498-3534.
12. If requested, the manufacturer must provide written confirmation from the CDR Directorate that the drug product is not eligible for review under the CDR Procedure.

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D) Interchangeable Drug Products

The following submission requirements pertain to multisource drug products submitted for listing in an interchangeable grouping in the *Alberta Health and Wellness Drug Benefit List*.

For Expedited and Full Reviews:

1. Consent Letter
 - an unrestricted letter authorizing Alberta Health and Wellness and its agent/designate to access, discuss, use, collect from, and disclose to its agents, consultants, Health Canada, the Canadian Agency for Drugs and Technologies in Health (CADTH) and all persons, parties or entities involved in the CDR Procedure, the Patented Medicine Price Review Board (PMPRB), Alberta Health Services and the government of any province or territory in Canada, all submission information and information in the possession of Health Canada, CADTH, PMPRB, Alberta Health Services and the government of any province or territory in Canada
2. Letter Confirming Ability to Supply
 - a letter signed by a senior official providing assurance that the manufacturer is able to supply the specific drug product and strength from the time of listing in a quantity sufficient to meet the anticipated demand in Alberta for a minimum of 6 months.
3. Copy of completed Drug Identification Number (DIN) notification form
4. Copy of Notice of Compliance (NOC)
 - Note: For Old Drug Products (a drug product where the active ingredient is designated as an “old drug” by Health Canada and the drug product was approved on the basis of a DIN application), a Notice of Compliance is not required.
5. Current Patent Status
 - a signed statement from the manufacturer stating that the submitted product does not infringe any patents
6. *For Pseudo-Generic Drug Products:* Letters from both the manufacturer of the submission drug product and the manufacturer of the innovator brand or a currently listed drug product within the submission product’s interchangeable grouping, stating that the submission drug product is manufactured under the identical master formula and manufacturing and quality control specifications, as the innovator brand or the currently listed drug product.
7. Price Information
 - The proposed pricing in Alberta must be in compliance with the Price Policy. Exceptions to the Fixed Pricing Rules may be considered at the sole discretion of the Minister. Accordingly, a request for an exception (as per sections 18-21 of the Price Policy) must accompany a submission that does not meet the Price Policy in order for it to be deemed complete.
8. Copy of completed and approved Certified Product Information Document (CPID)
 - Note: In lieu of the CPID, a Master Formula and Final Product Specifications must be provided
9. Product Monograph
 - in addition to a hard copy, an electronic (CD) copy of the TPD-approved Product Monograph compatible with Microsoft Word is required
 - Note: For Old Drug Products, the Prescribing Information may be provided in lieu of the Product Monograph.

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For FULL REVIEWS ONLY, the following ADDITIONAL information must be provided:

10. Evidence that the listing criteria for interchangeable drug products has been met. See *Criteria for Listing Drug Products* **and** *Interchangeable Drug Products* sections for specific applicable criteria.

E) Resubmissions

Resubmission Requests – General

1. A resubmission request may be made for a Drug Product that is not currently listed on the AHWDBL or List (collectively referred to as the “AHWDBL”) in a case where the Drug Product:
 - a. was previously listed on the AHWDBL;
 - b. was the subject of a previous submission for listing on the AHWDBL; or
 - c. is listed on the AHWDBL but is subject to restrictions.
2. A resubmission request:
 - a. must comply with the requirements set out below; and
 - b. may be made by a Manufacturer for a Drug Product only once in a 12 month period, running from April 1st through to March 31st, unless the Minister of Alberta Health and Wellness (Minister), in the Minister’s sole discretion, invites a Manufacturer to make a resubmission request.
3. The Minister, the Expert Committee on Drug Evaluation and Therapeutics (Expert Committee), and Alberta Health and Wellness (AHW):
 - a. may request information in addition to the requirements set out below; and
 - b. may from time to time set deadlines by which a resubmission request may be made, or a request for additional information must be provided.
4. In the case where:
 - a. additional information has been requested by the Minister, the Expert Committee or AHW, the resubmission request is not considered to be complete unless and until the requested additional information is provided to the Minister, the Expert Committee or AHW; and
 - b. a deadline has been set as referred to above, failure to provide a complete resubmission request within such deadline means that a resubmission request will not be reviewed by the Expert Committee or AHW or considered by the Minister.
5. The Minister may, in the Minister’s sole discretion, refer a Drug Product, that was the subject of a resubmission request which meets the requirements set out in this policy, to an Alberta Price Confirmation (APC) or Interim APC process.
6. In the event that a Drug Product is referred to an APC or Interim APC process, the Manufacturer must comply with the Price Policy and the Terms and Conditions of the APC or Interim APC. A referral to an APC or Interim APC or the submission of a Price Confirmation or Confirmed Price for the Drug Product by the Manufacturer does not obligate the Minister to list a Drug Product on the AHWDBL.

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7. In the event that the Minister, in the Minister's sole discretion, requires additional advice or input on a resubmission request, the Minister may refer the resubmission request to the CDR Procedure, the Expert Committee or any other entity for further advice or a full review.
8. For additional clarity, the provisions outlined under the "Submissions for Drug Reviews" are also deemed to apply to resubmission requests except as specifically modified by the provisions in this subsection "E) Resubmissions", in which case this subsection applies.

Resubmission Requests Requiring Expert Committee Review

9. In addition to the requirements in "Resubmission Requests – General" above, this section applies to a resubmission request for a Drug Product that was reviewed by the Expert Committee and a decision was made by the Minister to:
 - a. not add the Drug Product to the AHWDBL for reasons other than those specified in section 12 below;
 - b. add the Drug Product to the AHWDBL with restrictions; or
 - c. maintain current listing status of the Drug Product on the AHWDBL despite the Manufacturer's request for change.
10. A general resubmission request may be made for a previously submitted Drug Product on the *Resubmission for the Alberta Health and Wellness Drug Benefit List* form. The form can be obtained at www.ab.bluecross.ca/dbl/manufacturers.html or by contacting the Coordinator, Scientific and Research Services, Alberta Blue Cross by phone at (780) 498-8098 or by fax at (780) 498-3534.
11. A resubmission request must be complete and must include:
 - a. a completed *Resubmission for the Alberta Health and Wellness Drug Benefit List* form. A resubmission request requires review by the Expert Committee and a recommendation made by the Expert Committee for the Minister's consideration for listing or not listing the Drug Product on the AHWDBL. The form must contain new information not previously submitted for a review of the Drug Product by the Expert Committee, unless otherwise indicated;
 - b. an unconditional consent letter authorizing AHW and its employees, contractors, consultants and agents to collect and use information respecting a Drug Product and to disclose the subject information to AHW, its employees, contractors, consultants and agents, Health Canada, the Canadian Agency for Drugs and Technologies in Health (CADTH), all persons, parties or entities involved in the CDR Procedure, the Patented Medicine Price Review Board (PMPRB), Alberta Health Services (AHS) and the government of a province or territory in Canada. Information that may be collected, used and disclosed includes, but is not limited to, all Drug Product submission and resubmission information and information about the Drug Product in the possession of Health Canada, CADTH, all persons, parties or entities involved in the CDR Procedure, PMPRB, AHS, AHW, the Expert Committee, and the government of a province or territory;

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- c. a confirmation letter signed by a senior official of the Manufacturer stating that the Manufacturer is able and willing to supply the Alberta market with the subject Drug Product in a quantity consistent with applicable APC or Interim APC requirements; and
- d. a revised Budget Impact Assessment (BIA) form in the case where new economic information about the Drug Product is available, that has not been previously submitted, to support the resubmission request.

Resubmission Requests based on the AHWDBL Price Policy

12. In addition to the requirements in “Resubmission Requests – General” above, this section applies to resubmission requests for a Drug Product that:
 - a. has not been listed on the AHWDBL, or that has been removed from the AHWDBL, by the Minister where the requirements of an Alberta Price Confirmation (APC), Interim APC or the Price Policy were not satisfied; or
 - b. has been removed from the AHWDBL at the request of the Manufacturer.

13. A price policy resubmission request may be made on the *Alberta Price Policy Resubmission Form for the Alberta Health and Wellness Drug Benefit List*. The form can be obtained at www.ab.bluecross.ca/dbl/manufacturers.html or by contacting the Coordinator, Scientific and Research Services, Alberta Blue Cross by phone at (780) 498-8098 or by fax at (780) 498-3534.

14. A resubmission request must be complete and must include:
 - a. a completed *Alberta Price Policy Resubmission Form for the Alberta Health and Wellness Drug Benefit List* ;
 - b. an unconditional consent letter authorizing AHW and its employees, contractors , consultants and agents to collect and use information respecting a Drug Product and to disclose the subject information to AHW, its employees, contractors, consultants and agents, Health Canada, the Canadian Agency for Drugs and Technologies in Health (CADTH), all persons, parties or entities involved in the CDR Procedure, the Patented Medicine Price Review Board (PMPRB), Alberta Health Services (AHS) and the government of a province or territory in Canada. Information that may be collected, used and disclosed includes, but is not limited to, all Drug Product submission and resubmission information and information about the Drug Product in the possession of Health Canada, CADTH, all persons, parties or entities involved in the CDR Procedure, PMPRB, AHS, AHW, the Expert Committee, and the government of a province or territory; and
 - c. a confirmation letter signed by a senior official of the Manufacturer stating that the Manufacturer is able and willing to supply the Alberta market with the subject Drug Product in a quantity consistent with applicable APC or Interim APC requirements.

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Criteria for Listing Drug Products

- The *Criteria for Listing Drug Products* apply to all drug product submissions.
- If more than one criterion apply, at the sole discretion of the Expert Committee on Drug Evaluation and Therapeutics (Expert Committee), Alberta Health and Wellness or the Minister, the most stringent and/or appropriate combination of criteria will apply.
- For multisource drug products seeking a designation of interchangeability, the drug product must also meet the additional criteria outlined under “*Interchangeable Drug Products*”.

1. Clinical studies must have demonstrated the safety and efficacy of the product in appropriate populations.

2. The product must:

- a. possess therapeutic advantage over other presently accepted therapies or treatments of the disease entity for which the product is indicated, or
- b. be more cost-effective than presently accepted therapy.

3. Assessment of therapeutic advantage may include consideration of:

- i. clinical efficacy;
- ii. risk/benefit ratio;
- iii. toxicity;
- iv. compliance;
- v. clinical outcomes;
- vi. Health Canada warnings and advisories;
- vii. population health issues; or
- viii. any other factor which affects the therapeutic value of the product.

4. The Expert Committee, Alberta Health and Wellness and/or the Minister may, in addition to all of the factors listed above, also consider any factors that they consider appropriate, including but not limited to any or all of the following:

- i. the recommendations from the CDR review,
- ii. failure by a manufacturer to supply a sufficient quantity of drug product to meet the demand in Alberta (as determined by Alberta Health and Wellness at its sole discretion, and based on any information it deems appropriate),
- iii. failure by a manufacturer to provide
 - (A) a Price Confirmation, or
 - (B) a Price Confirmation or Confirmed Price in accordance with the Price Policy and/or the Alberta Price Confirmation (APC) Terms and Conditions;
- iv. failure by a manufacturer to comply with any APC Terms and Conditions;

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- v. type of drug, drug product, class or category and indications for use,
 - vi. other available alternative products, treatments or therapies,
 - vii. whether the product is interchangeable,
 - viii. cost of the product and/or potential cost savings or impact on drug expenditures under the List,
 - ix. volume of use and amounts paid out for similar products, classes or categories,
 - x. utilization patterns
 - xi. expenditure management and resources,
 - xii. patent issues,
 - xiii. coverage provided by other programs,
 - xiv. for interchangeable products, concerns that are related to or affect the interchangeability of the drug product,
 - xv. issues, concerns, objectives, goals and/or mandates related to any government policies, plans or programs, and
 - xvi. patient care concerns related to factors external to the drug product.
5. New Chemical Entities, New Combination Products and other single source products not eligible for review under the CDR Procedure may, at the sole discretion of Alberta Health and Wellness and/or the Minister, be considered for priority review and possible addition to the *List* if the product submission is otherwise complete, and the product has been granted "Priority Review" status by the Therapeutic Products Directorate, Health Canada. A copy of documentation from the Therapeutic Products Directorate granting 'Priority Review' status is required.
6. The onus is on the manufacturer to formally request, in writing, consideration on a priority review basis if, in the opinion of the manufacturer, the product meets any of the above priority review criteria. Request for priority review does not automatically mean that the submission will be considered on that basis. The decision whether to conduct a priority review will be made by Alberta Health and Wellness and/or the Minister at their sole option and discretion.

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Interchangeable Drug Products - Additional Criteria

Principle:

Decisions respecting interchangeability and drug lists remain in the domain of the institution responsible for the costs of the product which includes hospitals, provincial governments and other third party payers (6/9/95 *Canada Gazette Part II, Vol. 129, No. 18*)

Preface:

The *Alberta Health and Wellness Drug Benefit List (AHWDBL)* contains designations of interchangeability for approved multisource drug products. The Expert Committee on Drug Evaluation and Therapeutics makes recommendations on interchangeability to Alberta Health and Wellness through the Executive Director, Pharmaceutical Funding and Guidance Branch, Health Policy and Service Standards Division. The Minister of Health and Wellness makes the final decisions on interchangeability after reviewing the recommendations of the Expert Committee and/or Alberta Health and Wellness.

Definitions:

(Note: additional definitions in the applicable Appendices may apply)

Interchangeable Drug Product: An interchangeable drug product is a drug product that has been designated as interchangeable by the Minister of Health and Wellness after reviewing the recommendations of the Expert Committee or Alberta Health and Wellness. Recommendations regarding interchangeability are made taking into consideration the scientific, therapeutic, clinical and socio-economic merits of drug products in accordance with the published criteria. Drug products designated as interchangeable are expected to be safe when interchanged with other drug products in the interchangeable grouping, and to have the same therapeutic effectiveness when administered to patients under the conditions specified in the labeling. The designation of interchangeability is made only for the purpose of funding of drug benefits covered under the Alberta government-sponsored drug benefit programs and is not to be used as a scientific reference or prescribing guide.

Multisource Drug Product: Drug products are considered to be multisource drug products when they are manufactured and/or distributed by more than one manufacturer.

Pharmaceutical Alternative: Drug products may be considered to be pharmaceutical alternatives if they use the same route of administration and contain the same active therapeutic ingredient(s) but are different salts, esters or complexes of that moiety, or are different dosage forms or strengths.

Pharmaceutical Equivalent: Drug products are considered to be pharmaceutical equivalents if they contain the same active therapeutic ingredient(s), are of comparable dosage form(s), route of administration and are identical in strength or concentration.

Pseudo-Generic Drug Product: A pseudo-generic drug product is a drug product that is manufactured under the identical master formulae and manufacturing and quality control specifications as a) the innovator brand of the drug; or b) any drug product that is currently listed on the *AHWDBL* within the submission product's interchangeable grouping.

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TPD Reports - refers collectively to the following Health Canada Therapeutic Products Directorate (TPD) guidance publications as of December 31, 2009:

- *Conduct and Analysis of Bioavailability and Bioequivalence Studies - Part A: Oral Dosage Formulations Used for Systemic Effects, and Part B: Oral Modified Release Formulations*; (which may be referred to in the List as “**TPD Part A**”, and “**TPD Part B**”); and
- *Report C: Report on Bioavailability of Oral Dosage Formations, Not in Modified Release Form, of Drugs used for System Effects, Having Complicated or Variable Pharmacokinetics* (which may be referred to in the List as “**TPD Report C**”); and
- *Bioequivalence Requirements: Comparative Bioavailability Studies Conducted in the Fed State*.

Interchangeable Reviews:

- A. The Expert Committee and/or Alberta Health and Wellness and/or the Minister may, in addition to considering the *Interchangeable Drug Products* criteria, also consider any other criteria in the AHWDBL, including but not limited to the *Criteria for Listing Drug Products*.**
- B. Recommendations regarding interchangeability are made taking into consideration the scientific, therapeutic, clinical and socio-economic merits of drug products in accordance with the published criteria. Drug products designated as interchangeable are expected to be safe when interchanged with other drug products in the interchangeable grouping, and to have the same therapeutic effect when administered to patients under the conditions specified in the labeling.**
- C. Issuance of a Notice of Compliance by the TPD which includes a Declaration of Equivalence does not mean the drug product will automatically be designated as interchangeable.**

Expedited Reviews

1. Multisource drug products seeking a listing designation as interchangeable may be eligible for an expedited review if:
 - a. The drug product submission complies with the submission requirements.
 - b. The drug product does **NOT** fall into any of the categories of drug products that require a Full Review (below), unless the drug product is a Pseudo-Generic Drug Product.
 - c. The drug product is not a subsequent entry biologic (subsequent entry biologics are not eligible for review as interchangeable products).

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- d. The drug product has been granted a Notice of Compliance by Health Canada that includes a declaration of bioequivalence with a Canadian brand/innovator reference product that is listed (or at the sole discretion of Alberta Health and Wellness and/or the Minister, has been previously listed) on the *Alberta Health and Wellness Drug Benefit List*.
- e. The drug product must be a pharmaceutical equivalent to the Canadian innovator reference product.
- f. The proposed price in Alberta provided in the manufacturer's submission complies with the Price Policy.
- g. Even if the drug submission review is expedited, Alberta Health and Wellness and/or the Minister may refuse to list a drug product, or the listing of the drug product may be delayed, if the manufacturer has failed
 - (A) to provide a Price Confirmation,
 - (B) to provide a Price Confirmation or Confirmed Price in accordance with the Price Policy and/or the applicable APC Terms and Conditions; or
 - (C) to comply with the terms and conditions of an applicable APC.

Full Reviews

Multisource drug products seeking a listing designation as interchangeable that fall within the categories listed below are required to undergo a Full Review by the Expert Committee. The following additional interchangeability criteria will apply to Full Reviews:

1. The drug product must be a
 - a. pharmaceutical equivalent; or
 - b. pharmaceutical alternative,as determined at the sole discretion of the Expert Committee.
2. The drug product is not a subsequent entry biologic (subsequent entry biologics are not eligible for review as interchangeable products).
3. The proposed price in Alberta contained in the manufacturer's submission complies with the Price Policy.
4. The drug product has been demonstrated to be bioequivalent, or has provided evidence of comparative therapeutic efficacy, with the reference drug product as outlined below;
 - a. For drug products in the following categories, for which bioequivalence studies CAN be conducted:**
 - i. For Critical Dose Drug Products, the drug product must meet the criteria in the *Critical Dose Drug Product Appendix*.
 - ii. For Non-Linear Drug Products, the drug product must meet the criteria in the *Non-Linear Drug Product Appendix*.

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- iii. For Rapid Onset Drug Products, the drug product must meet the criteria in the *Rapid Onset Drug Product Appendix*.
- iv. For Drug Products for which Bioequivalence is Supported by Metabolite Data, the drug product must meet the criteria in the *Drug Products with Metabolite Data Appendix*.
- v. For Drug Products for which Bioequivalence is Supported by Measurement of the Drug in a Matrix other than Plasma or Serum (e.g., Whole Blood, Urine, Tissue), the drug product must meet the criteria in the *Drug Product with Alternate Matrix Measurement Appendix*.
- vi. For Old Drug Products, the product must meet the criteria in the *Old Drug Product Appendix*.
- vii. For Drug products which possess complex delivery systems, the product must meet the criteria in the *Complex Delivery System Drug Product Appendix*.

b. For drug products in the above categories for which bioequivalence studies CANNOT be conducted:

- i) Evidence of comparative therapeutic efficacy of the submitted product with the reference product via:
 - (A) a therapeutic equivalence study; or
 - (B) Studies that meet the requirements and standards for pharmacodynamic studies outlined in TPD Report C;

and
- ii) Sufficient rationale for why a bioequivalence study cannot be conducted.

c. For drug product submissions using a Non-Canadian Reference Product (NCRP):

- i) An NCRP may only be used when it meets the *Criteria for use of a Non-Canadian Reference Product* as set out in Health Canada's *Drugs Directorate Policy regarding the use of a Non-Canadian Reference Product under the provisions of Section C.08.002.1(c) of the Food and Drug Regulations* (the "NCRP Criteria"). See also *Interpretation Notice #1*.
- ii) If the NCRP Criteria is met, the drug product must demonstrate bioequivalence to the NCRP through studies that meet the requirements and standards of the applicable TPD Reports.

5. The drug product must meet all other criteria outlined in the applicable Appendix.

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6. In addition, the Expert Committee may also consider any other factor that may affect the interchangeability of a drug product, including but not limited to:
 - characteristics of the drug product (e.g. shape, scoring, configuration, packaging, labelling);
 - excipients and non-medicinal ingredient(s) (e.g. sugar, sodium);
 - expiration times;
 - storage conditions.

Interchangeable Drug Products - Additional Criteria APPENDICES

Critical Dose Drug Product Appendix

Critical Dose Drug: Is a drug where comparatively small differences in dose or concentration lead to dose- and concentration-dependent, serious therapeutic failures and/or serious adverse drug reactions which may be persistent, irreversible, slowly reversible or life threatening, which could result in inpatient hospitalization or prolongation of existing hospitalization, persistent disability or incapacity, or death.

Critical dose drugs include:

- a) Any drug listed in *Appendix I - List of Critical Dose Drugs* of Health Canada's Guidance for Industry entitled *Bioequivalence Requirements: Critical Dose Drugs*; and
- b) Any other drug that the Expert Committee determines meets the above definition, which determination may include consideration of any other matter that may affect the interchangeability of a product containing a critical dose drug.

Criteria: Bioequivalence studies must meet the requirements and standards in the TPD Reports, with the exception that the following standards will be used:

1. The 90% confidence interval of the relative mean AUC of the test to reference formulation should be within 90.0 to 112.0%; the relevant AUC or AUCs as described in TPD Reports A and B are to be determined.
2. The 90% confidence interval of the relative mean measured C_{max} of the test to reference formulation should be between 80.0 and 125.0%.
3. These requirements are to be met in both the fasted and fed states.
4. These standards should be met on log transformed parameters calculated from the measured data and from data corrected for measured drug content (percent potency of label claim).
5. If a steady-state study is required, the 90% confidence interval of the relative mean measured C_{min} of the test to reference formulation should also be between 80.0 and 125.0%.

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Non-Linear Drug Product Appendix

Non-Linear Drug: A drug is considered to be a Non-Linear Drug if the Health Canada approved product monograph for the Canadian innovator drug product states that it is a non-linear drug.

Criteria:

1. Bioequivalence studies must meet the requirements and standards in the TPD *Reports*, and these requirements and standards should be met in single dose studies in both the fasted and fed states, with the following exceptions:

a) if non-linearity occurs after the drug enters the systemic circulation, a fed study may be waived unless there is sufficient evidence, at the Expert Committee's sole discretion, that a product exhibits a food effect; or

b) if a condition (fasted or fed) for product ingestion is contraindicated, that condition may be waived in a bioequivalence trial. For bioequivalence testing the fasting and fed doses should be the same.

2. At the sole discretion of the Expert Committee, it may be acceptable to conduct bioequivalence studies at either the highest or lowest strength of a range of proportionally formulated strengths as outlined below:

a) For drugs with non-linear pharmacokinetics in the single unit dose range of approved strengths resulting in **greater than proportional increases in AUC** with increasing dose, the bioequivalence studies should be conducted on at least the **highest** strength. That is, where non-linearity arises from capacity-limited clearance, the highest strength for the proposed indications should be tested. For drugs where the non-linear concentration range is reached only after multiple doses within the approved dosing regimen, studies utilizing multiple units of the highest formulation strength or steady-state studies in the non-linear range may be required. Where steady-state studies are conducted, single dose studies will not be required. In all situations, safety in dosing should be considered.

b) For drugs with non-linear pharmacokinetics in the single unit dose range of approved strengths resulting in **less than proportional increases in AUC** with increasing dose, the bioequivalence studies should be conducted on at least the **lowest** strength (single dose unit). That is, where non-linearity arises from capacity-limited absorption, the test dose should be a single unit of the lowest strength.

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Rapid Onset Drug Product Appendix

Rapid Onset Drugs: Are as defined in TPD Report C.

Criteria: Bioequivalence studies must meet the requirements and standards in the TPD *Reports*, except that the relative mean $AUC_{\text{Ref}t_{\text{max}}}$ of the test to reference formulation should be within 80 to 125%, where $AUC_{\text{Ref}t_{\text{max}}}$ for a test product is defined as the area under the curve to the time of the maximum concentration of the reference product, calculated for each study subject.

Drug Product with Metabolite Data Appendix

For drug product submissions for which evidence of bioequivalence is supported by metabolite, rather than the parent drug, data.

Criteria:

1. Bioequivalence studies must meet the requirements and standards in the TPD Reports.
2. If the parent drug is not detectable due to rapid biotransformation or limitations in available assay methodology, the use of metabolite data may be acceptable.
3. The measured metabolite must be a primary (first step) measurable by a validated assay, and there must be sufficient scientific justification for a waiver of the measurement of the parent drug and the use of metabolite data.
4. The choice of using the metabolite instead of the parent drug is to be clearly stated, *a priori*, in the objective of the study in the study protocol.
5. The use of metabolite concentrations in urine is not acceptable.

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Drug Product with Alternate Matrix Measurement Appendix

For drug product submissions for which bioequivalence data is supported by measurement of the drug in a matrix other than plasma or serum (e.g., whole blood, urine, extravascular tissue).

Criteria:

- Bioequivalence studies must meet the requirements and standards in the TPD *Reports*.
- The assay used for measurement of the drug (or metabolite) must be validated for the alternate matrix of measurement.
- Sufficient rationale for why the use of an alternate matrix measurement study is appropriate.

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Old Drug Product Appendix

Old Drugs: Are drug products where the active therapeutic ingredient(s) is designated as an “old drug” by Health Canada and the drug product is approved on the basis of a DIN application (i.e. an NOC is not issued by Health Canada).

Criteria:

1. Bioequivalence studies must meet the requirements and standards in the TPD *Reports*.
2. For old drug products for which bioequivalence studies CANNOT be conducted, the submission must include:
 - i) Evidence of comparative therapeutic efficacy of the submitted product with the reference product via:
 - (A) a therapeutic equivalence study; or
 - (B) studies that meet the requirements and standards for pharmacodynamic studies outlined in TPD Report C; or
 - (C) surrogate comparisons using *in vivo* or *in vitro* test methods.

and
 - ii) Sufficient rationale for why a bioequivalence study cannot be conducted.

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Complex Delivery System Drug Product Appendix

Complex Delivery System Drugs: Are drug products that possess complex drug release characteristics in the pharmaceutical dosage form that are intended to:

- (1) deliver the drug at a rate that is independent of time and the concentration of the drug (i.e. zero order process), or
- (2) deliver the drug to a specific physiological site (i.e. site-specific release).

Criteria:

1. Bioequivalence studies must meet the requirements and standards in the TPD Reports.
2. A detailed description of the pharmaceutical dosage forms and specific drug release characteristics of the submitted drug product and reference drug product must be provided to permit evaluation of the similarity of drug release of the respective formulations.

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Review of Benefit Status (ROBS) Criteria

The Expert Committee and/or Alberta Health and Wellness may at any time review the benefit status of a drug product, a group of drug products, a class or classes of drug products, or a category or categories of drug products listed or being considered for listing on the *AHWDBL* (collectively “Products”). The Expert Committee and/or Alberta Health and Wellness may, at their sole option and discretion, recommend altering or discontinuing the benefit status for Products if one or more of the following criteria are met. These are general criteria only, which are intended to be applied flexibly, having regard to each individual case. The criteria may be modified or adapted as the situation may require, and not all criteria will apply to each case:

1. There has been a significant change to the Product(s). Significant changes may include changes in NOC, DIN, product name, manufacturer or distributor, indication, product monograph, packaging, formulation, or any change that could potentially affect the bioavailability or bioequivalence of a product.
2. The Product(s), no longer possesses demonstrated therapeutic advantage compared to other presently accepted therapies or treatments of the disease entity for which the Product(s) is/are indicated. Assessment of therapeutic advantage may include consideration of clinical efficacy, risk/benefit ratio, toxicity, compliance, clinical outcomes, Health Canada advisories, population health issues, and any factor which affects the therapeutic value of the product, class or category.
3. The Product(s) is/are no longer cost-effective compared to other presently accepted therapies or treatments of the disease entity for which the Product(s) is/are indicated.
4. To enable broader coverage of higher priority Product(s).
5. When a product has been discontinued by the manufacturer.
6. When Product(s) is/are changed from prescription to non-prescription status, the Expert Committee may recommend continuing, altering or discontinuing benefit status of the Product(s) based upon scientific, therapeutic, clinical and socio-economic merits of the Product(s).
7. For all ROBS reviews, the Expert Committee, Alberta Health and Wellness and/or the Minister may, in addition to all of the factors listed above, also consider any factors that they consider appropriate, including but not limited to any of the criteria for listing drug products and interchangeable drug products.

Unsolicited information from manufacturers relating to ROBS Reviews will not be put before the Expert Committee. However, if the Expert Committee determines that a change in benefit status may be warranted, manufacturers of the affected Product(s) will be notified and provided with an opportunity to make submissions to the Expert Committee prior to the final recommendation being made. Notification will include advice regarding the form of submission that will be accepted, the deadline for filing the submission and any other relevant advice. Any submissions that do not comply with the notification advice will not be put before the Expert Committee.

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Supply Shortages

Where a manufacturer has not supplied, or is not supplying, a sufficient quantity of drug product to meet the demand in Alberta (as determined by Alberta Health and Wellness at its sole option and discretion, and based on any information it deems appropriate):

1. If the unavailable product is a single-source product on the *List*, products not otherwise allowed as benefits may be added temporarily or temporarily reimbursed for the Alberta government-sponsored drug programs.
3. Products added or reimbursed under this policy may remain as temporary benefits until the supply shortage is rectified.
4. In order to remain as benefits after the shortage is rectified, manufacturers of these products must follow the usual submission and review process for listing.
5. Alberta Health and Wellness may recover any cost difference from the manufacturer unable to supply a drug product.
6. Alberta Health and Wellness may at its sole discretion, take any other steps or require any information from a manufacturer or other person, that is reasonably required to manage a supply shortage.
7. Alberta Health and Wellness may:
 - refuse to list any product of the manufacturer,
 - refuse to consider any product submission of the manufacturer for expedited or priority review; or
 - cancel or modify the listing of the product that is not meeting the supply demand.

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Units of Issue for Pricing

These units of issue are used for presenting prices in the *List*.

Dosage Form	Unit of Issue Priced in <i>AHWDBL</i>
Ampoules	Millilitre
Bladder Irrigation Solutions	Millilitre
Dental Pastes	Gram
Devices	Device
Inhalation Capsules	Capsule
Inhalation Cartridges	Cartridge
Inhalation Disks	Disk
Inhalation Solutions or Suspensions	Millilitre – all preparations including nebulas
Inhalation Unit Dose Solution	Millilitre
Injections	Vial – where reconstitution is required (or Millilitre or Unit where indicated)
Injections	Millilitre – where no reconstitution is required (or Vial where indicated)
Injections – Cartridges	Millilitre
Injections – Emulsion	Millilitre
Injections – Syringes	Syringe (or Millilitre where indicated)
Injection – Implant	System
Injection Syringe/Oral Capsule	Kit
Injection Vial/Oral Capsule	Kit
Injection Vial/Oral Tablet	Kit
Injection Syringe/Oral Tablet	Kit
Intrauterine Insert	System
Irrigating Solutions	Millilitre
Lock Flush	Millilitre
Metered Dose Aerosols	Dose
Metered Inhalation Powder	Dose
Nasal Metered Dose Aerosols	Dose
Nasal Metered or Unit Dose Sprays	Dose
Nasal Solutions	Millilitre
Nasal Sprays	Millilitre
Ophthalmic Solutions or Suspensions or Drops	Millilitre
Ophthalmic Gels or Ointment	Gram
Ophthalmic Long Acting Gellan Solutions	Millilitre
Oral Caplets	Caplet
Oral Capsules – all formulations	Capsule
Oral Drops	Millilitre
Oral Granules	Bulk size – Gram
Individual Packet	Packet

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Units of Issue for Pricing, continued

Dosage Form	Unit of Issue Priced in AHWDBL
Oral Liquids – all formulations	Millilitre
Oral Powders	Gram (or Dose where indicated)
Oral Powder Packets.....	Individual Packet
Oral Rinses	Millilitre
Oral Tablets – all formulations.....	Tablet
Oral Tablets – oral contraceptives.....	Tablet
Oral Tablet/Capsule.....	Kit
Oral Wafer	Wafer
Otic Ointments or Gels	Gram
Otic Solutions or Suspensions or Drops	Millilitre (or Vial where indicated)
Rectal Enemas	Enema
Rectal Foams.....	Gram
Rectal Ointments	Gram
Rectal Retention Enemas.....	Enema
Rectal Suppositories - all formulations	Suppository
Scalp Lotions	Millilitre
Scalp Solutions	Millilitre
Sublingual Metered Dose Spray.....	Dose
Sublingual Tablet.....	Tablet
Topical Bars.....	Gram
Topical Cleansers	Millilitre
Topical Creams/Ointments - all formulations	Gram
Topical Gauzes.....	Dressing
Topical Gels - all formulations	Gram
Topical Jellies	Millilitre
Topical Lotions.....	Millilitre or Gram
Topical Powders	Gram
Topical Solutions	Millilitre
Topical Washes	Millilitre or Gram
Transdermal Gel.....	Gram
Transdermal Patches	Patch
Vaginal Capsules or Ovules or Tablets	Capsule or Ovule or Tablet
Vaginal Creams or Ointments or Gels.....	Gram
Vaginal Douches.....	Millilitre
Vaginal Ovule/Topical Cream.....	Kit
Vaginal Slow Release Rings	Ring
Vaginal Suppositories	Suppository

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Alberta Health and Wellness Expert Committee on Drug Evaluation and Therapeutics: Policy for Administering Interchangeability Challenges

Note: This Policy is not applicable for drug products that are eligible for, and are reviewed under, the Expedited Review Process for interchangeable drug products.

From time-to-time, the Expert Committee on Drug Evaluation and Therapeutics receives unsolicited information (“Challenge Information”) from a manufacturer (the “Challenger”) suggesting that additional information should be taken into account when a submission for interchangeability for a multisource product is being considered by the Expert Committee. Alberta Health and Wellness is not prepared to have any Challenge Information considered by the Expert Committee unless the manufacturer whose product is being challenged (the “Applicant”) is provided with a full copy of the Challenge Information and is given an opportunity to respond to it.

As a result, Alberta Health & Wellness has developed and approved the following process for the handling of Challenge Information.

1. Challenge Information must comply with the following conditions.
2. Challenge information must be received by Alberta Blue Cross:
 - For first-entry interchangeable product submissions – Within 15 days of the date of issuance of the NOC for the Applicant’s product.
 - For all other submissions, by the submission deadline date.
3. All Challenge Information must include an unconditional Written Consent, signed by the Challenger, authorizing Alberta Health and Wellness and its agent/designate to (a) disclose to the Applicant all Challenge Information; and (b) to access, discuss, use, collect from, and disclose to its agents, consultants, Health Canada, the Canadian Agency for Drugs and Technologies in Health (CADTH) and all persons, parties or entities involved in the CDR Procedure, the Patented Medicine Price Review Board (PMPRB), Alberta Health Services and the government of any province or territory in Canada, all submission information and Challenge Information and any information in the possession of Health Canada, the Canadian Agency for Drugs and Technologies in Health (CADTH), the Patented Medicine Price Review Board (PMPRB), Alberta Health Services and the government of any province or territory in Canada.
4. If the above unconditional Written Consent is not submitted as required, the Challenge Information will not be considered by the Expert Committee.
5. If Written Consent is submitted as required, the Challenge Information will be duplicated in its entirety and forwarded by Alberta Blue Cross to the Applicant, inviting a response (“Applicant Response”). The Applicant Response must be received by Alberta Blue Cross no later than 15 days after the date of the letter from Alberta Blue Cross.
6. If an Applicant Response is not received by Alberta Blue Cross within the time provided, only the Challenge Information will be provided to the Expert Committee for consideration. If an Applicant Response is received within the time provided, both the Applicant Response and the Challenge Information will be provided to the Expert Committee for consideration.
7. No further information may be submitted to the Expert Committee for consideration.

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8. The Applicant Response should only address information contained in the Challenge Information. Anything in the Applicant Response that does not relate to information contained in the Challenge Information may, at the sole discretion of the Expert Committee, be disregarded.
9. It is a condition of each and every Submission and Challenge that the terms, conditions, criteria and time limitations contained in this policy will apply and that:
 - a) Applicants, by filing a Submission and Applicant Response; and,
 - b) Challengers, by submitting Challenge Information agree to and are bound by this policy.
10. In the event the anticipated Applicant submission is not received, Challenge Information will be destroyed 6 months after receipt.

Inquiries may be made to:

**Senior Manager
Scientific and Research Services
Alberta Blue Cross
10009 - 108 Street NW
Edmonton AB T5J 3C5
Phone: (780) 498-5978
Fax: (780) 498-3534**

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Your Comments are Important to Us

To improve the high standards established for this publication, the Alberta Health and Wellness Expert Committee on Drug Evaluation and Therapeutics would like to offer you an opportunity for input. Should you have any concerns and/or suggestions concerning product listings or criteria for coverage of products available via special authorization, etc. please let us know. If you are writing in support of a product listing change or a revision to the special authorization criteria for coverage, you must provide evidence in support of your comments from the peer-reviewed scientific literature. In order to meet the expectations of stakeholders relative to objectivity and transparency, all individuals providing comments are required to advise the Expert Committee of any potential conflicts of interest below (please check appropriate box):

Please note: this is not a mechanism for an appeal for a specific patient.

Conflict of Interest: Yes No

If Yes, please indicate the nature of the potential conflict of interest below:

Please provide your comments in the space provided below:

Contact Information:

Name and Address: _____

Phone/Fax: _____

Please print form and mail/fax to:

Alberta Health and Wellness Expert Committee on Drug Evaluation and Therapeutics

*c/o Senior Manager
Scientific and Research Services
Alberta Blue Cross
10009 108 Street NW
Edmonton, Alberta T5J 3C5
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