

**ALBERTA HEALTH AND WELLNESS
PRODUCT LISTING AGREEMENT POLICY
October 14, 2011**

ALBERTA HEALTH AND WELLNESS DRUG BENEFIT LIST – PRODUCT LISTING AGREEMENT POLICY

Policy Statement

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

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

To address the issues of timely access and financial pressure, Alberta Health and Wellness has developed this policy for the purpose of enabling single source patented drugs, 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 Minister of Health and Wellness reserves the right to make decisions regarding AHWDBL policies, including possible PLAs, which the Minister considers to be in the best interest of the public and the health care system.

AHW is committed to ongoing dialogue with industry. This policy defines clear parameters to establish and execute PLA’s 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 AHW’s needs, preferences and priorities with manufacturers to help ensure a collaborative PLA process.

Definitions and Interpretation

Definitions: The following definitions apply in this Policy:

“Advisor” means a Minister-appointed expert advisory committee, AHW, CEDAC, CDR, ECDET and any other person who provides evidence and advice to the Minister regarding the listing of drugs on the AHWDBL.

“Alberta Health and Wellness” or **“AHW”** means the department of the Government of Alberta with a mandate to administer the AHWDBL and includes its employees and agents.

“Alberta Health and Wellness Drug Benefit List” or **“AHWDBL”** 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 AHWDBL policies.

Specifically, the term “AHWDBL” 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.

“Alberta Health Services” 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 for listing on the AHWDBL, in accordance with the AHW Price policy. The APC process determines the price that a Manufacturer will offer a drug 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.

“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 Expert Drug Advisory Committee” or **“CEDAC”** 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.

“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.

“Common Drug Review” or **“CDR”** means the process supported by CADTH through which clinical evidence and pharmacoeconomic information for drugs is compiled for review by CEDAC to make recommendations about the inclusion of drugs in various publicly funded drug plans across Canada.

“Confidential Business Information” includes information provided by an Applicant to Alberta Health and Wellness for the purpose of obtaining a PLA or fulfilling the obligations thereunder, whether provided before or after 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 sales or marketing strategy. Any designation of information under this definition shall be identified by the manufacturer as such. Where information provided to AHW 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 AHW 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 AHW. Confidential Business Information shall not include:

- i. The name of the drug or drug product in the PLA submission, the name of the manufacturer making the PLA submission, and the existence of a PLA agreement (if any) between AHW and the manufacturer;
- ii. Information which was lawfully and without legal restriction in the possession of the GOA 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 GOA 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 GOA pursuant to the PLA Policy, or any other unauthorized act.

“drug” means:

- a drug defined as defined in the *Pharmacy and Drug Act*;
- a drug therapy;
- a device; a vaccine;
- a biologic; and
- any material, substance or thing which may be designated in the AHWDBL as a drug.

“Drug Product” means a drug that is authorized for sale in Canada and that is listed or specifically under consideration for listing by the Minister on the AHWDBL.

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

“GOA” means Government of Alberta.

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

“Manufacturer” means an entity that is issued a Notice of Compliance or Notice of Compliance with Conditions for the drug product and includes an authorized representative of the Manufacturer.

“Minister” means Her Majesty the Queen in Right of Alberta, as represented by the Minister of AHW or their designate.

“Notice of Compliance” or **“NOC”** means the authorization issued by Health Canada to market a drug 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 product, 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 R&D spending by pharmaceutical patentees.

“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).

“PLA submission” means a proposal for a PLA that is submitted by a Manufacturer in response to an RFPLA or otherwise.

“PLA Submission Form” means a form required by the Minister from an Applicant who is making a PLA submission.

“Price policy” means the price policy that forms part of the AHWDBL, as may be amended from time to time.

“Product Listing Agreement” or **“PLA”** means an agreement between an Applicant 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 on the AHWDBL and which may include but is not necessarily limited to the following forms of agreement:

- **Price/Volume Agreement** is a type of PLA designed to make high cost drugs more affordable for the government sponsored drug plans through provisions that may address the drug 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 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 (UMA)** is a type of PLA that is designed to improve the accountability and appropriateness for how drugs 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 where there is a defined clinical uncertainty and features of the agreement are designed to facilitate the acquisition of evidence to address that uncertainty.

“Province Wide Services” are a set of highly specialized medical interventions and include high cost drugs such as: Transplant Drugs – Transplant patients are eligible for immunosuppressants; HIV Drugs – Drugs for the treatment of patients with human immunodeficiency virus type 1 (HIV-1) infection are dispensed through the Southern and Northern Alberta Clinics. Other Drugs; Other drugs funded by Province Wide Services which include Pulmozyme (for cystic fibrosis), human growth hormone (for pediatric growth hormone deficiency and chronic renal failure), Flolan (for primary pulmonary hypertension) and Visudyne (for classic form of wet age-related macular degeneration).

“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.

“Schedule of Cancer Drugs” means a plan or program, which Alberta Health Services – Cancer Care provides for use in the direct treatment of cancer.

“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).

“therapeutic advantage” means that a drug provides an improvement in the treatment, diagnosis, or prevention of a disease when compared to another Drug Product or, if there is no comparable Drug Product, 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 Product.

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

PRODUCT LISTING AGREEMENTS

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

A PLA submission from an Applicant must be made in accordance with any PLA Submission Form and must satisfy the Minister that the proposed PLA will provide a drug that:

- is able to demonstrate whether or not it is equivalent therapeutically or provides a therapeutic advantage over other presently accepted therapies or treatments of the disease entity for which current Drug Products are indicated;
- is more cost-effective than presently listed Drug Products on the AHWDBL, or offers significant cost savings for the AHWDBL or, in the case of Coverage with Evidence Development submissions will enable the drug to demonstrate whether or not it offers cost-effectiveness or significant cost savings.

A PLA submission is not a substitute for, and does not replace any policy, process or other requirements for the review of drugs required by law for the provision of drugs to the public.

Any PLA submissions that include Drug Products 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 required by the Minister, in the Minister's sole discretion.

The Minister, in the Minister's sole discretion, will determine if and when a PLA is an appropriate mechanism for listing a drug on the AHWDBL.

In order to maintain a PLA policy and process that is consistent with AHW 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 not yet finalized in a PLA. For PLAs that are the subject of a signed agreement, any amendment to the terms of the PLA agreement that are deemed appropriate must be undertaken with the written consent of both Parties.

A PLA submission that purports to exclude, restrict or limit, in any way, any drug from being listed, or continuing to be listed on the AHWDBL (whether as an unrestricted benefit or otherwise) will be rejected.

PLA SUBMISSIONS

Eligible Drug Products

No drug 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; and,
- is a single source patented drug; or,
- is a patent pending drug.

Drug Products intended for coverage under the Schedule of Cancer Drugs or Province Wide Services are not eligible for PLA Submissions under this PLA Policy.

Initiation

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. 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.

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 AHWDBL.
- 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.
- An RFPLA is not a tender; it is not a competitive bidding process.

RFPLA

An 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, single source patented drugs, patent pending drugs or on some other basis.

An RFPLA may specify a specific form of PLA that the Minister is seeking, such as a Price/Volume Agreement, Health Research Capacity Development Agreement, Utilization Management Agreement, Coverage with Evidence Development Agreement, or some other form.

In the case where a PLA submission is made for a drug that is not currently listed on the AHWDBL, the drug will not be added to the AHWDBL until the PLA has been executed by all parties.

Filing of PLA Submissions

Information on PLA Submission Forms, format, deadlines and delivery instructions will be provided in the RFPLA.

PLA submissions are made at the Applicant's own cost and risk.

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 of therapeutic advantage, cost effectiveness and/or cost savings that the subject drug may provide. In addition, a 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:

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 AHW a manufacturer may designate materials in whole or in part as Confidential Business Information as defined in this Policy.
- The manufacturer will authorize AHW to disclose all PLA submission materials, including any Confidential Business Information to any department or agency of the Government of Alberta that AHW determines is necessary to evaluate a PLA submission.
- The manufacturer will further authorize AHW 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, and Canadian Intellectual Property Office all PLA submission information, except Confidential Business Information that AHW determines is relevant for the evaluation of a PLA submission. AHW 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 AHW 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, AHW shall not make disclosure of the Confidential Business information it will give the manufacturer.
- The manufacturer will further authorize AHW 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 AHW's possession for the purpose of evaluating a PLA submission. Prior to disclosing any Confidential Business Information to these persons or organizations AHW 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 AHW 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. AHW 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 AHW 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 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.
- Where the Manufacturer has made a submission for a patent pending drug a detailed description of the risk mitigation strategies in relation to any of the above activities and risk mitigation strategies if the patent pending drug for whatever reasons fails to obtain a patent 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 all Alberta government sponsored drug plans, as will any PLA that may be entered into as a result of such PLA submission; and ,
 - that in the case of a single source drug there is no impediment, in law or otherwise, to the Manufacturer entering into a PLA.
 - That in the case of a patent pending drug the Manufacturer shall indemnify and hold harmless the Minister for any losses or claims that may arise where the Manufacturer fails to obtain a listing on the Patent Register during the term of the PLA.

- That in the case of a patent pending drug the Manufacturer:
 - i) is the entity that has applied for the patent;
 - ii) has applied for patents that allow the Drug Product to meet the eligibility requirements as set in the *Patented Medicines (Notice of Compliance Regulations)*;
 - iii) there is no known impediment in law or otherwise to the granting of a patent; and,
 - iv) that except for the granting of the patent there is no other impediment in law or otherwise to the Manufacturer entering into the PLA.

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.

RECEIVING, SCREENING AND EVALUATING PLAS

The general process for receiving screening, evaluating and negotiating a PLA submission is as follows:

- The Minister issues an RFPLA.
- AHW conducts an initial screening of the PLA Submission Forms that respond to the RFPLA to determine if the PLA submission is complete and meets the submission requirements as set out in this policy, the RFPLA and the PLA Submission Form.

- In the event that the PLA Submission is deemed to be incomplete, AHW will contact the Applicant to discuss the deficiencies and allow the Applicant a time-constrained opportunity to rectify the deficiencies.
 - AHW will reject a PLA submission that fails screening.

- If, in the opinion of the Minister or AHW, additional information is required for the purpose of screening or evaluating a PLA submission, AHW may request the required information in accordance with the provisions for “Additional Information” set out below. The Minister is not obligated to request Additional Information and may reject a PLA submission that the Minister considers does not provide sufficient information for screening or evaluation.

- A PLA Submission that meets the requirements of this policy, the RFPLA and the PLA Submission Form may be evaluated. The evaluation will be based on the factors listed in the PLA Submission Form and may include, but are not limited to, factors such as:
 - recommendations of Advisors;
 - the therapeutic advantage, therapeutic equivalency, cost effectiveness and/or cost savings that the drug may provide;
 - the effectiveness with which a drug 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 on cost or volume basis;
 - c) a defined therapeutic gap or opportunity within the AHWDBL;
 - d) a chronic condition that affects a significant proportion of the population.
 - 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 to the AHWDBL;
 - the complexity of the proposed agreements;
 - health system priorities, including health research needs;
 - health policy objectives;
 - any other factors that the Minister, in his or her sole discretion, considers relevant.

The priority given to a PLA submission and the timing of screening or evaluating a PLA submission or negotiating a PLA will be determined by the Minister, in the Minister’s sole 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.

Patent pending drugs

That in addition to any other requirements under this PLA Policy for PLA Submissions for patent pending drugs the following will also apply:

- i) Where a Manufacturer has obtained a PLA for a patent pending drug and during the term of the PLA the Manufacturer fails to obtain a listing on the Patent Register during or withdraws his patent application for the patent pending drug the Minister shall in his discretion terminate the PLA.
- ii) Where another manufacturer successfully obtains a listing on the Patent Register for a drug that was a patent pending drug under a PLA the Minister can at his discretion invite this manufacturer with the listing on the Patent Register to make a PLA submission.
- iii) Where upon the execution of a PLA for a patent pending drug the Minister believes that the Manufacturer will not obtain a listing on the Patent Register within a reasonable time period before the expiry of the PLA the Minister may at his discretion terminate the PLA.
- iv) Where during the term of a PLA for a patent pending drug the Manufacturer obtains a listing on the Patent Register for the patent pending drug the following will occur:
 - a. The Manufacturer must notify the Minister of the patent including any providing any proof of patent status as requested by the Minister.
 - b. Advise the Minister of the price for the drug as established by the PMRB.
 - c. Where the prices for the drug as established by the PMRB is lower than the price established by the PLA the Minister can at his own discretion do the following:
 - i. Request the Manufacturer to revise the terms of the PLA based on the price of the drug as established by the PMRB.
 - ii. Terminate the PLA and at the Minister's discretion request the Manufacturer to re-submit a PLA submission for the drug.

PMPRB

In addition to the other criteria under this PLA Policy the following will apply when during the term of the PLA PMRB conducts an investigation on a drug product, which results in:

- a Voluntary Compliance Undertaking (VCU) by the manufacturer to reduce the price and take other measures to comply with the Guidelines; or,
 - a public hearing to determine if the price is excessive and, if so, the issuance of a remedial order by the Board.
- i. If the VCU or remedial order results in a price that the Manufacturer must charge for the drug product being lower than the price agreed to between the Manufacturer and the AHW in the 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 PMRB; or,
 - ii. terminate the PLA and, at the Minister's discretion, request the Manufacturer to re-submit a PLA Submission for that drug.

Additional Information

The Minister reserves the right to request Additional Information at any time from the Applicant or another person that, in the Minister's sole discretion, is required for a review of a PLA submission.

When a request for Additional Information is made, the Minister or AHW 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 AHW 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
- AHW may request Additional Information through the Applicant or directly from the specified source;
- set deadlines for when the Additional Information must be provided;
- in the event a deadline for the provision of Additional Information is missed, declare a PLA submission to be incomplete and/or 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.

PLA NEGOTIATIONS

Prior to PLA negotiations commencing, the Applicant and AHW will establish a timetable for negotiations. If for any reason AHW 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.

NO OBLIGATION ON MINISTER TO REQUEST, REVIEW OR NEGOTIATE

Notwithstanding any other provision of this policy, the Minister reserves the right to reject or defer any PLA submission or delay or terminate the screening, evaluation or negotiation of any PLA Submission on any basis, for any or even no reason, based on the Minister's sole discretion.

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 withdrew the PLA submission at its own discretion prior to a PLA being reached. The Minister is not obligated to grant the request.

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.

AHWDBL PRICE POLICY AND ALBERTA PRICE CONFIRMATION PROCESS

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

INQUIRIES

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

Senior Manager, Drug Utilization and Agreements
Pharmaceutical Funding and Guidance Branch
18th Floor, Telus Plaza North Tower
10025 Jasper Avenue
Edmonton, AB T5J 1S6

Lobbying

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

APPLICANT RESPONSIBILITIES

It is the responsibility of an Applicant, Manufacturer or other person interested in making a PLA submission to ensure that it complies with all the requirements of the AHWDBL, including this PLA policy including any amendments thereto.

NO LIABILITY

The PLA policy is an extraordinary process conducted solely in the discretion of the Minister. The Minister, AHW 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 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 submission made pursuant to or related thereto. Statements in this PLA policy of AHW 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.

CONFIDENTIALITY

All information submitted to or accessed by the Minister or AHW under this policy, an RFPLA or a 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 AHW 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. AHW 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.