ALBERTA HEALTH
PRODUCT LISTING AGREEMENT POLICY

Effective: May 18, 2022

ALBERTA HEALTH
PRODUCT LISTING AGREEMENT POLICY

I. POLICY STATEMENT

The Government of Alberta sponsors a number of drug plans for the general purpose of making certain drugs and devices available, on an affordable basis, to Albertans. Alberta Health provides for the ongoing availability of drugs and devices to these drug plans through the implementation of policies and processes that provide for drug and device reviews, pricing and "listing". Collectively, the policies, processes the specific drugs and devices that are identified and listed through the policies, and any drug and device access rules, make up the overall Alberta Drug Benefit List (ADBL).

Albertans who have coverage 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 and devices available to Albertans are listed on the ADBL in accordance with the ADBL Price Policy and Alberta Price Confirmation process. However, there are certain drugs and devices that are not listed on the ADBL for various reasons, even though there are indications that the drugs or devices may offer some public benefits.

The Alberta government sponsored drug plans face continuous financial pressure that requires the Government of Alberta to address their financial sustainability. Financial sustainability needs to be balanced with responsible access to therapies for Albertans that are funded by the Government of Alberta. Therefore, maintaining the ADBL on a comprehensive and sustainable basis is a key objective of the related policies.

To address the issues of timely access and financial pressure, AH has developed this policy for the purpose of enabling marketed drugs and devices authorized for sale in Canada to be considered for listing through an agreement more commonly known as a Product Listing Agreement or "PLA". The PLA process is intended to support improved health outcomes and promote best value for Alberta's government-sponsored drug plans. The decision whether a particular drug or device will receive a PLA is determined by the Minister of Health where the drug or device meets all the necessary policy criteria including whether a PLA is in the best interest of the public and the health care system.

AH is committed to ongoing dialogue with industry. The intent of this policy is to define and set clear parameters to establish and execute PLAs through a collaborative, predictable and sustainable process between government and industry. PLAs will support the best use of resources and help to manage risk and uncertainty. PLAs can also create opportunities for research investment within Alberta. Appropriate efforts will be made throughout the process to discuss AH's needs, preferences and priorities with Manufacturers to help ensure a collaborative PLA process.

II. DEFINITIONS AND INTERPRETATION

Definitions: The following definitions apply in this Policy:

“Advisor” means a Minister-appointed expert advisory committee such as CDEC, ECDET and any other person or group, such as CDR or AH, who provides evidence and advice to the Minister regarding the listing of drugs and devices on the ADBL.

“Alberta Health” or **“AH”** means the department of the Government of Alberta with a mandate to administer the ADBL, which also includes its employees and agents.

“Alberta Drug Benefit List” or **“ADBL”** means, collectively:

- the complement of policies and processes that address the requirements for listing drugs and devices as benefits for participants in government-sponsored drug plans; and,

- the specific list of Drug Products and Devices 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 and Devices that are included as benefits under the government-sponsored drug plans and the policies and processes that govern how a Drug Product or Device may be included on the list.

“Alberta Health Services” or **“AHS”** means the regional health authority that has been established and operates under the *Regional Health Authorities Act*.

“Alberta Price Confirmation” or **“APC”** means the process outlined in the Price Policy wherein the Minister issues a request from time to time to Manufacturers to propose drugs or devices for listing on the ADBL, in accordance with the AH Price Policy. The APC process determines the price that a Manufacturer will offer a drug or device for sale to Albertans. Reference to “APC” includes an “interim APC” as provided for in the Price Policy.

“Applicant” means a Manufacturer that is making a submission for a PLA through the RFPLA process.

“Biosimilar” means a biologic drug that is highly similar to a biologic drug that was already authorized for sale in Canada.

“Canadian Agency for Drugs and Technologies in Health” or **“CADTH”** means the national body that provides Canada’s federal, provincial and territorial health care decision makers with evidence-based information about the effectiveness and efficiency of drugs and other health technologies.

“Canadian Drug Expert Committee” or **“CDEC”** is the independent advisory body composed of individuals with expertise in drug therapy and drug evaluation that is appointed by and reports to CADTH and that makes recommendations to various federal, provincial, and territorial governments regarding the inclusion (or “listing”) of drugs in their publicly funded drug plans.

“Common Drug Review” or **“CDR”** means the process supported by CADTH through which clinical evidence and pharma-economic information for drugs is compiled for review by CDEC for the purpose of making recommendations as to whether particular drug under review should be included as benefits by Canada’s publicly funded drug plans.

"**Confidential Business Information"** includes information provided by an Applicant or a Manufacturer to Alberta Health for the purpose of obtaining a PLA or fulfilling the obligations thereunder, whether provided before or after the Effective Date of a PLA or the date a PLA submission is made, 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 a PLA and the type of financial or any other information that could be used to infer the Applicant's or Manufacturer's sales or marketing strategy. Any designation of information under this definition shall be identified by the Manufacturer as such. Where information provided to AH is provided otherwise than in writing and the Manufacturer wishes to designate that information as being Confidential Business Information, it shall provide written notice to AH that it wishes to designate this information as Confidential Business Information no later than two business days after the date of communication of the subject information to AH. Confidential Business Information shall not include:

i. The name of the drug or device which is the subject of the PLA or PLA submission, the name of the Manufacturer, and the existence of a PLA agreement (if any) between AH and the Manufacturer;
ii. Information which was lawfully and without legal restriction in the possession of the Government of Alberta other than through disclosure in the PLA Submission, PLA negotiations or the PLA itself;
iii. Information derived independently of disclosure in the PLA submission, PLA negotiations or the PLA itself;
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 the PLA Policy, or any other unauthorized act.

"device" means a product approved by Health Canada as per the *Food and Drug Act* as a device.

"Device" means a device that may be listed or under consideration for listing by the Minister on the ADBL.

.

"drug" means:

- a drug as defined in the *Pharmacy and Drug Act*;
- a gene or cell therapy;
- a vaccine;
- a biologic;
- any material, substance or thing which is authorized for sale in Canada by Health Canada

"Drug Product" means anything drug or drug related that is listed or under consideration for listing by the Minister on the ADBL.

"Expert Committee on Drug Evaluation and Therapeutics" or **"ECDET" or "Expert Committee"** means the committee established by the Minister to review a Drug Product or Device submission and make recommendations about the merits of listing the Drug Product or Device on the ADBL.

"Generic Drug Product" means a drug that is pharmaceutically equivalent to a patented drug as it contains identical medical ingredients, in the same amounts and in a similar dosage form which demonstrates the similar safety, efficacy or quality of drug compared to the patented drug. It also means any drug that must comply with the Fixed Pricing Rules of the Alberta Price Policy.

"Health Canada" means the department of the Government of Canada responsible for federal health policy and programs.

"Letter of Intent" or **"LOI"** means a document which details the agreed upon terms and conditions for reimbursement of a drug or device between jurisdiction(s) or the pan-Canadian Pharmaceutical Alliance and a Manufacturer.

"Manufacturer" means an entity that is issued a Notice of Compliance or Notice of Compliance with Conditions for a drug or a Medical Device Licence or Establishment Licence for a device and includes an authorized representative of the Manufacturer.

"Medical Device Establishment Licence" means the authorization issued by Health Canada's Medical Devices Bureau to market a class I Device in Canada when the *Medical Devices Regulations* (Canada) are met.

"Medical Device Licence" means the authorization issued by Health Canada's Medical Devices Bureau to market a class II, III or IV Device in Canada when the *Medical Devices Regulations* (Canada) are met.

"Minister" means Her Majesty the Queen in right of Alberta, as represented by the Minister of Health or their designate.

"Notice of Compliance" or **"NOC"** means the authorization issued by Health Canada allowing that drug to be marketed in Canada when regulatory requirements for the safety, efficacy, and quality are met.

"Notice of Compliance with Conditions" or **"NOC/c"** means the authorization issued by Health Canada to market a drug under Health Canada's "Notice of Compliance with Conditions" policy and which indicates that the Manufacturer has agreed to undertake additional studies to confirm the clinical benefit of the drug.

"Patented Medicine Prices Review Board" or **"PMPRB"** means the independent quasi-judicial body established under *Patent Act* (Canada) to:

- review the price of each patented drug, including each strength of each dosage form of each patented medicine sold in Canada; and,
- report on pharmaceutical trends of all medicines, and on the research and development spending by pharmaceutical patentees.

"pan-Canadian Pharmaceutical Alliance" or "pCPA" means the alliance of participating jurisdictions, of which Alberta is a member, created by the Premiers of Canada through the Council of the Federation's Health Care Innovation Working Group with the mandate to enhance patient access to clinically relevant and cost-effective drug treatment options. It serves this mandate by conducting collective, expert-informed, negotiations for drugs and devices.

"PLA Submission" means a proposal for a PLA that is submitted by a Manufacturer in response to an RFPLA.

"PLA Submission Form" means a form required by the Minister from an Applicant who is making a PLA Submission through the RFPLA process.

"Price Policy" means the Alberta Price Policy that forms part of the ADBL, as may be amended from time to time.

"Product Listing Agreement" or **"PLA"** means an agreement between an Applicant or Manufacturer and Her Majesty the Queen in Right of Alberta, as represented by the Minister that sets out the terms and conditions for the listing of certain drugs and devices on the ADBL and may include, but is not limited to, the following forms of agreement:

- **Price/Volume Agreement** is a type of PLA designed to make high cost drugs or devices more affordable for the government sponsored drug plans through provisions that may address the price based on possible price/volume and/or cost recovery (rebate) provisions.

- **Health Research Capacity Agreement** is a type of PLA that is to provide investment in the area of drug or device development, the refinement of health policy, the identification of health outcomes and overall health research and to facilitate collaboration within the Alberta research community.

- **Utilization Management Agreement** is a type of PLA that is designed to improve the accountability and appropriateness for how drugs or devices are prescribed or utilized (e.g. to facilitate appropriate prescribing, disease management, patient adherence or appropriate marketing and promotion).

- **Coverage with Evidence Development Agreement** is a type of PLA that is to provide conditional access to a drug or device where there is a defined clinical uncertainty and features of the agreement are designed to facilitate the acquisition of evidence to address that uncertainty.

"RFPLA" means a "Request for PLA Submission" which is a mechanism by which the Minister may request a proposal from a Manufacturer for a PLA.

"Single Source Drug" means a drug containing a unique chemical, strength, dosage form and route of administration and is sold only by one Manufacturer.

"Single Source Patented Drug" means a drug containing a unique chemical, strength, dosage form and route of administration, sold by one Manufacturer that is on the patent list as per the *Patented Medicines (Notice of Compliance) Regulations* pursuant to the *Patent Act* (Canada).

"Subsequent Entry Non-Biologic Complex Drug" means a synthetic compound that contains different closely related molecular structures that cannot be fully characterized by physiochemical analytical means and demonstrate similarity in safety and efficacy to its originator drug.

"Therapeutic Advantage" means a drug that provides an improvement in the treatment, diagnosis, or prevention of a disease when compared to another drug or, if there is no comparable drug, when assessed for the indicated condition. An Advisor will make recommendations about whether or not a drug provides a therapeutic advantage based on the following factors:

- clinical efficacy;
- risk/benefit ratio;
- toxicity;
- adherence;
- clinical outcomes;
- Health Canada warnings and advisories;
- population health issues; or,
- any other factor which affects the efficacy of the drug.

Interpretation:
References in this policy to:

- a PLA Submission, includes a PLA Resubmission; and
- 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.

III. PRODUCT LISTING AGREEMENTS

A. Introduction

This policy forms part of the ADBL and sets out the requirements that must be met for a drug or device to be listed on the ADBL. Where a drug or device is listed on the ADBL through a PLA that drug or device is subject to ADBL policies and processes, as the Minister determines is appropriate. In all cases the Minister, in its sole discretion, will determine if and when a PLA is an appropriate mechanism for listing a drug or device on the ADBL.

In order to maintain a PLA Policy and process that is consistent with AH health policies, health system objectives and that serves the general public interest, the Minister may require, in the Minister's sole discretion, that the PLA Policy undergo reviews and amendment from time to time. Such amendments may apply retroactively to PLA Submissions and PLAs not yet finalized in a signed PLA with the Minister. It may also be the case that the Minister in his sole opinion may also require amendments to a signed PLA, that as a result of changes to the PLA Policy affecting the ADBL, requires that signed PLA be updated.

Eligible Drug Products, Devices, and Other Goods or Products

No drug or device will be considered for a PLA unless:

- the drug has been approved for sale in Canada as evidenced by a Notice of Compliance; or, Notice of Compliance with Conditions from Health Canada;
- the device has been approved for sale in Canada as evidenced by a Medical Device Licence or Medical Device Establishment Licence from Health Canada's Medical Devices Bureau.

The Minister may enter into a PLA with a Manufacturer and any other party(ies) for a drug that is a Generic Drug Product, a Single Source Patented Drug Product, a Single Source Drug, a Biosimilar, a Subsequent Entry Non-biologic Complex Drug, or a device.

The Minister may enter into the PLA for any other good or product that is not identified above where the Minister, in its own discretion, determines that the good or product is a benefit to Albertans and a PLA is appropriate to provide the good or product as a benefit under the ADBL.

PLA Initiation

The Minister, in the Minister's sole discretion, may enter into a PLA under the following circumstances:

1. As a result of a Manufacturer's PLA Submission successfully meeting the conditions in the RFPLA process (Section B) to obtain a PLA; or
2. Where Alberta has participated, either on its own or with other Canadian jurisdictions, in negotiations with a Manufacturer outside of the RFPLA process resulting in an executed letter of intent (LOI), or other agreement, whereby the Manufacturer will extend terms in that LOI or agreement that Alberta can accept for the purposes of entering into a PLA (Section C).

B. Request for Product Listing Agreement Submission (RFPLA) Process

1. Initiation of RFPLA

The Minister may, in the Minister's sole discretion, issue an RFPLA inviting specific Manufacturers or all Manufacturers, as the case may be, to submit a PLA Submission for consideration by the Minister. The invitation by the Minister to Manufacturers to make a PLA Submission is not intended to be a representation or commitment that any or all PLA Submissions made in response to an RFPLA will be screened, evaluated, negotiated or result in an signed PLA.

For greater clarity:

- The Minister may issue an RFPLA on any basis the Minister determines appropriate, in the Minister's sole discretion, for the purposes of maintaining or developing the ADBL.
- An RFPLA may be issued by the Minister at any time. Once issued, an RFPLA may be withdrawn or discontinued by the Minister, in the Minister's sole discretion, at any time.

A RFPLA may specify that the Minister is seeking a PLA in respect of one or more drugs, type of drugs, class of drugs, category of drugs, specific devices or category of devices or on any other basis as determined by the Minister.

A RFPLA may also specify the specific form of PLA that the Minister is seeking. These forms include a Price/Volume Agreement, Health Research Capacity Development Agreement, Utilization Management Agreement, Coverage with Evidence Development Agreement, or some other form as determined by the Minister.

In the case where a PLA Submission is made for a drug or device that is not currently listed on the ADBL, the drug or device will not be added to the ADBL until the PLA has been executed by the Minister and all other parties to the PLA.

2. PLA Submission

A PLA Submission will require an Applicant to submit a PLA Submission Form to the Minister.

The PLA Submission must satisfy the Minister that the drug or device that is the subject of the PLA Submission does the following:

- is able to demonstrate that the drug or device is therapeutically equivalent or provides a therapeutic advantage over other presently accepted therapies, devices or treatments of the disease entity for which current Drug Products and Devices are indicated, where applicable; and

- is more cost-effective than presently listed Drug Products or Devices, or offers significant cost savings or, in the case of Coverage with Evidence Development submissions, will enable the drug or device to demonstrate whether or not it offers cost-effectiveness or significant cost savings.

A PLA Submission is not a waiver, substitution, or replacement of any policy, process or review required by law for the sale or provision of drugs and devices to the public.

Any PLA Submissions that include Drug Products or Devices that are under review by the ECDET will be deferred in the PLA process until a recommendation is made from the ECDET.

A PLA Submission may be subject to any policy, process or other requirements for the review and listing of drugs or devices as required by the Minister and in the Minister's sole discretion.

A PLA Submission that purports to exclude, restrict or limit, in any way, any other drug or device from being listed, or continue to be listed on the ADBL (whether as an unrestricted benefit or otherwise) or any other publicly funded program will not be approved as a condition for the Applicant to enter into a PLA will not be accepted.

3. Filing of PLA Submissions

Information for Applicants as to PLA Submission Forms, format, deadlines and delivery instructions will be provided in the RFPLA.

A PLA Submission is to be made at the sole expense of the Applicant and the Applicant can not ask, and the Minister will not pay, for any expenses incurred by the Applicant in preparing its PLA Submission.

In addition, the Applicant is liable for any costs and risk associated by failing to submit its PLA Submission to the Minister by the deadline set out in the RFPLA.

4. Contents of the PLA Submission

A PLA Submission must include the information required by the PLA Submission Form and the RFPLA as well as details as to the subject drug's or device's therapeutic advantage, cost effectiveness and/or cost savings.

In addition to the PLA Submission Form, the PLA Submission must include:

- An Executive Summary,
- A signed consent and confidentiality acknowledgement letter,
- A completed PLA Submission Form,
- A summary of promotional activities and risk mitigation strategies; and,
- A certificate signed by the Applicant.

For greater clarity, the PLA Submission must comply with the following requirements:

Executive Summary:

The Applicant shall provide a high-level summary of its PLA Submission that details the specific PLA terms being proposed by the Applicant.

The Consent and Confidentiality Acknowledgement Letter

The Applicant must prepare a consent and confidentiality letter than contains the following:

- A designation of those portions of its PLA Submission and any other materials provided to AH that are Confidential Business Information as defined in this Policy;
- An authorization permitting 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;
- An authorization permitting AH to access, discuss, use, collect from, and disclose to Health Canada, the CADTH, CDR, and the PMPRB 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 Applicant or otherwise, with the prior written consent of the Applicant.
- A further authorization permitting AH to access, discuss, use, collect from, and disclose to an agency or department of another province or territory, for purposes related to the evaluation of the PLA submission, 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 provinces or territories by the Applicant or otherwise, with the prior written consent of the Applicant.
- The Applicant will further authorize AH to access, discuss, use, collect from, and disclose to its employees, agents, consultants, contractors and Advisors, all information include in a PLA Submission, 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 Applicant of the existence of such Confidentiality and Disclosure Agreements.
- When an Applicant no longer considers particulars contained in a PLA Submission to be Confidential Business Information it shall 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 or Court order will take precedence over the contents of this letter.

The Summary of Promotional Activities and Risk Mitigation Strategies

The Applicant shall provide the Minister with a summary of its promotional and risk strategies that must include the following:

- A description of the Applicant's mechanisms, strategies and key tactics to facilitate appropriate utilization and prescribing by medical practitioners as identified in the Applicant's marketing plan (including a description of how these mechanisms and strategies align with medically endorsed, Canadian Clinical Practice Guidelines, where applicable).
- An explanation as to the Applicant's proposed binding obligations including a detailed description of mechanisms for risk mitigation if cost and / or sales projections for the subject drug or device 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

The Applicant must provide in a form satisfactory to the Minister a signed certificate that warrants and contains the following:

- Confirmation that the Applicant has read and understands the PLA policy;
- Confirmation that the information contained in the PLA Submission reflects the Applicant's best information and estimates in respect of the Alberta government sponsored drug plans;
- Confirmation that the PLA Submission applies to all Alberta government sponsored drug plans, as will any PLA that may be entered into as a result of such PLA Submission; and,
- Confirmation that there is no impediment, in law or otherwise, to the Applicant entering into a PLA for the drug or device.

A PLA Submission for a Utilization Management Agreement (UMA) 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 Government 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.

A PLA Submission with multiple elements must:

- Satisfy the submission requirements for each type of PLA that comprises the PLA Submission.

5. Receiving, Screening and Evaluation of PLA Submissions

The Minister shall use the following process for screening, evaluating, and negotiating a PLA Submission:

- Upon receipt of a PLA Submission AH will conduct an initial screening of the PLA Submission Forms to determine if the PLA Submission is complete and meets the requirements of the RFPLA, PLA Submission Form, and any other the relevant sections of this policy.
- In the event that AH considers a PLA Submission to be incomplete, AH may contact the Applicant to discuss the deficiencies and allow the Applicant a time-constrained opportunity to remedy and correct any deficiencies.
- Where AH determines that it requires additional information for the purpose of screening or evaluating a PLA Submission, AH may request the required information in accordance with the provisions for “Additional Information” set out below.
- AH is not required to request Additional Information and may reject a PLA Submission that it considers does not provide sufficient information to determine if a PLA should be granted on the basis of that submission.
- A PLA Submission that meets the initial screening requirements of this policy, shall then proceed to be evaluated.
- The evaluation will be based on the factors listed in the PLA Submission Form and may include, but is not limited to, the following:

    i.) Recommendations of Advisors;
    ii.) The therapeutic advantage, therapeutic equivalency, cost effectiveness and/or cost savings that the drug or device may provide;
    iii.) The effectiveness with which a drug or device addresses:
        a) defined urgent medical need regarding a rare, severe or life threatening condition of a certain patient or category of patients;
        b) an area of significant growth in demand for a certain therapy option and presents an opportunity to price the drug or device on cost or volume basis;
        c) a defined therapeutic gap or opportunity;
        d) a chronic condition that affects a significant proportion of the population.
    iv.) The value of the financial offset that the PLA may provide, such as for health research, against any incremental cost that may arise from the addition of a drug or device to the ADBL or other government sponsored program including:
        a) the complexity of the proposed agreements;
        b) health system priorities, including health research needs;
        c) health policy objectives;
        d) any other factors that the Minister, in its discretion, considers relevant.

The timing and priority given to the evaluation and screening of a PLA Submission and negotiation of a PLA will be determined by the Minister, in the Minister’s discretion. In addition to the evaluation factors set out above, factors that may affect the overall PLA submission

process may include but are not limited to the number of PLA submissions that have been received.

6. Additional Information

The Minister may at any time request from the Applicant or any other person further information or other particulars that the Minister determines is required for the Minister's review of a PLA Submission.

When a request for additional information is made, the Minister or AH may:

- Specify that the information is required from a specific source, such as:
  - an Advisor;
  - Health Canada;
  - the Chair of the Expert Committee;
  - a Medical Director of Alberta Health Services;
  - clinicians or other external stakeholders identified by AH as having expertise in drug therapy, economics, PLAs, the factors applied to screen or evaluate a PLA Submission, the structure of PLAs; or
  - any other person
- Request additional information through the Applicant or directly from the specified source;
- Set deadlines for when the additional information must be provided; or
- in the event a deadline for the provision of additional information is missed, declare a PLA Submission to be incomplete and reject the PLA Submission.

In the event that the quantity and complexity of the requested additional information is significant, or if an entity, other than the Applicant, is delayed in providing the additional information, there may be a delay in the review of a PLA Submission. In no circumstance does the Minister commit to reviewing a PLA Submission within a certain time period or at all.

7. Negotiations

Where the Minister has evaluated a PLA Submission and determined that it should proceed to the negotiation of a PLA the parties shall establish a timetable for the negotiations.

If for any reason AH and the Applicant do not finalize the terms of 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.

Not withstanding the aforementioned timetable, the Minister will review the progress of negotiations within six months of the commencement of negotiations. In the event that negotiations with the Applicant 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 Applicant or the Minister may withdraw from any negotiations at any time prior to the signing of a PLA.

8. No Obligation on Minister to Request, Review or Negotiate

Notwithstanding any other provision of this policy, the Minister may at any time reject or defer any PLA Submission or delay or terminate the screening, evaluation or negotiation of any PLA Submission on any basis with or without cause.

9. PLA Resubmissions

An Applicant may make a request to resubmit a PLA Submission in the event that the PLA Submission was made in response to an RFPLA and the Applicant voluntarily withdrew its PLA Submission prior to a PLA being signed. The Minister is not obligated to grant the request for a re-submission.

In all other cases, a PLA resubmission may only be made in accordance with an RFPLA that includes the drug that is the subject of a resubmission, if the RFPLA specifies that resubmissions will be considered.

10. Applicant Responsibilities

It is the responsibility of an Applicant making a PLA Submission to ensure that it complies with all the requirements of the ADBL and other publicly funded program policies and processes, including this PLA Policy including any amendments thereto.

C. PLAs Resulting from a Successful Negotiation Outside of the RFPLA Process

The Minister may, in its sole discretion, participate in negotiations with a Manufacturer that is not subject to the RFPLA process set out in this policy for drugs or devices.

For greater clarity, the Minister may:
- participate in negotiations as a participating jurisdiction with the pCPA;
- participate in negotiations with other jurisdictions outside of the pCPA process; or
- participate in negotiations with a Manufacturer for any other reason.

In the case where a negotiation is successful for a Drug Product or Device that is under review by the ECDET or an Advisor, the drafting of a PLA will be deferred until a recommendation is made from the ECDET or Advisor. The Minister, in their sole discretion, may choose not to enter into a PLA should the ECDET or Advisor recommend that the drug or device should not listed on the ADBL.

If a negotiation is for a drug or device is not currently listed on the ADBL the drug or device will not be added to the ADBL until the PLA has been executed by the Minister and all other parties to the PLA.

D. General Information

The following information will apply to all PLAs.

1. Contracting and Listing

Following negotiations that result in AH and the Manufacturer agreeing to enter into a PLA, the PLA shall be based on the PLA format as proposed by the Minister. The Minister may at any time defer, delay or decline to not enter into a PLA with the Manufacturer with or without cause.

Where a Manufacturer and the Minister agree to enter into a PLA, the PLA will be entered into using Alberta's form of PLA. The Manufacturer agrees that as a condition to entering into a PLA with the Minister, the Manufacturer will agree to the terms in the Minister's form of PLA that are not specific to the letter or intent or other agreement. The Minister, in the Minister's sole discretion, may make changes, edits or updates to the form of PLA as the Minister consider appropriate.

AH will provide the Manufacturer with a draft PLA for review incorporating the terms agreed to by the parties and an eventual final PLA for execution. If the Manufacturer chooses to execute the PLA by way of a wet signature, then two copies of the PLA should be printed, signed and sent by courier to the Minister. Manufacturers can also choose to provide an electronic signature where permitted by the Minister with the signed document to be send by email to the Director of Professional and Industry Relations. Such signatures shall be in compliance with the *Electronics Transactions Act* of Alberta. Regardless of the signature method chosen, unless otherwise directed, the Effective Date on the PLA must be left blank.

For a Drug Product or Device that is to be listed on the ADBL, updates to the ADBL occur on the first day of every month. In order for a Drug Product or Device to be considered for the considered for inclusion in an update, the PLA signed by the Manufacturer, either the hard copy or the electronically signed PLA, must be received from the Manufacturer at minimum 10 business days prior to the end of the previous month or other timeline as the Minister deems appropriate. Regardless of whether the manufacturer-signed PLAs is received within timelines, AH is unable to guarantee inclusion on any specific ADBL update as all listings are subject to internal review and approval.

The Minister may, in its sole discretion, countersign the PLA and enter the Effective Date, resulting in the full execution of the PLA.

A copy of the executed PLA will be sent by the Minister to the Manufacturer by mail for those PLAs with wet signature and by email for those PLAs with electronic signature.

The Manufacturer may be notified of whether their Drug Product or Device will be listed on the ADBL no sooner than five business days prior to the end of previous month.

2. ADBL Price Policy and Alberta Price Confirmation Process

The Minister may, in the Minister's sole discretion, refer a drug or device that is the subject of a PLA or PLA Submission, to an Alberta Price Confirmation or Interim APC process.

3. Inquiries

Unless otherwise specified, all PLAs, PLA submissions or inquiries in regards to PLAs may be sent to the attention of:

Director, Professional and Industry Relations

Pharmaceutical and Health Benefits
Alberta Health
11th floor ATB Place North
10025 Jasper Avenue NW
Edmonton, AB T5J 2N3

4. Lobbying

Any lobbying in regard to a RFPLA, a PLA Submission or a PLA must be in accordance with the *Lobbyists Act.*

5. No Liability

The PLA Policy is an extraordinary process conducted solely in the discretion of the Minister. The Minister, AH and its employees and agents do not, by issuing, amending, suspending, postponing, or cancelling this PLA policy, or by any communication or documentation made or provided in connection with this PLA policy, any application or non application of this policy, including the issuance of an RFPLA and the screening, evaluation or rejection of any PLA or PLA Submission, incur any duty of care or contractual obligation to any Applicant, Manufacturer or other person, and expressly disclaim any liability or obligation whatsoever to any Applicant, Manufacturer or other person arising out of or relating to this PLA policy, including any PLA or PLA Submission made pursuant to or related thereto. Statements in this PLA policy of AH or the Minister's expectations in relation to PLAs and the PLA policy and process are relied upon or acted upon by Applicants, Manufacturers and other person solely at their own risk.

6. Confidentiality

All information submitted to or accessed by the Minister or AH under this policy, an RFPLA, PLA or PLA Submission will be subject to the access, use and disclosure provisions of the *Freedom of Information and Protection of Privacy (FOIPP) Act* or the *Health Information Act* as applicable.

Where AH has been requested by applicable 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.

7. Termination and De-listing

The Minister in accordance with the terms of any PLA and this policy may at any time, terminate a PLA, without cause, upon thirty (30) days prior written notice to the Manufacturer.

The Minister may, in accordance with the terms of any PLA and this policy, also immediately terminate a PLA upon written notice to the Manufacturer if the Minister becomes aware that there is a patient safety concern related to the use of the Drug Product or Device or the Manufacturer fails to comply with the provisions of the ADBL.

The Minister or Manufacturer may also immediately terminate this PLA where Health Canada requires the Drug Product or Device to be removed for sale from the Canadian market.

For Drug Products or Devices that are listed on the ADBL by way of a PLA, the Minister may cancel, modify, or take any other action the Minister considers appropriate in regards to the listing of the Drug Product or Device as outlined in the Alberta Price Policy.

Should any or all of the Drug Products or Devices that are the subject of a PLA be de-listed from the ADBL, the PLA to which those de-listed Drug Products or Devices shall not be considered to be terminated until such time as the Minister or the Manufacturer, as the case may be, terminate the PLA in accordance with the PLA and this policy.

Furthermore the PLA shall continue to apply to any of the Drug Products or Devices in that PLA yet to be removed from the ADBL until such time as the PLA to which those Drug Products or Devices applies is terminated.