REQUEST FOR PRODUCT LISTING AGREEMENT ("RFPLA") NUMBER 12-016

ALBERTA HEALTH

DRUG PRODUCTS:
indicated for the treatment of Attention- Deficit/Hyperactivity Disorder (ADHD)

RFPLA Issue Date:	**December 11, 2012**
RFPLA Closing Date:	**January 18, 2013 at 16:00:59 Alberta Time**
Send Responses to:	**Senior Manager, Drug Utilization and Agreements** **Pharmaceutical Funding and Guidance Branch** **11th Floor, Telus Plaza North Tower** **10025 Jasper Avenue** **Edmonton, AB T5J 1S6** **Attention: Filip Palasz**
Direct Questions to RFPLA Facilitator:	**Filip.Palasz@gov.ab.ca**

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1. INTRODUCTION

1.1 PREAMBLE

Albertans covered under government-sponsored drug plans require access to innovative therapies in a timely manner to support improved health outcomes and enhanced patient care. Most Drug Products are listed on the ADBL in accordance with the ADBL price policy and Alberta Price Confirmation process. However, there are certain drugs that are not listed for various reasons, even though there are indications that the drugs may offer some public benefits.

The government sponsored drug plans face financial pressures. Financial sustainability of the drug plans need to be balanced with responsible access to therapies for Albertans covered under government-sponsored drug plans. Therefore, maintaining the ADBL on a comprehensive and sustainable basis is key objective of the related policies.

The Minister may, in the Minister's sole discretion, issue an RFPLA to invite certain or all Manufacturers to make a PLA submission for the consideration of the Minister.

Manufacturer(s) are invited to submit a response according to the specifications, terms and conditions set out in this RFPLA.

An RFPLA is not a tender; it is not a competitive bidding process. No representation or commitment is made that any or all PLA submissions made in response to an RFPLA will be screened, evaluated, negotiated or result in a PLA. Failure to satisfy any term, condition or mandatory requirement of the RFPLA submission requirements may result in rejection of the PLA Submission.

1.2 OBJECTIVES

The objectives of PLA Policy and RFPLA are to:

1. Provide Albertans covered under government-sponsored drug plans with access to innovative therapies in a timely and responsible manner to support improved health outcomes and enhanced patient care.
2. Define clear parameters to establish and execute product listing agreements (PLAs) through a collaborative, predictable and sustainable process between government and industry.
3. Support the best use of resources and promote best value for Alberta's government-sponsored drug plans.
4. Manage risk and uncertainty through cost/budget impact projections.
5. Build capacity and support investment in Alberta-based initiatives aligned with the goals of Alberta's health research and innovation agendas.

1.3 RFPLA TERMINOLOGY

Headings are used for convenience only, and they do not affect the meaning or interpretation of the clauses.

"Alberta Time" means Mountain Standard Time or Daylight Saving Time as provided for in the Daylight Saving Time Act of Alberta.

"**Alberta Health**" or **"AH"** means Her Majesty the Queen in right of Alberta, as represented by the Minister of Health and Wellness.

"Alberta Drug Benefit List" or "**ADBL**" means, collectively:

- the complement of policies and processes that address the requirements for listing drugs as benefits for participants in government sponsored drug plans; and,
- the specific list of Drug Products that form part of the benefits available under government sponsored drug plans, in accordance with the ADBL policies.

Specifically, the term "**ADBL**" refers to both the "**list**" of specific Drug Products that are included as benefits under the government sponsored drug plans and the policies and processes that govern how a Drug Product may be included on the list.

"Applicant" means a Manufacturer that is making a submission for a PLA.

"Business Day" means 08:15 to 16:30, Alberta Time, Monday to Friday, excluding holidays observed by Her Majesty.

"Business Hours" means 08:15 to 16:30 Alberta Time on Business Days.

"Canadian Intellectual Property Office" is the federal government body established by the Patent Act (Canada) that accepts, examines, and grants applications for patents for drug products in Canada.

"Contract" means the written agreement between a successful Applicant and Her Majesty.

"Evaluation Team" means individuals who will evaluate the RFPLA Submissions on behalf of Her Majesty.

"Her Majesty" means Her Majesty the Queen in right of Alberta.

"Materials" means all the working papers, surveys, notes, plans, designs, reports, records, studies, drawings, examinations, assessments, procedures, specifications, evaluations, results, conclusions, interpretations, calculations, analyses, systems, software, source code, documents, writings, programs, hardware, devices, data or any components of these, regardless of how they are represented, stored, produced, or

acquired.

"**Minister**" means Her Majesty the Queen in Right of Alberta, as represented by the Minister of AH or their designate.

"must", "mandatory", "required", "shall" means a requirement that must be met in a substantially unaltered form in order for the RFPLA Submission to receive consideration.

"optional" means a requirement not considered essential, but for which preference may be given.

"Patent Pending Drug" means a Drug Product sold in Canada by a Manufacturer who has applied for a patent in Canada in accordance with the Patent Act (Canada). The Drug Product, under which the PLA submission is submitted, is a Drug Product that:

i. meets the requirements to have patents listed under on Health Canada's Patent Register (Patent Register); and,
ii. a request to be added to the Patent Register for the Drug Product has been filed by the Manufacturer as of the closing date of the RFPLA; however, the Drug Product does not appear on the Patent Register as of the closing date of the RFPLA.

"Patent Register" means the alphabetical listing of medicinal ingredients and their associated patents, the patent expiry dates and other related information established in accordance with the Patented Medicines (Notice of Compliance) Regulations [SOR/133-93 as amended] and is administered by Health Canada and lists only patents that meet the eligibility requirements as set out in the *Patented Medicines (Notice of Compliance Regulations)*.

"Personal Information" means recorded information about an identifiable individual, including:

(i) the individual's name, home or business address or home or business telephone number;
(ii) the individual's race, national or ethnic origin, colour or religious or political beliefs or associations;
(iii) the individual's age, sex, marital status or family status;
(iv) an identifying number, symbol or other particular assigned to the individual;
(v) the individual's fingerprints, blood type or inheritable characteristics;
(vi) information about the individual's health and health care history including information about a physical or mental disability;
(vii) information about the individual's educational, financial, employment or criminal history, including criminal records where a pardon has been given;
(viii) anyone else's opinions about the individual; and,
(ix) the individual's personal views or opinions, except if they are about someone else.

"RFPLA Submission" means the Applicant's response to the RFPLA and includes the RFPLA, the Applicant's attachments to the RFPLA, the PLA Submission form and attachments to the PLA Submission form.

"Request for Product Listing Agreement Submissions (RFPLA)" means the solicitation of proposals from manufacturers interesting in entering into a PLA with the Alberta government-sponsored drug plans.

"Services" means the functions, duties, tasks and responsibilities to be provided by the Applicant as described in the Contract.

"should", "desirable" means a provision having a significant degree of importance to the objectives of the RFPLA.

***Interpretation*:**

Headings are used for convenience only, and they do not affect the meaning or interpretation of the clauses.

References in this policy to:

- to the singular, includes the plural, unless a contrary intention is stated.

The ADBL may be amended from time to time and, unless the contrary is stated, a reference to the ADBL is to the most current version.

1.4 PLA POLICY

The PLA policy forms part of the ADBL and combined with this RFPLA sets out the requirements that must be met for a PLA Submission to be considered for listing on the ADBL through a PLA. Any drug that is listed on the ADBL through a PLA is subject to ADBL policies and processes, as the Minister determines are appropriate. The application of the PLA policy is subject at all times to the sole discretion of the Minister of Health and Wellness.

1.5 RFPLA AVAILABILITY

The Applicant should, when submitting a RFPLA Submission, obtain the RFPLA directly from the Alberta Blue Cross website to facilitate receiving any RFPLA updates/amendments issued by Alberta Health. RFPLA Submissions that do not comply with the RFPLA requirements, including if the RFPLA has been updated/amended, will be rejected.

1.6 RFPLA SCHEDULE OF EVENTS

RFPLA Issue Date:	December 11, 2012
RFPLA Closing Date:	January 18, 2013 at 16:00:59 Alberta Time

The RFPLA will close at 16:00 Alberta Time on the RFPLA closing date. RFPLA Submissions shall be received by Alberta Health before 16:01 Alberta Time on the RFPLA closing date.

The above dates are provided for information only and are subject to change at the sole discretion of Her Majesty.

2. RFPLA INFORMATION

2.1 RFPLA OBJECTIVE

The objective of this RFPLA is to receive a PLA submission for Drug Products indicated for the treatment of Attention- Deficit/Hyperactivity Disorder (ADHD)

2.2 RFPLA REQUIREMENTS (MANDATORY AND DESIRABLE)

2.2.1 DRUG PRODUCTS (MANDATORY)

The Drug Product included in the PLA Submission must:

- Have been approved for sale in Canada as evidenced by a Notice of Compliance or Notice of Compliance with Conditions from Health Canada;
- Be a single source patented drug or is a single source patent pending drug; AND,
- Include a price/volume type of PLA offer as part of the PLA Submission.

2.2.2 PLA SUBMISSION REQUIREMENTS

A PLA submission must include the information required by the PLA Submission Form and this RFPLA as well as details of therapeutic advantage, therapeutic equivalency, cost effectiveness and/or cost savings that the subject drug may provide.

The PLA submission must comply with the following requirements:

- **The Executive Summary must:**
  - Provide a high-level summary of the PLA submission that details the specific terms of the agreement being proposed.

- **The Consent and Confidentiality Acknowledgement Letter must contain the following elements:**
  - When submitting its PLA submission and any other materials requested by AH a manufacturer may designate materials in whole or in part as Confidential Business Information as defined in this Policy.
  - The manufacturer will authorize AH to disclose all PLA submission materials, including any Confidential Business Information to any department or agency of the Government of Alberta that AH determines is necessary to evaluate a PLA submission.
  - The manufacturer will further authorize AH to access, discuss, use, collect from, and disclose to Health Canada, the Canadian Agency for Drugs and Technologies in Health, CDR, the Patented Medicine Prices Review Board all PLA submission information, except Confidential Business Information that AH determines is relevant for the evaluation of a PLA submission. AH will only disclose Confidential Business Information, that has not already been provided to any of the aforementioned organizations by the manufacturer or otherwise, with the prior written consent of the manufacturer.
  - Where AH contemplates disclosure of any Confidential Business Information to an agency or department of a province or territory, not otherwise identified in this section, for purposes related to the evaluation of the PLA submission, AH shall not make disclosure of the Confidential Business Information without the prior written consent of the manufacturer.
  - The manufacturer will further authorize AH to access, discuss, use, collect from, and disclose to its agents, consultants, and advisors, all PLA submission information, including any Confidential Business Information and information in AH's possession for the purpose of evaluating a PLA submission. Prior to disclosing any Confidential Business Information to these persons or organizations AH will obtain Confidentiality and Disclosure Agreements with such party(ies), and advise the affected manufacturer of the existence of such Confidentiality and Disclosure Agreements.

- Where AH has received a request under applicable Freedom of Information and Protection of Privacy (FOIPP) legislation or in any other legal proceedings to disclose Confidential Business Information it will give the manufacturer written notice of such a request. The manufacturer can, to the extent permitted by law, make any representations before the relevant public body or Court about why the Confidential Business Information should not be disclosed. AH will not be compelled to defend a manufacturer's designation of information as being Confidential Business Information that should not be disclosed or the manufacturer's ability to make representations to the public body or Court.
- When a manufacturer no longer considers particulars contained in a PLA submission to be Confidential Business Information it may inform AH of this change in status.
- Where there is any conflict in this Consent and Confidentiality Acknowledgement Letter and an applicable statute or Court order the applicable statute of Court order will take precedence over the contents of this letter.

- **The Summary of promotional activities and risk mitigation strategies must**:
  - include a description of the Manufacturer's mechanisms, strategies and key tactics to facilitate appropriate utilization and prescribing by medical practitioners as identified in the Manufacturer's marketing plan (including a description of how these mechanisms and strategies align with medically endorsed, Canadian Clinical Practice Guidelines);
  - explain the Manufacturer's proposed binding obligations including a detailed description of mechanisms for risk mitigation if cost and / or sales projections for the subject drug product are exceeded in any of the years while the PLA is in effect;
  - identify any current or proposed registries or Phase IV trials that will be executed during the PLA term.

- **The Certificate must:**
  - Be provided by the Applicant.
  - Be in a form satisfactory to the Minister.
  - Confirm and warrant that:
    - the Applicant has read and understands the PLA policy;
    - the information contained in the PLA submission reflects the Applicant's best information and estimates in respect of the Alberta government sponsored drug plans;
    - the PLA submission applies to the Alberta government sponsored drug plans as outlined in Section 2.2.4, as will any PLA that may be entered into as a result of such PLA submission; and
    - there is no impediment, in law or otherwise, to the Manufacturer entering into a PLA.

In addition to Price/Volume type of agreement proposals, if a PLA Submission by an Applicant includes an element of a:

- Utilization Management Agreement
- Coverage with Evidence Development Agreement
- Health Research Capacity Development

the PLA Submission must satisfy the submission requirements for each type of PLA that comprises the overall PLA submission. For greater clarity:

A PLA submission for an Utilization Management Agreement must:

- outline the planned methodology for utilization management in detail;
- explain the environment required to conduct the UMA including:
  - availability, accessibility and complexity of accessing of personnel, facilities and infrastructure required to execute, implement and perform the UMA.

A PLA submission for a Coverage with Evidence Development Agreement must:

- outline the conceptual or clinical framework, proposed design and methodology for evidence development;
- provide a preliminary plan for evidence development and explain how and to whom the evidence will be disseminated, including any and all potential outlays of funding and/or resources to be made by the pharmacy program and the Province of Alberta;
- explain the environment required to develop evidence including: availability, accessibility and complexity of accessing of personnel, facilities and infrastructure required to execute the PLA.

A PLA submission for a Health Research Capacity Development must:

- if in the form and nature of a restricted research grant, include a funding brief that outlines the proposed use and objectives of the funding including proposed recipients;
- If in the form and nature of an unrestricted grant, identify amount and payment terms.

2.2.3 TYPES OF PLA

Type of PLA		Mandatory or Desirable
1.	**Price/Volume Agreement**	Mandatory
2.	**Health Research Capacity Agreement**	Desirable
3.	**Utilization Management Agreement**	Desirable
4.	**Coverage with Evidence Development Agreement**	Desirable

2.2.4 PLA POPULATION

The PLA Submission will apply to all Alberta government-sponsored drug plans, specifically:
It shall also include any drug programs established by Her Majesty the Queen in Right of Alberta during the Term of the PLA including any amalgamations, additions or deletions from enumerated drug programs below:

- the Alberta Blue Cross *Non-Group Coverage (Group 1)* offered by the Alberta Health Care Insurance Plan,

- the Alberta Blue Cross *Coverage for Seniors (Group 66)* provided to all Alberta senior citizens and those on the Alberta Widows' Pension Plan *(Group 66A)*, or

- the drug coverage provided to individuals approved by Alberta Health for *Palliative Care Drug Coverage.* (For these individuals the *Palliative Care Drug Benefit Supplement* must also be considered), or

- the drug coverage provided to Alberta Employment and Immigration, Alberta Children and Youth Services and Alberta Seniors and Community Supports (AISH) clients. (For these clients the *Alberta Employment and Immigration Drug Benefit Supplement* must also be considered.)

2.2.4.1 PLA Population and PLA Submission Form:

The PLA Submission form requests data specific to the AH sponsored drug plans. AH may extrapolate this information to include the other Alberta government-sponsored drug plans.

3. PLA SUBMISSION GUIDELINES

3.1 PLA SUBMISSION FORMAT

Applicants must deliver their RFPLA Submissions in hardcopy format i.e. paper. Facsimile or digital RFPLA Submissions in any form (e.g. diskette files, disk files, tape files, e-mailed files) will not be accepted as the Applicant's RFPLA Submission. However, to assist the Evaluation Team to perform searches within the RFPLA Submission, Applicants are requested to provide an electronic copy of the RFPLA Submission (in Microsoft Office format on CD) for the Evaluation Team's convenience. This electronic copy, when provided, will not be accepted in place of the required hardcopy version. If there are any conflicts, discrepancies, errors or omissions between the electronic and hardcopy versions of the RFPLA Submission, the hardcopy version will take precedence and govern.

RFPLA Submissions may be delivered by hand, courier or mail.

- Applicants should be aware that Canada Post only delivers Government of Alberta mail with Edmonton addresses to the main Canada Post depot in

Edmonton. The Government of Alberta then picks up the mail and distributes it in accordance with the address label. Applicants should consider the above when choosing the method of delivery for their RFPLA Submission as it is the Applicant's responsibility to ensure its RFPLA Submission is received before the RFPLA closing date and time at the location specified in the RFPLA.

In responding to this RFPLA, your attention is drawn to the following:

a) The RFPLA Submission Form in the RFPLA, or a similar representation of the same information as in that letter, must be completed, signed by an authorized representative of the Applicant and included in the RFPLA Submission.
b) RFPLA Submissions received unsigned or after the RFPLA's closing date and time will be rejected.
c) Ambiguous, unclear or unreadable RFPLA Submissions may be cause for rejection.
d) RFPLA Submissions must be sealed and clearly marked with the RFPLA's number and RFPLA closing date and addressed as follows:

Senior Manager, Drug Utilization and Agreements
Pharmaceutical Funding and Guidance Branch
11th Floor, Telus Plaza North Tower
10025 Jasper Avenue
Edmonton, AB T5J 1S6
Attention: Filip Palasz

(Note: waybills accompanying deliveries of PLA Submissions by courier should contain the RFPLA number and the RFPLA's closing date and time.)

(e) Submit three (3) bound copies (bound in such a manner that the pages lie and remain flat when opened), one (1) unbound copy, and one (1) electronic copy of the PLA Submission.

To facilitate ease of evaluation by the Evaluation Team, and to ensure each PLA Submission receives full consideration, PLA Submissions should be organized in the following format using the section titles and sequence listed below:

- Executive Summary,
- Consent letter,
- PLA Submission Form (Appendix B),
- Specific PLA Submission requirements as applicable in section 2.2.3,
- Summary of promotional activities and risk mitigation strategies,
- Certificate (signed by the Applicant); and,
- PLA Submission Summary Form (Appendix A).

3.2 PLA SUBMISSION CONTENT

It is required that PLA Submissions include responses to requirements described with a "mandatory" or a "must" in this RFPLA. Failure to provide a response to requirements described with a "mandatory" may result in rejection of the PLA Submission. It is

recommended that PLA Submissions also respond to requirements described with a "desirable" in this RFPLA. The mandatory and desirable requirements in this RFPLA will be utilized in evaluating each PLA Submission.

3.2.1 PLA Submission Form

The PLA Submission Form in Appendix B of this RFPLA, must be completed, and included in the PLA Submission.

3.2.1.1 Prices Quoted

Prices quoted shall be in Canadian dollars and exclusive of the Goods and Services Tax and the Harmonized Sales Tax. In the event of any inconsistency between words and numbers, words shall govern.

3.2.2 RFPLA Requirements

(a) RFPLA Terms and Conditions

The "RFPLA Terms and Conditions" contained in section 4 of this RFPLA must be agreed to in their entirety by the Applicant, without alteration.

(b) Contractual Terms and Conditions

Applicants, by submitting a PLA Submission, are deemed to have accepted the "RFPLA Terms and Conditions" contained in Appendix C of this RFPLA.

Unless the PLA Submission contains an express provision to the contrary, Applicants by submitting a PLA Submission are deemed to have accepted each of the provisions of the Contractual Terms and Conditions exactly as drafted (including any Schedules) attached as Appendix C. If the Applicant does not accept the Contractual Terms and Conditions provisions exactly as drafted, the Applicant must expressly indicate in its PLA Submission that it does not accept the Terms and Conditions provisions and provide the Applicant's final position on the provision i.e. the wording that the Applicant requires for the Applicant to enter into a contract. Her Majesty will deem any alternative wording, including suggested, recommended, or proposed wording, as reflecting the Applicant's final position on the provision. Her Majesty will determine whether the alternative wording meets the needs of the Alberta government-sponsored drug plans.

The application of these Terms and Conditions are at the sole discretion of Her Majesty. Her Majesty reserves the right to provide for amendments to the Terms and Conditions during the RFPLA screening, evaluation and negotiation process, with any amendments to the Terms and Conditions being made with the written consent of both parties.

(b) Contractual Warranties

Claims made in the RFPLA Submission shall constitute contractual warranties. Any provisions in the RFPLA Submission may be included in the main body of the Contract or attached as a schedule to the Contract.

3.2.3 Appendices

If the Applicant wishes to include any other material not specifically requested by this RFPLA, it may do so by including additional appendices in the PLA Submission.

4. RFPLA TERMS AND CONDITIONS

4.1 CONFIDENTIALITY AND SECURITY OF INFORMATION

The Applicant shall:

(a) keep strictly confidential all information concerning Her Majesty or third parties, or any of the business or activities of Her Majesty or third parties acquired as a result of participation in the RFPLA; and
(b) only use, copy or disclose such information as necessary for the purpose of submitting a PLA Submission or upon written authorization of Her Majesty.
(c) The Applicant shall maintain security standards, including control of access to data and other information, consistent with the highest standards of business practice in the industry.

(d) No press release or other public announcement relating to this RFPLA or any resulting PLA Contract shall be issued without the prior written consent of the Minister.

4.2 FOIP

The Applicant acknowledges that:

(a) The Freedom of Information and Protection of Privacy Act of Alberta (FOIP) applies to all information and records relating to, or obtained, generated, created, collected or provided under, the RFPLA or the Contract and which are in the custody or control of Her Majesty. FOIP allows any person a right of access to records in Her Majesty's custody or control, subject to limited and specific exceptions as set out in FOIP;
(b) FOIP imposes an obligation on Her Majesty, and through the RFPLA and Contract on the Applicant, to protect the privacy of individuals to whom information relates. The Applicant shall protect the confidentiality and privacy of any individual's Personal Information accessible to the Applicant or collected by the Applicant

pursuant to the RFPLA or the Contract;

(c) The Applicant, if it considers portions of its RFPLA Submission to be confidential, shall identify those parts of its RFPLA Submission to Her Majesty considered to be confidential and what harm could reasonably be expected from disclosure. Her Majesty does not warrant that this identification will preclude disclosure under FOIP;

(d) Materials produced by the Applicant, in connection with or pursuant to the RFPLA or the Contract, which are the property of Her Majesty pursuant to the RFPLA or the Contract, could be considered records under the control of a public body and could therefore also be subject to the FOIP before delivery to Her Majesty. As such, the Applicant must conduct itself to a standard consistent with FOIP in relation to such Materials.

(e) For the records and information obtained or possessed by the Applicant in connection with or pursuant to the RFPLA or the Contract, and which are in the custody or control of Her Majesty, the Applicant must conduct itself to a standard consistent with FOIP when providing the services or carrying out the duties or other obligations of the Applicant under the RFPLA or the Contract.

4.3 CONSENT TO THE USE OF PERSONAL INFORMATION

The purpose for collecting Personal Information for this RFPLA is to enable Her Majesty to ensure the accuracy and reliability of the information, to evaluate the PLA Submission, and for other related program purposes of Her Majesty. Authority for this collection is the *Government Organization Act*, as amended from time to time.

The Applicant consents, and has obtained the written consent from any individuals identified in the RFPLA Submission, to the use of their Personal Information in the RFPLA Submission by Her Majesty, Her Majesty's employees, subcontractors and agents, to enable Her Majesty to evaluate the RFPLA Submission and for other program purposes of Her Majesty. This consent specifies to whom the Personal Information can be disclosed and how the information may be used. The Applicant shall provide such consents to Her Majesty for confirmation and review upon Her Majesty's request.

4.3.1 Security Measures

Prior to the start of the Contract by the successful Applicant, the Applicant, if requested by Alberta Health, must provide a detailed plan describing the security measures to be implemented to ensure the protection of personal privacy and to ensure that only those employees, subcontractors and agents of the Applicant who are required to have access to, or to collect, Personal Information for the purposes of providing the obligations required under the Contract, are permitted access to that Personal Information. The plan shall address the following requirements, as appropriate for the RFPLA Submission:

(a) manner of collection;

(b) notification of collection purposes;

(c) assurance of accuracy;

(d) plans and controls over data matching and linkage;
(e) controls over uses and consistent uses;
(f) controls over disclosure of Personal Information;
(g) provision for retention and disposal of Personal Information;
(h) protection of Personal Information from unauthorized access, and
(i) collection, use, disclosure or disposal.

4.4 LOBBYIST ACT

The Applicant acknowledges that:

(a) the Lobbyists Act establishes certain obligations and prohibitions with respect to lobbying and contracts for paid advice, as those terms are defined in the Lobbyists Act; and
(b) it is responsible for complying with the Lobbyists Act during the RFPLA process, and if the successful Applicant, during the Contract.

4.5 CONFLICT OF INTEREST

Applicants must fully disclose, in writing to the Senior Manager, Drug Utilization and Agreements on or before the closing date of the RFPLA, the circumstances of any possible conflict of interest or what could be perceived as a possible conflict of interest if the Applicant were to become a contracting party pursuant to the RFPLA. Alberta Health shall review any submissions by Applicants under this provision and may reject any RFPLA Submissions where, in the opinion of Alberta Health, the Applicant could be in a conflict of interest or could be perceived to be in a possible conflict of interest position if the Applicant were to become a contracting party pursuant to the RFPLA.

4.6 PLA SUBMISSION ACCEPTANCE/REJECTION

AH is not required to accept a PLA Submission, and may reject any or all PLA Submissions.

4.7 PLA SUBMISSION IRREGULARITY OR NON-COMPLIANCE

Her Majesty reserves the right to waive an irregularity or non-compliance with the requirements of the RFPLA where the irregularity or non-compliance is minor or inconsequential. The determination of what is or is not a minor or inconsequential irregularity or non-compliance, and the determination of whether to waive or not waive the irregularity or non-compliance, shall be at Her Majesty's sole discretion.

4.8 PLA SUBMISSION RETURN

PLA Submissions and accompanying documentation, upon receipt by AH, will become the property of and will be retained by Her Majesty, subject to section 4.9.

4.9 PLA SUBMISSION ALTERATION

Applicants may amend or rescind their PLA Submission prior to the RFPLA closing date and time by submitting a clear and detailed written notice to AH in accordance with section 4.2 (d). Subject to section 4.9.1, all PLA Submissions become irrevocable after the RFPLA closing date and time.

In either of the following circumstances:

a) the Applicant has rescinded a PLA Submission prior to the RFPLA closing date and time; or
b) AH has received the PLA Submission after the RFPLA closing date and time;such a PLA Submission will, at the Applicant's choice, either be returned to the Applicant at the Applicant's expense after the RFPLA closing date and time, or destroyed by AH after the RFPLA closing date and time.

4.9.1 Period of Commitment

RFPLA Submissions shall be final and binding on the Applicant for 90 days from the RFPLA's closing date and time or such time period at the Minister's sole discretion.

4.10 INCURRED COSTS

The Applicant is responsible for all costs of preparing and presenting its PLA Submission and, if applicable, Contract finalization.

4.11 NEGOTIATIONS AND CONTRACT FINALIZATION

Prior to PLA negotiations commencing, the Applicant and AH will establish a timetable for negotiations. If for any reason AH and the Manufacturer do not finalize a PLA within the timetable established, the PLA submission shall be deemed to be of no effect, unless the Minister, in the Minister's sole discretion, extends the timeframe.

Notwithstanding the aforementioned timetable, the Minister will review the progress of negotiations within six months of negotiations. In the event that negotiations with the manufacturer appear to be not progressing, or potentially protracted, at the Minister's sole discretion the PLA submission may be deemed to be of no effect.

The manufacturer or the Minister may withdraw from PLA negotiations at their discretion.

4.12 AGREEMENT ON INTERNAL TRADE

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4.13 MULTIPLE PLA SUBMISSIONS

If multiple PLA Submissions are offered as distinct proposals, the Applicant must submit each PLA Submission separately in the same format as outlined in this RFPLA. PLA Submissions must meet the fundamental intent of this RFPLA. The Evaluation Team will decide the acceptability of each PLA Submission.

4.14 RECAPITULATION OF PLA SUBMISSIONS

AH reserves the right to publish the names of responding Applicants.

4.15 APPLICANT DEBRIEFING

Alberta Health will, at the written request of an unsuccessful Applicant who responded to the RFPLA, conduct a debriefing for the purpose of informing the Applicant as to why their RFPLA Submission was not selected. The unsuccessful Applicant's written request for a debriefing must be received by Alberta Health within ten (10) Business Days of notification to the Applicant that they are unsuccessful.

4.17 APPLICANT QUESTIONS

All questions and any form of communications with Her Majesty regarding the RFPLA must be in writing and only be directed to the Senior Manager, Drug Utilization and Agreements unless otherwise advised in writing from the Senior Manager, Drug Utilization and Agreements. Her Majesty is not responsible nor liable for statements or representations made by any other persons in relation to this RFPLA and may disqualify any Applicant who fails to comply with this provision. Enquiries to, and responses of, the Senior Manager, Drug Utilization and Agreements will be recorded. The Senior Manager, Drug Utilization and Agreements will respond in writing to the enquiring Applicant and this may, in Her Majesty's discretion, be distributed to all Applicants.

The Applicant has the responsibility to notify the Senior Manager, Drug Utilization and Agreements in writing, of any ambiguity, divergence, error, omission, oversight, contradiction, or item subject to more than one interpretation in the RFPLA, as it is discovered, and to request any instruction, decision, or direction required to prepare the RFPLA Submission.

In order for Alberta Health to deal effectively with Applicant questions or concerns about any terms, conditions or requirements of the RFPLA including the Contract provisions, such questions or concerns must be communicated in writing to the Senior Manager, Drug Utilization and Agreements at least seven (7) Business Days prior to the RFPLA's closing date. Questions received after this time may be answered if time permits.

Verbal responses to enquiries are not binding on any party.

4.18 EXCLUSION OF LIABILITY

In no event shall AH be liable in any way to any Applicant or prospective Applicant related to:

- The manner in which the RFPLA process is conducted;
- AH awarding a contract under this RFPLA; or
- AH not awarding a contract under this RFPLA.

Applicants shall not have any claim for compensation of any kind as a result of participating in this RFPLA's process, and by submitting a PLA Submission, each Applicant shall be deemed to have waived its right to make a claim.

4.19 PLA SUBMISSION EVALUATION

4.19.1 Screening

Upon receipt of PLA Submissions, the Evaluation Team will screen each to assess the Applicant's compliance with the mandatory requirements of this RFPLA. Applicants must provide sufficient detail in their PLA Submission to substantiate compliance with this RFPLA's mandatory requirements. In addition, Applicants should provide cross references to any parts of the PLA Submission that contain information that they wish to be considered in the evaluation of any given requirement.

After the PLA Submission has passed the initial screening, the Evaluation Team will then analyze the details of the PLA Submission.

4.19.2 Evaluation

The Evaluation Team will utilize evaluation criteria to rate responses to various requirements. Subject to the requirements of FOIPP, such ratings shall be confidential, and no totals or scores of such ratings shall be released to any party.

4.19.3 PLA Submission Clarifications

At any time during the screening, evaluation and negotiation process, AH may request the Applicant to clarify statements made within its PLA Submission.

4.19.4 Modified RFPLA Process

In the event the PLA Submissions received do not meet the fundamental intent of the requirements of the Alberta government-sponsored drug plans, Her Majesty reserves the right to undertake a Modified RFPLA Process.

- The necessity, scope and the timing of such a Modified RFPLA Process will be at Her Majesty's discretion;
- Details regarding the manner and form of the Modified RFPLA Process

and the expected deliverables may be posted on the Alberta Blue Cross website or communicate by any means the Minister deems appropriate.

APPENDIX A TO THE RFPLA - PLA SUBMISSION SUMMARY FORM

(Date)

Filip Palasz
Senior Manager, Drug Utilization and Agreements
Pharmaceutical Funding and Guidance Branch
11th Floor, Telus Plaza North Tower
10025 Jasper Avenue
Edmonton, AB T5J 1S6

RE: Request for PLA Submissions (RFPLA) Number 12-016

Applicant's Full Legal Name: _____
Mailing Address: _____

_____

_____

Contact Name: _____
Telephone: _____
Facsimile: _____
E-mail Address: _____

PLA Submission:

_____
Authorized Signature

_____
(Print Name)

_____
(Title)

APPENDIX B TO THE RFPLA - PLA SUBMISSION FORM

Product Listing Agreement Submission Form

for the

Alberta Health and Wellness Drug Benefit List

November 13, 2012

Note the PLA Submission Completion Checklist included in this form must be completed and signed. Failure to do so may result in the PLA Submission being deemed incomplete.

Government of Alberta ■
Health and Wellness

General Requirements Regarding Product Listing Agreement (PLA) Submissions:

1. The information presented in this PLA Submission Form will be used when screening and evaluating PLA Submissions. In the event that a decision is made to proceed to the negotiation stage, the PLA Submission Form may serve as a starting point.
2. All fields must be completed. Failure to do so may result in the PLA Submission being deemed incomplete and rejected or it may result in delays in screening.
3. Alberta specific data (e.g. prevalence of disease states, projected market shares, etc) should be used, where possible. If Alberta specific data is not available, other sources may be used if justification is provided, sources are adequately referenced and assumptions stated.
4. A PLA Submission must have a minimum three year time horizon and all projections in the submission must align with this timeframe.
5. Additional information may be appended to the PLA Submission Form if necessary.

Directions for Use:

PLA Submission Form Completion Checklist

- Upon completion of the PLA Submission Form, the 'Checklist' must be completed and signed. Failure to do so may result in the PLA Submission being deemed incomplete.

CONFIDENTIALITY

THIS SUBMISSION FORM MAY CONTAIN CONFIDENTIAL BUSINESS INFORMATION, AS THAT TERM IS DEFINED IN THE PLA POLICY, AND AS IDENTIFIED BY THE MANUFACTURER MAKING THIS SUBMISSION. THE USE AND DISCLOSURE OF THIS CONFIDENTIAL BUSINESS INFORMATION SHALL BE GOVERNED BY THE PLA POLICY AND ANY APPLICABLE ACCESS TO INFORMATION AND FREEDOM OF INFORMATION LAWS IN ALBERTA ("ATI"). ALL ATI NOTICES ARE TO BE SENT TO THE MANUFACTURER AT THE ADDRESS INDICATED IN SECTION 1

Section 1: Drug Information

- Complete the table in full including a list of all relevant comparators. If there are non-drug alternatives (e.g. surgery) then state these in this comparator section. Indicate the category of listing sought and the proposed criteria.

Section 2: Indication/Dosage Information

- List all indications that have been proposed for reimbursement eligibility along with their recommended dosage and duration.
- If treatment or dosage guidelines currently exist for a specific indication, these must be adequately referenced.
- Identify any potential utilization that is not aligned with the indications and conditions of use set out in the Health Canada authorized product monograph that could be expected with an open listing of the drug on the ADBL.

Section 3: Prescription Cost/Patient/Month for Each Indication (Based on Recommended Dose)

- Total prescription cost/patient/month should be based on the acquisition cost of the medication, the inventory allowance and the dispensing fee as described in the *Alberta Blue Cross Pharmacy Agreement Schedule of Prices.* Note that the *Schedule of Prices* represents the maximum allowable price/prescription that can be charged.

- From April 1, 2011 to March 31, 2012 the schedule is as follows:

Effective date (04/01/11 – 03/31/12)	**Inventory Allowance***	**Dispensing Fee**
Actual Acquisition Cost of $0.00 - $74.99	$2.71	$10.22

Actual Acquisition Cost of $75.00 - $149.99	$2.00	$15.53
Actual Acquisition Cost of $150.00 or greater	$5.03	$20.94

- The additional inventory allowance field has been increased to allow for a transitional allowance to be incorporated. The transitional allowance will apply as follows:

April 1, 2011 – March 31, 2012	$2.71
April 1, 2012 – March 31, 2013	$1.71
April 1, 2013 – March 31, 2014	$0.71

- The actual acquisition cost (AAC) is defined as the cost of the drug borne by the pharmacy; therefore, the AAC may include a wholesaler distribution allowance (markup), if applicable.
- All drugs that are available only via wholesaler should utilize a wholesaler distribution allowance of no more than 7.5% in their calculations.
- In the case of medications where recommended duration of use is less than 30 days (e.g. antibiotics), this should be specified and the cost calculated accordingly. For example, if the recommended duration of use is 14 days, then the cost should be based on the AAC of 14 days supply of the medication, the inventory allowance and a dispensing fee.
- In the case of insulin and oral contraceptives, the prescription cost does not exceed the actual acquisition cost of the drug product x 5/3.
- For injectable drugs other than insulin, the prescription cost does not exceed the actual acquisition cost of the injectable drug x 5/3, to a maximum of $100.00 more than the actual acquisition cost of the injectable drug.
- In general, the net prescription cost to Alberta Health sponsored drug programs should be calculated as 70% of the total prescription cost calculated above. The remaining 30% would reflect the patient's co-payment portion. However, if 30% of the prescription cost exceeds $25.00, Alberta Health will pay for the balance of the prescription cost that exceeds $25.00 and this should be reflected in the calculations.

Section 4: Prevalence of Disease State(s)/Condition(s) for which the Drug is Indicated

- List the prevalence of the disease state and/or indication for which the medication is intended for the total Alberta population and for the population covered by the Alberta Health sponsored drug programs.
- Data should be Alberta specific and not simply an extrapolation of Canadian national data or data from other provinces to the Alberta population. If Alberta specific data is not available, a justification for why this is so must be provided.
- It is recognized that prevalence data may not be available in some instances. In such cases, prevalence data may be extrapolated from claims data. Justification must be provided for calculating prevalence in this manner and necessary assumptions and sources appropriately cited.

Section 5: Projected Market in Alberta

- List projected market shares as total number of patients and percentage of the total market for each disease state/indication.
- Market shares for years one, two and three must be reported for a full calendar year (12 months) after proposed listing date. (e.g., April 2012 to April 2013). Optionally, data for five years can be provided.
- State where and what proportion of the proposed market is coming from (e.g. new patients, gain from another product's market share). Cite all relevant references.

Section 6: Direct Prescription Costs

- Calculate the direct prescription costs that the Alberta Health sponsored drug programs will incur if the product is listed according to the category of listing sought (refer to Section 1).
- Prescription costs should be an extension of the prevalence of the disease state/indication, the projected market share of the product for the disease state/indication and the prescription costs to the Alberta Health sponsored drug programs as calculated in Sections 4, 5 and 6.
- List all of the assumptions used in calculating the values and cite all relevant references.

Section 7: Incremental Prescription Costs (Savings)

- Calculate incremental prescription costs or savings that the Alberta Health sponsored drug programs would incur if the drug product were listed according to the category of listing requested by the Manufacturer.
- Use the lowest cost alternative (LCA) price for relevant drug comparators where applicable.
- List all of the assumptions used in calculating the values and cite all relevant references.

Section 8: Systemic Benefit

- Identify any indirect costs / savings to the health system (Alberta) related to the drug product and proposed listing status. (eg: professional administration of the drug, impact on hospital visits, surgical interventions etc.)
- Use the lowest cost alternative (LCA) price for relevant drug comparators where applicable.
- List all of the assumptions used in calculating the values and cite all relevant references.

Section 9: Sensitivity Analyses

- Calculate one-way and/or multi-way sensitivity analyses for direct prescription costs and incremental prescription costs (savings).
- An explanation of the methods used to calculate the sensitivity analyses must be included as well as the assumptions used in calculating the values.
- Cite all relevant references.

Section 10: Additional Information

- Include any additional information that is relevant to the assumptions or calculations.
- Utilization data from other jurisdictions or countries where the product is reimbursed should be included or referenced, as applicable.

- Append treatment or dosage guidelines if applicable and ensure that they are adequately referenced.
- Indicate whether the listing of this medication will have a significant impact on health care services (e.g., laboratory testing, diagnostic testing) and explain the precise nature of the impact.
- Append Additional Budget Impact Analysis that provides additional information, as applicable.

Section 11: Budget Impact Conclusions

- Indicate all conclusions resulting from the budget impact analysis (use copy per the current BIA submission form).

Section 12: PLA Identification and Overview

- Identify the type(s) of PLA that is being proposed as part of this PLA Submission.

Section 13: Price/Volume Agreement

- Complete the tables provided in Sections 11a through 11c, as an adjunct to the information provided in Sections 1-9 and include any additional assumptions, demonstrate the impact on market share and the Alberta Health sponsored drug programs that may flow from the proposed PLA,
- Calculate one-way and/or multi-way sensitivity analyses for direct prescription costs and incremental prescription costs (savings).
- Include an explanation of the methods used to calculate the sensitivity analyses as well as the assumptions used in calculating the values.
- Cite all relevant references.

Section 14: Utilization Management Agreement

- As an adjunct to Sections 1-9 and including any additional assumptions, summarize the following:
    - The proposed incremental cost to the Alberta Health sponsored drug programs over a 3 - 5 year period for implementing the Utilization Management Agreement including measurable potential impacts to the utilization of non-drug healthcare services including real-world effectiveness, improvement in quality of life, and health outcomes for beneficiaries.
    - The incremental cost or benefit to the Alberta Health sponsored drug programs over a 3 - 5 year period.

Section 15: Health Research Capacity Agreement

- As an adjunct to the PLA Submission, provide a summary of proposed investment(s) for Health Research Capacity PLAs. Provide the investment by each type of PLA if a hybrid PLA is being presented.

Section 16: Coverage with Evidence Development Agreement

- Provide the terms of the agreement in detail and complete the tables as outlined in the section.
- Detail the objectives of the Coverage with Evidence Development Agreement.

- Detail the outcomes of Coverage with Evidence Development Agreement
- Provide a preliminary plan for the Coverage with Evidence Development Agreement the dissemination of the findings of the PLA, including all potential outlays of funding and/or resources to be made by the Alberta Health sponsored drug programs and other identified sources

Section 17: Conclusions

- State the conclusions of Sections 1- 9 and the proposed cost impact to the Alberta Health sponsored drug programs.
- Referencing the conclusions of Sections 1-9 and the overall proposed cost impact to the Alberta Health sponsored drug programs, summarize the Product Listing Agreement identifying how the value of the PLA Submission as outlined in Sections 9-12 meets or exceeds the potential impact to the ADBL budget and identifying the key terms being offered to AH and the terms being required of AH.

Section 18: Summary of Revenue and Research and Development Activities (Alberta)

- Please provide a summary of all expenditures made during the previous three years by the manufacturer towards the cost of research and development carried out in Alberta by or on behalf of the Manufacturer. For clarity, these are research and development expenditures that are defined under the Patented Medicines Regulations and should include:
  - ❑ a description of the type of research and development, the expenditures associated with the research and development activity and the name of the person or entity that carried out the research and development,
  - ❑ the total gross revenues from all drug product sales in Alberta during the previous year by the manufacturer
- Manufacturers may provide separately any additional investments in Alberta that are have not being included in the research and development expenditures that are defined under the Patented Medicines Regulations.

Budget Impact Assessment and Product Listing Agreement Completion Checklist

- Upon completion of the PLA Submission, the 'Checklist' must be completed and signed. Failure to do so may result in the PLA Submission being deemed incomplete and/or delays in potential listing decisions.

General

- ❑ All fields and sections of the PLA Submission form are complete.
- ❑ Alberta specific data is used.
  - ❑ Justification is provided where Alberta specific data has not been used.
- ❑ Projections are for a 3 – 5 year time horizon.
- ❑ Projections are for the Alberta Health sponsored drug programs.

Sections 1 – 12

- ❑ All relevant comparators are stated, including non-drug alternatives.
- ❑ All approved indications are listed, with recommended dosages and durations.
- ❑ Total prescription cost/patient/month (or shorter duration, where applicable) is calculated, for each indication, based on recommended dose and using **CURRENT** inventory allowances and dispensing fees as listed on page 2
  - ❑ Calculated using actual acquisition cost (AAC) (including allowable wholesale mark up, if applicable) + inventory allowance + current dispensing fee.
  - ❑ For insulin and oral contraceptives, the prescription cost does not exceed 5/3 x the AAC of the drug product.
  - ❑ For injectables other than insulin, the prescription cost does not exceed 5/3 x the AAC of the drug product, to a maximum of $100 more than the AAC of the drug product.
- ❑ Net prescription cost to AH is 70% of the total prescription cost, plus the balance of the co-payment portion (30%) that exceeds $25 (i.e. patient co-pay maximum is $25).
- ❑ Disease state prevalence information, specific to Alberta and the Alberta Health sponsored drug programs., are provided.
  - ❑ Justification is provided where Alberta specific data has not been used.
- ❑ Projected market is reported as total number of patients, and percentage of total market.
- ❑ Market is projected for a full calendar year (12 months) from proposed listing date.
- ❑ Source of market, and proportion of market from each source, are reported.
- ❑ Direct prescription costs are reported as the AH portion.
  - ❑ Projections are calculated using prevalence, market share and prescription costs stated.
  - ❑ All assumptions are listed, and references cited.
- ❑ Incremental prescription costs are reported for the Alberta Health sponsored drug programs..
  - ❑ All assumptions are listed, and references cited.
  - ❑ LCA price is used as the AAC for comparators, where applicable.
- ❑ One-way or multi-way sensitivity analyses are conducted.
  - ❑ For direct prescription costs.
  - ❑ For incremental prescription costs.
  - ❑ An explanation of the sensitivity analysis methods is included.
  - ❑ All assumptions are listed, and references cited.
- ❑ The conclusions of the BIA are stated.
- ❑ Summary of Revenue and Research and Development Activities (Alberta)

PLA Submission Summary

1. Indicate the type of listing status requested for the drug
   - ❑ Addition to the ADBL
   - ❑ Change in listing criteria

2. Indicate the Benefit Status that is being requested
   - ❑ Open Listing
   - ❑ Restricted Benefit

3. Indicate if the drug (Check all that apply)
   - ❑ Received Priority Review (Health Canada)
   - ❑ Received Priority Review (Common Drug Review)
   - ❑ Breakthrough / Substantial Improvement (PMPRB)
   - ❑ Non-CDR Review Drug

4. Indicate if the type(s) of PLA agreement proposed (Check all that apply)
   - ❑ Price / Volume Agreement
   - ❑ Utilization Management Agreement
   - ❑ Coverage with Evidence Development Agreement
   - ❑ Health research Capacity Development Agreement

Optional

❑ Additional relevant information may be attached (**optional**):
- ❑ Utilization from other jurisdictions
- ❑ Treatment or dosage guidelines
- ❑ Comments on whether listing will significantly affect health care spending
- ❑ Additional BIAs appended that do not conform to this format (if applicable)

Signature: _____ Date: _____

Section 1: Drug Information

Manufacture Contact Information	

Brand name:	
Generic name:	
Dosage form(s)/strength(s) and associated (retail) cost per unit.	
Therapeutic Category/PTC:	
Relevant comparators (including non-drug alternatives):	
Category of listing sought (e.g., unrestricted benefit, special authorization, restricted benefit) and proposed criteria (if applicable).	

- Complete the table listing all relevant comparators (including non-drug alternatives).
- Indicate category of listing and proposed criteria (if applicable).

Section 2: Indication/Dosage Information

Indication(s) for which listing is sought:	Usual recommended dose/duration per indication

- List all indications proposed for reimbursement eligibility, recommended dose and duration.
- Reference treatment or dosage guidelines (if applicable).
- Identify any potential utilization that is not aligned with the indications and conditions of use set out in the Health Canada authorized product monograph that could be expected with an open listing of the drug on the ADBL.

Section 3: Prescription Cost/Patient/Month for Each Indication (Based on Recommended Dose)

Indication	Total prescription cost/patient/month	Net Cost to Alberta Health /patient/month

- Total prescription cost/patient/month should be based on the CURRENT acquisition cost of the medication, inventory allowance and dispensing fee. Wholesale mark-up and distribution fees should be included in the cost if applicable. See Directions for Use (Section 3) for further information.
- Net cost to Alberta Health should be calculated as 70% of the prescription cost. The remaining 30% would reflect the patient's co-payment portion. However, if 30% of the prescription cost exceeds $25.00, Alberta Health will pay for the balance of the cost that exceed $25.00. This should be reflected in the calculations.
- In the case of medications where the recommended duration is less than 30 days, this should be specified and the costs calculated accordingly.

*Assumes 1 dispensation over a 90 day period (3 30 day months), dispensing fees are allocated evenly over 3 month period.

Section 4: Prevalence of Disease State(s)/Condition(s) for which the Drug is Indicated

A) TOTAL ALBERTA POPULATION

	Prevalence in Alberta (Number of Patients)				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

B) Population Covered by Alberta Health

	Prevalence in Alberta (Number of Patients)				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

- List the prevalence of the disease state/indication for which the medication is intended for the Alberta population and for those covered by the Alberta Health sponsored drug programs.
- Demographic data may be accessed via the Alberta Health Statistical Supplement.

List all relevant assumptions and cite references.

Section 5: Projected Market in Alberta

A) Total Alberta Population

	Projected Market in Alberta (Total number of patients)				
Disease State/Indication	Year 1	Year 2	Year 3	Year 4 (Optional)	Year 5 (Optional)

	Projected Market in Alberta (% Market Share)				
Disease State/Indication	Year 1	Year 2	Year 3	Year 4 (Optional)	Year 5 (Optional)

B) Population Covered By the Alberta Health sponsored drug programs.

	Projected Market in Alberta (Total number of patients)				
Disease State/Indication	Year 1	Year 2	Year 3	Year 4 (Optional)	Year 5 (Optional)

	Projected Market in Alberta (% Market Share)				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

- List projected market shares as total number of patients and percentage of total market for each disease state/indication.
- Market shares for years one, two and three must be reported for a full calendar year.
- State where the proposed market is coming from (e.g., new patients, cannibalization of another product's market share).
- All tables must be completed.

List all relevant assumptions and cite references.

Section 6: Direct Prescription Costs

	Direct drug costs to the Alberta Health sponsored drug programs.				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

- Calculate the direct prescription costs that the Alberta Health sponsored drug programs.would incur if the product were listed according to the category of listing sought.
- Prescription costs should be an extension of the prevalence of the disease state/indication, the projected market share of the product and the prescription costs to the Alberta Health sponsored drug benefit program as calculated in Section 3.

List all of the assumptions used in calculating the values and cite all relevant references.

Section 7: Incremental Prescription Costs (Savings)

	Incremental prescription costs (savings) to Alberta Health sponsored drug programs				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

- Calculate the incremental prescription costs or savings that the Government-Sponsored Drug Plans would incur if the product were listed according to the category of listing sought.
- Use the lowest cost alternative (LCA) price for all relevant drug comparators where applicable.

List all of the assumptions used in calculating the values and cite all relevant references.

Section 8: Systemic Benefit

	Systemic (non-drug plan) costs (savings) to Alberta Health and/or Alberta Health Services				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

- Identify any indirect costs / savings to the health system (Alberta) related to the drug product and proposed listing status. (eg: professional administration of the drug, impact on hospital visits, surgical interventions etc.)
- Use the lowest cost alternative (LCA) price for relevant drug comparators where applicable.

List all of the assumptions used in calculating the values and cite all relevant references.

Section 9: Sensitivity Analyses

A) Sensitivity Analyses for Direct Prescription Costs to the Government-Sponsored Drug Plans

	Range of Direct Prescription Costs				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

B) Sensitivity Analyses for Incremental Prescription Costs (Savings)

	Range of Incremental Prescription Costs (Savings)				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

- Calculate one-way and/or multi-way sensitivity analyses for the direct prescription costs and incremental prescription cost (savings).

List all of the assumptions used in calculating the values and cite all relevant references.

Section 10: Additional Information

- Include any additional information that is relevant to the assumptions or calculations.
- Utilization data from other jurisdictions or countries where the product is reimbursed are welcomed.
- Append treatment or dosage guidelines if applicable and ensure that they are adequately referenced.
- Comment on whether this listing of this medication will have a significant impact on health care services (e.g., laboratory testing, diagnostic testing, etc).
- Additional BIAs completed by the manufacturer that do not conform to this BIA format, but provide additional information, are welcome and may be appended to this form.

Section 11: Budget Impact Conclusions

- Indicate all conclusions resulting from the budget impact analysis (use copy per the current BIA submission form)

Section 12: PLA Identification and Overview

- Identify the type of PLA that is being offered. Hybrid PLA's are acceptable (Check all that apply)
  - ❑ Price/Volume Rebate
  - ❑ Utilization Management Agreement
  - ❑ Health Capacity Resource Development
  - ❑ Evidence Development

Section 13: Price/Volume Agreement

- Indicate the terms of the agreement in detail:
- Complete the following tables based on the preceding Sections 1- 9 to demonstrate the further impact of the PLA Submission.

Section 13A: Market Share

- As an adjunct to Sections 1-8 and including any additional assumptions, demonstrate the impact on market share as a result of the PLA Submission.

	Projected Market in Alberta as a Result of the PLA Terms (% Market Share)				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

- List projected market shares as total number of patients and percentage of total market for each disease state/indication resulting from the PLA Submission.
- Market shares for years one, two and three must be reported for a full calendar year.
- State where the proposed market is coming from (e.g., new patients, cannibalization of another product's market share).

	Incremental Change in Market in Alberta as a Result of the PLA Submission (% Market Share)				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

- Indicate the net change in market share from the original BIA as a result of the PLA Submission.

List all of the assumptions used in calculating the values and cite all relevant references.

Section 13B: Net Prescription Cost

- As an adjunct to Sections 1-9 and including any additional assumptions, demonstrate the impact on pharmacy program costs as a result of the PLA Submission.

	Direct drug costs to the Alberta Health sponsored drug programs as a Result of the PLA Terms				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

- Calculate the direct prescription costs that the Government-Sponsored Drug Plans would incur as a result of the PLA Submission.
- Prescription costs should be an extension of the prevalence of the disease state/indication, the projected market share of the product and the prescription costs to the Government-Sponsored Drug Plans as calculated in Section 3.

	Incremental Direct drug to the Alberta Health sponsored drug programs as a Result of the PLA Terms				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

- Calculate the incremental change in direct prescription costs from outlined in Sections 1-9 that the Alberta Health sponsored drug benefit programs would incur as a result of the PLA offer

List all of the assumptions used in calculating the values and cite all relevant references.

Section 13C: Sensitivity Analysis

- Calculate relevant one-way and/or multi-way sensitivity analyses for direct prescription costs and incremental prescription cost changes outlined in Sections 1-9 as a result of the PLA offer.

A) Sensitivity Analyses for Direct Prescription Costs (Savings) as a Result of the PLA Offer

	Range of Direct Prescription Costs				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

B) Sensitivity Analyses for Incremental Prescription Costs (Savings) as a Result of the PLA Offer

	Range of Incremental Prescription Costs (Savings)				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

- An explanation of the methods used to calculate the sensitivity analyses must be included as well as the assumptions used in calculating the values. Cite all relevant references.

List all of the assumptions used in calculating the values and cite all relevant references.

Section 14: Utilization Management Agreement

- Provide likely off-label uses for the drug product, if any.
- Identify the gaps or factors in utilization of the drug product that may contribute to sub-optimal outcomes.
- Indicate the planned methodology for utilization management in detail.
- As an adjunct to Sections 1-9 and including any additional assumptions, complete the following tables to demonstrate the impact of an utilization management agreement:

	Incremental Change in Market in Alberta as a Result of the PLA Terms (% Market Share)				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

- Indicate the net change in market share from Sections 1-9 as a result of the PLA Submission.

	Incremental Direct drug costs to Alberta Health sponsored drug programs **as a Result of the PLA Terms**				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

- Calculate the incremental change in direct prescription costs from Sections 1-9 that the Government-sponsored Drug Plans would incur as a result of the PLA Submission.

List all of the assumptions used in calculating the values and cite all relevant references.

Section 15: Health Resource Capacity Agreement

- Provide the terms of the agreement in detail

Recipient	Nature of Commitment	Amount	Timing of Commitment

- In the table above, indicate the financial value of all funding commitments associated with this PLA Submission, the nature of the commitment, and the recipient proposed as a part of the PLA Submission. This would include research and innovation grants, educational grants, and health information grants. Provide attachments as necessary.
- Where committed funds are unrestricted in their use, indicate nature of commitment as 'unrestricted'
- As an adjunct to the Sections 1-9 and including any additional assumptions, complete the following tables to demonstrate the impact of a health resource capacity development agreement:

	Incremental Change in Market in Alberta as a Result of the PLA Terms (% Market Share)				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

- Indicate the net change in market share from the Sections 1-9 as a result of the PLA Submission.

	Incremental Direct drug costs to the Alberta Health sponsored drug programs **as a Result of the PLA Terms**				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

- Calculate the incremental change in direct prescription costs from Sections 1-9 that the Government-sponsored Drug Plans would incur as a result of the PLA Submission.

List all of the assumptions used in calculating the values and cite all relevant references.

Section 16: Coverage with Evidence Development Agreement

- Provide the terms of the agreement in detail.
- Detail the objectives of the Coverage with Evidence Development Agreement.
- Detail the outcomes of Coverage with Evidence Development Agreement
- Provide a preliminary plan for the Coverage with Evidence Development Agreement the dissemination of the findings of the PLA, including all potential outlays of funding and/or resources to be made by the Government-Sponsored Drug Plans and other identified sources.

Recipient	Nature of Commitment	Amount	Timing of Commitment

- In the table above, indicate the financial value of all funding commitments associated with the Coverage with Evidence Development Agreement, the nature of the commitment, and the recipient proposed as a part of the PLA Submission. This would include research and innovation grants, educational grants, and health information grants. Provide attachments as necessary.
- Where committed funds are unrestricted in their use, indicate nature of commitment as 'unrestricted'

- Proposed manufacturer funding commitments for Coverage with Evidence Development Agreement

Recipient	Nature of Commitment	Amount	Timing of Commitment

- Proposed Government-Sponsored Drug Plans commitments for evidence development

Recipient	Nature of Commitment	Amount	Timing of Commitment

- Proposed funding commitments for evidence development from other sources

Source	Recipient	Nature of Commitment	Amount	Timing of Commitment

- As an adjunct to the preceding BIA and including any additional assumptions, complete the following tables to demonstrate the impact of a health resource capacity development agreement:

	Incremental Change in Market in Alberta as a Result of the PLA Terms (% Market Share)				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

- Indicate the net change in market share from the original BIA as a result of the PLA offer.

	Incremental Direct drug costs to the Alberta Health sponsored drug programs **as a Result of the PLA Terms**				
Disease State/Indication	**Year 1**	**Year 2**	**Year 3**	**Year 4 (Optional)**	**Year 5 (Optional)**

- Calculate the incremental change in direct prescription costs from the original BIA that the Alberta Health sponsored drug benefit programs would incur as a result of the PLA offer

List all of the assumptions used in calculating the values and cite all relevant references.

Section 17: Conclusions

Referencing the conclusions of the budget impact assessment and the overall proposed cost impact to the Alberta Health sponsored drug programs summarize the PLA Submission identifying how the value of the PLA offsets the impact to the ADBL budget and identifying the key terms being offered to AH and the terms being required of AH.

Section 18: Summary of Revenue and Research and Development Activities (Alberta)

- Please provide a summary of all expenditures made during the previous three years by the manufacturer towards the cost of research and development carried out in Alberta by or on behalf of the Manufacturer. For clarity, these are research and development expenditures that are defined under the Patented Medicines Regulations and should include:
  - a description of the type of research and development, the expenditures associated with the research and development activity and the name of the person or entity that carried out the research and development,
  - the total gross revenues from all drug product sales in Alberta during the previous year by the manufacturer .
- Manufacturers may provide separately any additional investments in Alberta that are have not being included in the research and development expenditures that are defined under the Patented Medicines Regulations.

APPENDIX C TO THE RFPLA – CONTRACTUAL TERMS AND CONDITIONS

CONTRACT NUMBER:_____

THIS PRODUCT LISTING AGREEMENT MADE EFFECTIVE
THE ____DAY OF _____, 20___.

BETWEEN:

HER MAJESTY THE QUEEN IN RIGHT OF ALBERTA,
as represented by the Minister of Health and Wellness
(the "**Minister**")

- and -

[NAME OF MANUFACTURER]
(the "**Manufacturer**")

1. In this Agreement:

(a) **"Alberta Government Sponsored Drug Plans**" are those drug plans provided to residents of Alberta as described in Schedule A to this Product Listing Agreement.

(b) "**Alberta Health**" or "**AH**" means Her Majesty the Queen in right of Alberta, as represented by the Minister of Health.

(c) "**Alberta Drug Benefit List**" or "**ADBL**" means, collectively:

- the complement of policies and processes that address the requirements for listing drugs as benefits for participants in Alberta Government Sponsored Drug Plans; and

- the specific list of drug products that form part of the benefits available under Alberta Government Sponsored Drug Plans, in accordance with the ADBL policies.

Specifically, the term "ADBL" refers to both the list of specific drug products that are included as benefits under Alberta Government Sponsored Drug Plans and the policies and processes that govern how a drug product may be included on the list.

(d) "**Drug Product**" means the drug product sold in Canada by the Manufacturer that is the subject of this Product Listing Agreement, and is described as follows:
<LEFT INTENTIONALLY BLANK>

(e) "**Effective Date**" means the date first above written.

(f) "**FOIPP Act**" means the *Freedom of Information and Protection of Privacy Act* (Alberta), as amended from time to time.

(g) "**HIA**" means the *Health Information Act* (Alberta), as amended from time to time.

(h) **"IC Drug"** means a drug product that is listed, or is under consideration for listing, as interchangeable with one or more drug products as determined by the Minister in accordance with the requirements relating to interchangeability in the ADBL.

(i) **"IC Grouping"** means a category on the ADBL where there are two or more IC Drugs listed or under consideration for listing as part of one grouping on the ADBL as determined by the Minister.

(j) **"Minister**" means the Minister of Alberta Health.

(k) **"Manufacturer's Confidential Business Information"** includes information provided by the Manufacturer to Alberta Health for the purpose of obtaining this PLA or fulfilling the obligations thereunder, whether provided before or after the Effective Date of this PLA , extending to information provided orally, in writing, or otherwise, and includes, strategic and business plans, prices, profit margins, marketing contacts, market intelligence, sales invoices, the terms and conditions of licensing agreements, the financial terms of this PLA and the type of financial or any other information that could be used to infer the Manufacturer's sales or marketing strategy. Where information provided to AH is provided otherwise than in writing and the Manufacturer wishes to designate that information as being Manufacturer's Confidential Business Information it shall provide written notice to AH that it wishes to designate this information as Manufacturer's Confidential Business Information no later than two business days after the date of communication of the subject information to AH. Manufacturer's Confidential Business Information shall not include:

(i.) The name of the Drug Product that is the subject of this PLA, the name of the Manufacturer, and the existence of a PLA agreement between the Minister and the Manufacturer;

(ii.) Information which was lawfully and without legal restriction in the possession of the Government of Alberta other than through disclosure pursuant to this PLA;

(iii.) Information derived independently of disclosure pursuant to this PLA;

(iv.) Information which the Government of Alberta lawfully and without legal restriction obtained from a person having the right to disclose such information without legal restriction; or

(v.) Information which is or becomes part of the public domain not as a result of any unauthorized act, or omission, on the part of the Government of Alberta pursuant to this PLA or any other unauthorized act.

(l) "**Personal Information**" means personal information as defined in the FOIPP Act and health information as defined in the HIA.

(m) "**Product Listing Agreement**" or "**PLA**" means this document and all attached Schedules.

(n) **"Reimbursement Amount"** means the amount which may be payable by the Manufacturer, in accordance with Schedule A of the PLA.

(o) "**Single Source Patented Drug and/or Drug Listed on Health Canada's Register of Innovative Drugs**" means a drug containing a unique chemical, strength, dosage form and route of administration, sold only by the Manufacturer that is on the patent list as per the *Patented Medicines (Notice of Compliance) Regulations* pursuant to the *Patent Act* (Canada) and/or on Health Canada's Register of Innovative Drugs.

TERM OF PLA

2.

(a) The term ("Term") of this PLA is the period from the Effective Date to <Left intentionally blank>

(b) The Term of the PLA may be extended for a <Left intentionally blank>

PROVISION OF DRUG PRODUCT

3.

(a) The Manufacturer agrees to provide the Drug Product to eligible members of Alberta Government Sponsored Drug Plans in accordance with the ADBL and the provisions of this PLA.

(b) The Manufacturer warrants that it has entered into contractual and other arrangements to the extent necessary to ensure that it can meet its obligations to supply the Drug Product in the required amounts throughout the Term.

(c) Should any actions or materials be required by the Manufacturer to meet its obligations contained in this PLA which are not expressly or completely described in this PLA, such actions or materials shall be deemed to be implied and required by this PLA, and the Manufacturer shall, at its expense, perform such actions and furnish such materials as if they were specifically described in this PLA.

(d) Subject to any price increases agreed to by the parties, the Manufacturer shall supply the Drug Product to the Alberta market throughout the Term at the Confirmed Price, in amounts sufficient to allow pharmacies within Alberta to dispense the Drug Product to patients, as needed and without delay.

LISTING, PRICING AND PAYMENT

4.

(a) The Manufacturer agrees to provide the Drug Product for Alberta Government Sponsored Drug Plans, and the Minister agrees to list the Drug Product on the ADBL, for the prices indicated in Schedule A and the criteria identified in Schedule B.

(b) Notwithstanding clause 4(a), the Minister may do either of the following:

(i) vary or waive any or all of the criteria identified in Schedule B of this PLA in deciding whether to extend coverage of the Drug Product where the Minister determines upon either the advice of experts or the patient's physician that the particular circumstances of a patient's medical condition and the course and stage of the disease merit varying or waiving the criteria as identified in Schedule B;or,

(ii) require amendments to Schedule B of this PLA should the ADBL be updated in a manner that, in the Minister's sole opinion, would require this PLA to also be updated. For greater clarity, this would include, but is not limited to, any conditions, restrictions or special authorization criteria that are outlined in this PLA.

(c) The Manufacturer agrees to provide the Reimbursement Amount to the Minister for the Drug Product, to be calculated as per Schedule A.

(d) Notwithstanding that the Minister agrees to list the Drug Product on the ADBL as per clause 4(a) and Schedule B, the Minister may, at any time during the Term, remove, as allowed by the ADBL, the Drug Product from listing on the ADBL.

(e) Where the Minister removes the Drug Product from the ADBL, the removal of the Drug Product shall not constitute an act of default under this PLA on the part of the Minister, and shall not constitute a termination of this PLA by the Minister as per clause 16, unless the Minister specifies that it is. The Manufacturer shall not pay any Reimbursement Amounts, which may be otherwise paid as per the terms of this PLA on claims submitted after the date of the removal of the Drug Product from the ADBL.

(f) Should the Drug Product be removed from the ADBL, the PLA shall only apply to existing patients that were eligible for the Drug Product up to and including the date of removal from the ADBL, until such time as the PLA is terminated as per clause 17 or the Term expires, whichever comes first.

(g) The Minister shall determine the volumes of the Drug Product sold pursuant to Alberta Government Sponsored Drug Plans each Fiscal Year Quarter (as defined in Schedule A of this Agreement) utilizing the Minister's data regarding reimbursement for the Drug Product pursuant to the Alberta Government Sponsored Drug Plans.

(h) The Minister shall compile claims data and provide it to the Manufacturer, as set out in Schedule A ("Claims Data"). The Manufacturer acknowledges that the Claims Data will not contain any individually identifying Personal Information, and that there is no obligation upon AH to collect, use or disclose any other information, or any information which it is prohibited by law from collecting, using and disclosing. The Manufacturer, at its' discretion, may retain an independent third party to review the Minister's Claims Data and verify it for accuracy and completeness.

(i) Alternatively, the Manufacturer, at the request of the Minister, shall compile Claims Data and provide it to the Minister as set out in Schedule A. The Minister, at its' discretion, may retain an independent third party to review the Manufacturer's Claims Data and verify it for accuracy and completeness.

(j) If at any time during the Term a Reimbursement Amount is payable by the Manufacturer to the Minister the Manufacturer shall pay the Reimbursement Amount to the Minister within forty-five (45) days of receiving the Claims Data from the Minister. Any Reimbursement Amount payable pursuant to this Product Listing Agreement shall be a debt owing to Her Majesty the Queen in the right of Alberta, as represented by the Minister of Finance with the amount payable to the Government of Alberta

(k) If the Manufacturer has any questions regarding the accuracy of the Claims Data during the forty-five (45) day period specified in 4(j) the parties shall meet in person or by conference call to discuss the issue. Notwithstanding any questions that the Manufacturer may have, the Manufacturer agrees that it shall make any required payments of any Reimbursement Amounts which may be owing within forty-five (45) days after the Minister has indicated in writing, subsequent to the meeting or conference call, its view that the Claims Data is correct.

Patented Medicine Prices Review Board ("PMPRB")

5.

(a) If at any time during the Term of this PLA the PMPRB conducts an investigation on the Drug Product, which results in:

(i.) a Voluntary Compliance Undertaking ("VCU") by the Manufacturer to reduce the price and take other measures to comply with the Guidelines; or,

(ii.) a public hearing to determine if the price is excessive and, if so, the issuance of a remedial Order by the PMPRB.

then clause 5(b) shall apply herein;

(b) If the VCU or Remedial Order results in a price that the Manufacturer must charge for the Drug Product that is lower than the Product Listing Agreement Price agreed to between the Manufacturer and AH as set out in Schedule A of this PLA then the Minister can at his discretion do one or both of the following:

(i.) re-negotiate the terms of the PLA based on the price established by the PMPRB; or,

(ii.) terminate the PLA and, at the Minister's discretion, request the Manufacturer to re-submit a PLA Submission for that drug.

RECORDS and REPORTING

6. At the discretion of the Minister, the Minister may request the Manufacturer to conduct a Drug Utilization Review (DUR)/market analysis as outlined in Schedule C.

NON-ASSIGNABILITY and SUBCONTRACTING

7.

(a) The Manufacturer shall not:

(i.) assign or otherwise dispose of any of its rights, obligations or interests in this PLA; or,

(ii.) subcontract any of its duties or responsibilities under this PLA

without the prior written consent of the Minister, which shall not be unreasonably withheld.

(b) If the Manufacturer retains any subcontractor(s) in connection with performance of its duties or responsibilities under this PLA, the Manufacturer shall:

(i.) be responsible for remunerating the subcontractor(s);

(ii.) be responsible for the performance and activities of the subcontractor(s); and,

(iii.) contractually obligate the subcontractor(s) to take action, or refrain from taking action, as necessary to enable the Manufacturer to fulfill its obligations under this PLA.

COMPLIANCE

8. The parties shall comply with the provisions of all laws, now in force or in force after the signing of this PLA, that expressly or by implication apply to the parties in performing their obligations under this PLA.

NON-DISCLOSURE OF INFORMATION – MINISTER'S INFORMATION

9.

(a) Except as provided in clauses 9 and 11, all information, regardless of form, including Personal Information, that is obtained, generated, provided or collected by the Manufacturer pursuant to this PLA (the "Minister's Information"), shall not be disclosed or published by the Manufacturer without the prior written consent of the Minister. The Manufacturer may disclose the Minister's Information to employees, subcontractors or agents of the Manufacturer who have a need to know for the purpose of performing duties or responsibilities under this PLA.

(b) Subject to clause 11(b), the Manufacturer's obligations in clause 9(a) do not apply to information or documents which:

(i.) are or become publicly available through no act or omission of the Manufacturer;

(ii.) are independently developed without benefit of the Minister's Information; or,

(iii.) are received by or from a third party without restriction and without a breach of an obligation of confidentiality.

(c) The Manufacturer shall retain the Minister's Information as confidential and shall make reasonable security arrangements against unauthorized access, use, disclosure or destruction of the Minister's Information. The Manufacturer shall immediately advise the Minister of any unauthorized access, use, or disclosure of the Minister's Information, and shall provide the Minister any assistance reasonably required to rectify such a situation.

(d) The Manufacturer shall return or deliver the Minister's Information to the Minister upon expiry of the Term or termination of this PLA, or upon request of the Minister.

(e) The Minister's Information may be disclosed to the extent required by law or court order, provided that the Minister is given reasonable notice and opportunity to seek to prevent or limit its disclosure.

(f) No press release, public announcement or other public commentary relating to this PLA shall be made by the Manufacturer without the prior written approval of the Minister.

NON-DISCLOSURE OF INFORMATION – MANUFACTURER'S CONFIDENTIAL BUSINESS INFORMATION

10.

(a) Subject to the FOIPP Act and HIA, the Minister may disclose the Manufacturer's Confidential Business Information to any department or agency of the Government of Alberta that the Minister determines is necessary to assist the Minister in administration of this PLA.

(b) The Manufacturer further authorizes the Minister to access, discuss, use, collect from, and disclose to its agents, consultants, and advisors, any PLA information, including Manufacturer Confidential Business Information, for the purpose of administering this PLA, provided that, prior to disclosing the Manufacturer's Confidential Business Information to agents, consultants or advisors, the Minister will ensure proper confidentiality and non-disclosure requirements or agreements are in place with such agents, consultants or advisors so as to prevent any further disclosure of the Manufacturer's Confidential Business Information that would be in contravention of this PLA. The Manufacturer acknowledges that such confidentiality and non-disclosure requirements already exist in respect of employees and contractors of the Minister.

(c) Where the Minister has received a request under the FOIPP Act or HIA, or in any other legal proceeding, to disclose the Manufacturer's Confidential Business Information, the Minister will give the Manufacturer written notice of the request. The Manufacturer can, to the extent permitted by law, make any representations before the relevant public body or Court about why the Manufacturer's Confidential Business Information should not be disclosed. The Minister will not be compelled to defend a Manufacturer's designation of information as being Manufacturer's Confidential Business Information that should not be disclosed or the Manufacturer's ability to make representations to the public body or Court.

(d) The Minister shall immediately advise the Manufacturer of any unauthorized access, use, or disclosure of the Manufacturer's Confidential Business Information, and shall provide the Manufacturer any assistance reasonably required to rectify such a situation.

(e) Upon the request of the Manufacturer the Minister shall return or deliver the Manufacturer's Confidential Business Information to the Manufacturer upon expiration of the Term or termination of this PLA.

(f) When the Manufacturer no longer considers particular PLA information to be Manufacturer's Confidential Business Information, it shall immediately inform the Minister of this change in status.

(g) Where the Minister wishes to disclose the Manufacturer's Confidential Business Information other than as specified in this PLA or as otherwise compelled by law, it shall do so only with the prior written consent of the Manufacturer.

(h) Where there is any conflict between the non-disclosure provisions in this clause 10 and an applicable statute or Court order, the applicable statute or Court order will take precedence over the non-disclosure provisions in this clause 10.

FREEDOM OF INFORMATION AND PROTECTION OF PRIVACY

11.

(a) The Manufacturer acknowledges that, subject to clause 10, this PLA may be subject to disclosure under the FOIPP Act or the HIA. The Manufacturer further acknowledges that the FOIPP Act and the HIA apply to the Minister's Information collected, used or disclosed in the performance of the Manufacturer's duties and obligations under this

PLA, and the Manufacturer shall adhere to the FOIPP Act in its collection, use and disclosure of any Personal Information.

(b) The Manufacturer shall not collect, use or disclose any Personal Information under this PLA except as reasonably required to fulfill its obligations under this PLA, or as otherwise expressly authorized in writing by the Minister.

(c) Upon request and subject to clause 10, the Manufacturer shall provide to the Minister, within seven days, any records that are requested under the access provisions of the FOIPP Act that are in the custody or under the control of the Manufacturer. Should the Manufacturer receive an access request under the FOIPP Act as it relates to records that are in the custody or under the control of the Minister, the Manufacturer shall not respond to it, but shall immediately forward the access request to the Minister for further handling.

(d) Where the Minister determines that the Manufacturer shall be receiving Personal Information from the Minister, pursuant to s. 42 of the Alberta FOIPP Act, the Minister shall give the Manufacturer ninety (90) days prior notice of the transmittal of Personal Information and the following shall apply upon the receipt of the Personal Information by the Manufacturer:

(i) The Manufacturer shall store or shall arrange to have stored all records of Personal Information which are disclosed to the Manufacturer under this PLA in Alberta, including records that are collected, used or stored on behalf of the Minister; and
(ii) The Manufacturer shall act on any direction that the Minister may provide with regard to the use, collection, access, security disclosure and destruction of the Personal Information.

INDEMNITY AND LIABILITY

12.

(a) The Manufacturer shall indemnify and hold harmless the Minister, its employees and agents against and from any and all third party claims, demands, actions, or costs (including reasonable legal costs on a solicitor-client basis) for which the Manufacturer is legally responsible that arise from or relate to the performance of any obligation of the Manufacturer under this PLA.

(b) The Manufacturer shall indemnify and hold harmless the Minister against and from any loss or damage to the real or personal property of the Minister for which the Manufacturer is legally responsible arising from or relating to the performance of any obligation of the Manufacturer under this PLA.

INSURANCE

13.

(a) The Manufacturer shall, at its own expense, and without limiting its liabilities or obligations under this PLA, insure its operations in an amount not less than $2,000,000 inclusive per occurrence, insuring against bodily injury, personal injury, and property damage including loss of use thereof.

(b) The Manufacturer shall provide the Minister with acceptable evidence of insurance, in the form of a detailed certificate of insurance, upon request of the Minister.

(c) The Manufacturer shall ensure that all its subcontractors obtain and maintain general liability insurance sufficient to meet the requirements in clause 13(a).

(d) When requested by the Minister, the Manufacturer shall provide evidence of endorsement to provide the Minister with 30 days advance written notice of cancellation of insurance coverage.

MANUFACTURER REPRESENTATIONS AND WARRANTIES

14. The Manufacturer represents and warrants that:

(a) The Drug Product has been approved for sale in Canada and received a Notice of Compliance from Health Canada on <Left intentionally blank>;

(b) In addition to the Notice of Compliance, the Manufacturer has, without limitation, the necessary patents, licenses or agreements to allow the Manufacturer to sell the Drug Product in Canada during the Term of the PLA;

(c) The Drug Product is a Single Source Patented Drug;

(d) The information about the Drug Product in Schedule A reflects the Manufacturer's best information and estimates in respect of Alberta Government Sponsored Drug Plans;

(e) The Manufacturer has the qualifications and expertise necessary to provide the Drug Product for sale to the public in accordance with the ADBL and the provisions of this PLA.

RELATIONSHIP OF PARTIES

15. The relationship of the Manufacturer to the Minister in performing its obligations under this PLA is that of an independent contractor, and nothing in this PLA is to be construed as creating an agency, partnership, joint venture or employment relationship between the Manufacturer and the Minister.

NOTICES

16.

(a) Any notice to be made under this PLA is to be made in writing, and is effective when delivered to the address or transmitted by fax to the fax number, as follows:

The Minister:
Executive Director,
Pharmaceutical Funding and Guidance
Health Benefits and Compliance Division
Alberta Health
11th Floor TELUS Plaza North Tower
10025 Jasper Avenue NW
Edmonton, AB T5J 2N3

Fax: 780 422 3646

The Manufacturer:
<Left intentionally blank>

The parties respectively designate for the time being, the individuals identified in this clause as having the authority to give notice, and notice given by these individuals is binding on the party giving the notice.

(b) Either party may change its address or fax number information by giving notice to the other in the manner described in clause 16(a). Any notice personally served or sent by fax shall be deemed received when actually delivered or received, if delivery or fax transmission is on a Business Day, where "Business Day" means 8:15 am to 4:30 pm in Alberta from Monday through Friday excluding holidays observed by the Minister, or if not on a Business Day, on the following Business Day.

TERMINATION

17.

(a) The Minister may, at any time prior to the expiry of the Term, terminate this PLA, without cause, upon thirty (30) days prior written notice to the Manufacturer.

(b) The Manufacturer may, at any time prior to the expiry of the Term, terminate this PLA, upon thirty (30) days prior written notice to the Minister, in the event the Minister removes the Drug Product from the ADBL.

(c) The Manufacturer may, at any time prior to the expiry of the Term, upon ninety (90) days prior written notice, terminate this PLA where it intends to voluntarily remove the Drug Product for sale in the Canadian market.

(d) The parties may immediately terminate this PLA where a Canadian authority requires the Drug Product to be removed for sale or otherwise from the Canadian market due to patient safety or public health reasons.

(e) Where the benefit status/listing criteria of the Drug Product is changed on the ADBL, the Manufacturer may give the Minister notice that it wishes to re-negotiate the terms of this PLA. Should this occur, the parties shall negotiate in good faith for a period of no less than ninety (90) days from the date of the notice, at which point if the parties cannot come to an agreement, the Manufacturer may, on a further ninety (90) days notice, terminate this PLA.

(f) If this PLA is terminated for any reason, the Minister shall, if applicable, compile a final report of Claims Data to the date of termination and provide it to the Manufacturer, within thirty (30) days of the date of termination, indicating if any amounts are owing by the Manufacturer pursuant to Schedule A or Schedule C and such amounts shall be a debt owing to Her Majesty the Queen in the right of Alberta, as represented by the Minister of Finance with the amount payable to the Government of Alberta.

PARTIES' REPRESENTATIVES

18.

(a) The Minister designates the Senior Manager, Drug Utilization and Agreements, Pharmaceutical Funding and Guidance Branch, Alberta Health as the Minister's representative for communications and ongoing contact between the Minister and the Manufacturer in matters relating to this PLA, other than giving notice pursuant to clause 16(a).

(b) The Manufacturer designates <Left intentionally blank>, as the Manufacturer's representative for communications and ongoing contact between the Minister and the Manufacturer in matters relating to this PLA, other than giving notice pursuant to clause 16(a).

(c) Either party may change their designated representative above by sending written notice to the other party of such change.

CONFLICT OF INTEREST AND ETHICAL CONDUCT

19.

(a) The Manufacturer shall ensure that there is not a conflict of interest or an apparent conflict of interest on the part of the Manufacturer or its employees, subcontractors or agents in relation to this PLA, and all of the Manufacturer's obligations under this PLA shall be performed in accordance with high ethical standards, including, without limitation, the following:

(i.) the Manufacturer or its employees, subcontractors or agents shall not influence, or seek to influence, or otherwise take part in a decision of the Minister knowing that the decision might further their private interests;

(ii.) where the Manufacturer's obligations under this PLA involve providing advice, making recommendations to the Minister or exercising discretionary authority regarding a right, permission, privilege, status, contract or benefit, then such advice, recommendations or discretion must be provided, made or carried out impartially and without bias;

(iii.) except as otherwise set out in this PLA, the Manufacturer or its employees, subcontractors or agents shall not accept any collateral gift, payment, commission or other direct benefit arising from or connected to this PLA;

(iv.) the Manufacturer or its employees, subcontractors or agents shall not have any financial interest in the business of a third party that causes, or would appear to cause, a conflict of interest in connection with this PLA;

(v.) the Manufacturer, upon request by the Minister, shall deliver copies of all written ethical standards, conflict of interest policies and codes of conduct established or observed by the Manufacturer in its business practices or in relation to its employees, subcontractors or agents; and,

(vi.) the Manufacturer shall comply with, and ensure that, its employees, subcontractors or agents comply with, the *Lobbyists Act* (Alberta).

(b) In the event the Manufacturer becomes aware of any matter that causes or is likely to cause a conflict of interest in relation to this PLA, the Manufacturer shall immediately disclose such matter to the Minister in writing. Upon such disclosure, the Manufacturer shall not commence or continue performance of any of the Manufacturer's obligations under this PLA without the prior written consent of the Minister. The Minister's consent under this paragraph may allow the Manufacturer to perform all or a portion of its obligations under this PLA. Such consent can be revoked at any time and the Minister may terminate this PLA if the Manufacturer, its employees, subcontractors or agents are in conflict of interest.

SURVIVAL OF TERMS

20. Notwithstanding any other provision of this PLA, those clauses which by their nature continue after the conclusion or termination of this PLA shall continue after such completion or termination, including, without limitation, the following:

(a) clause 4 Listing, Pricing and Payment

(b) clause 9 Non-Disclosure of Information – Minister's Information

(c) clause 10 Non-Disclosure of Information – Manufacturer's Confidential Business Information

(d) clause 11 Freedom of Information and Protection of Privacy

(e) clause 12 Indemnity and Liability

(f) clause 17 Termination

GENERAL

21. In the case of conflicts or discrepancies between clauses 1 through 31 of this product listing agreement and its' accompanying Schedules, clauses 1 through 31 shall take precedence over the Schedules.

22. Time is of the essence of this PLA.

23. This PLA contains the entire agreement of the parties concerning the subject matter of this PLA and except as expressed in this PLA, there are no other understandings or agreements, verbal or otherwise, that exists between the parties.

24. Any waiver by either party of the performance by the other of an obligation under this PLA must be in writing, and such waiver does not constitute a continuing waiver of the performance of that obligation unless a contrary intention is expressed in writing.

25. The rights and remedies of the parties under this PLA are cumulative and any one or more may be exercised.

26. The parties may amend this PLA only by mutual written agreement signed by the parties.

27. This PLA shall be governed by and interpreted in accordance with the laws in force in Alberta, and the parties irrevocably attorn to the exclusive jurisdiction of courts in Alberta.

28. This PLA shall be for the benefit of and binds the successors and assigns of the parties.

29. The headings in this PLA are inserted for convenience of reference only and shall not affect the meaning or construction of this PLA.

30. In this PLA, words in the singular include the plural and words in the plural include the singular.

31. This PLA may be executed in any number of counterparts or delivered by fax, each of which shall be deemed an original and all of which together shall constitute one and the same PLA.

HER MAJESTY THE QUEEN IN RIGHT OF ALBERTA, as represented by the Minister of Health	<Left intentionally blank>
Per:	Per: <Left intentionally blank>
Signature	Signature
Title	Title
Date	Date

Schedule A

1) Definitions

(a) **"Alberta Government Sponsored Drug Plans"** means the enumerated drug programs in existence as of the Effective Date. It shall also include any drug programs established by Her Majesty the Queen in Right of Alberta during the Term of the PLA including any amalgamations, additions or deletions from enumerated drug programs below:

- the Alberta Blue Cross *Non-Group Coverage (Group 1)* offered by the Alberta Health Care Insurance Plan, or
- the Alberta Blue Cross *Coverage for Seniors (Group 66)* provided to all Alberta senior citizens and those on the Alberta Widows' Pension Plan *(Group 66A)*, or
- the drug coverage provided to individuals approved by Alberta Health for *Palliative Care Drug Coverage* (for these individuals, the *Palliative Care Drug Benefit Supplement* must also be considered), or
- the drug coverage provided to Alberta Human Services clients including any *Drug Benefit Supplement* .

(b) **"Alberta Price Confirmation"** or "APC" is the unit price for drugs, as established from time to time by the price policy of the ADBL.

(c) **"Anniversary Year"** shall mean each subsequent twelve (12) month period during the Term commencing as of the Effective Date.

(d) **"Base Cost"** means the Manufacturer's list price per capsule of the Drug Product, as specified in Section 5 (a) of this Schedule A, and does not include any distribution allowance or other mark-up/fees.

(e) **"Confirmed Price"** shall mean the Base Cost of the Drug Product as permitted by the APC. For greater clarity, this is the published price on the ADBL.

(f) "**Fiscal Year Quarter**" means, as applicable, any of the following periods: (i) April 1 to June 30; (ii) July 1 to September 30; (iii) October 1 to December 31; or (iv) January 1 to March 31.

(g) "**Product Listing Agreement Price" or "PLA Price"** means the confidential price after rebate of the Drug Product as specified in Section 4 of this Schedule A.

(h) "**Reimbursement Amount**" means the amount payable, if any, by the Manufacturer to the Minister in accordance with this PLA.

2) Reimbursement Amount

(a) The Manufacturer agrees it will pay the Reimbursement Amount in accordance with this Schedule "A".

(b) The Manufacturer may not claim a refund, repayment or credit from the Minister if the Reimbursement Amount under this agreement is less than or equal to zero.

(c) The Manufacturer will pay the Reimbursement Amount to the Minister for the Drug Product covered in this PLA in accordance with the formula outlined in Section 6 of this Schedule A.

(d) The Reimbursement Amount will be payable by the Manufacturer to the Minister within forty-five (45) days of AH delivering the Claims Data as established by Section 3 of this Schedule A to the Manufacturer.

(e) The Manufacturer warrants that it has entered into contractual and other arrangements to the extent necessary to ensure that it can meet its obligations to supply the Drug Product in the required amounts throughout the Term.

(f) Should any actions or materials be required by the Manufacturer to meet its obligations contained in this PLA which are not expressly or completely described in this PLA, such actions or materials shall be deemed to be implied and required by this PLA, and the Manufacturer shall, at its expense, perform such actions and furnish such materials as if they were specifically described in this PLA.

(g) Subject to any price increases agreed to by the Parties, the Manufacturer shall supply the Drug Product to the Alberta market at the per unit, ex-factory maximum price of the Confirmed Price (as defined in Section 4 of this Schedule A) as established by the APC throughout the Term in amounts sufficient to allow all pharmacies within Alberta to dispense the Product to patients as needed and without delay.

3) Claims Data

(a) The following Claims Data will be provided for the Drug Product, for each Fiscal Year Quarter commencing after the Effective Date:

<Left intentionally blank>

4) Product Listing Agreement (PLA) Price Per Drug Product

(a) The Product Listing Agreement Price for the Drug Product as of the Effective Date and for the Term of the agreement, shall be:
<Left intentionally blank>

5) Confirmed Price

(a) The Confirmed Price for the Drug Product on the ADBL as of the Effective Date shall be:

(i) <Left intentionally blank>

6) Reimbursement Amount Formula

(a) Quarterly List Price Rebate:

(i) The Reimbursement Amount payable by the Manufacturer to the Minister for each Fiscal Year Quarter commencing after the Effective Date and each subsequent Fiscal Year Quarter during the Term shall be calculated using the following formula, based upon the Claims Data provided to the Manufacturer for the reporting period as per Section 3 of this Schedule A:

<Left intentionally blank>

Schedule B

Notwithstanding anything in this Schedule B the Minister may waive or vary any of the special authorization criteria as set out in this Schedule B to for a member of a Alberta Government Sponsored Drug Plan where the Minister believes that any such waiver or variation is in the best interest of that member of an Alberta Government Sponsored Drug Plan. Where such waiver or variation of the special authorization criteria results in the Minister incurring the cost of reimbursement of the Drug Product this reimbursement amount shall be used in the calculation for any amounts payable by the Manufacturer under Schedule A of this PLA.

The Minister agrees to list the Drug Product on the ADBL as a Special Authorization benefit with the following criteria:

<Left intentionally blank>

Schedule C

1. At the discretion of the Minister, the Manufacturer may be asked by the Minister to conduct a Drug Utilization Review (DUR)/market analysis concerning the Drug Product.

2. The Manufacturer will be responsible for the reasonable costs of the DUR/market analysis, up to a maximum of $<Left intentionally blank> per Anniversary Year.

3. The DUR/market analysis may be conducted by AH or any other party as may be designated by the Minister and agreed to by the Manufacturer.

4. The DUR/market analysis, will compare one or more comparator agents to the following:

    (a) Frequency and daily utilization of the drug product

    (b) Other market factors may be explored as agreed to by the Minister and the Manufacturer.

5. DUR/market analysis results may be used by the Minister to determine the necessity for corrective action and/or any needs to be put in place with respect to the listing status or special authorization mechanisms with respect to the Drug Product.

6. The parties agree that the Manufacturer shall not have access to any Personal Information as a result of any potential DUR/market analysis.