



pan-Canadian  
Pharmaceutical  
Alliance



Alliance  
pancanadienne  
pharmaceutique

# LOI Template



Version 1.0

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## RECORD OF UPDATES TO LOI TEMPLATE

**Original** – May 2018

During the course of an active negotiation, there may be an updated version: please check with your pCPA Lead negotiator(s).

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## INQUIRIES

All inquiries related to the LOI Template should be submitted in writing.

**Email:** [pCPA@ontario.ca](mailto:pCPA@ontario.ca)

**Mail:** 900 Bay Street  
Suite M2-61  
Toronto, Ontario  
M7A 2E1

[Month Day, Year]

[Manufacturer Contact]

[Role]

[Manufacturer Name]

[Manufacturer Address]

[Manufacturer Email]

**Re: [Insert DIN(s)] DIN(s): [Insert Drug Product(s)] (the “Drug Product(s)”)  
[Insert Manufacturer] (the “Manufacturer”)**

Dear [Ms/Mr. Manufacturer Contact Surname]:

Under the pan-Canadian Pharmaceutical Alliance, [Insert Jurisdiction] has been appointed as the lead jurisdiction for the purposes of this negotiation.

I am writing on behalf of the Federal/Provincial/Territorial authority of [Select applicable: British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Quebec, Nova Scotia, New Brunswick, Prince Edward Island, Newfoundland & Labrador, Yukon, Nunavut, North West Territories, Non-Insured Health Benefits (NIHB), Correctional Services Canada (CSC), and Veterans Affairs Canada (VAC)] (collectively, the “Participating Jurisdictions”) to confirm our agreement with respect to the Drug Product(s) eligible for publically funded/government sponsored coverage.

This Letter of Intent (“LOI”), along with the terms attached hereto as [Select applicable: Appendix “A”, Appendix “B”, and Appendix “C”] sets out the material terms of the agreement between the Participating Jurisdictions and the Manufacturer. It is intended that each Participating Jurisdiction will enter into its own separate agreement (“Listing Agreement”) or amendment to an existing agreement with the Manufacturer, the material terms of which will conform to those set out in [Select applicable: Appendix “A”, Appendix “B”, and Appendix “C”]. Individual Listing Agreements will be in such form as may be agreed to between each Participating Jurisdiction and the Manufacturer, and include any such additional terms and conditions as may be agreed to between each Participating Jurisdiction and the Manufacturer and as may be required by the laws of each Participating Jurisdiction. The terms of each Listing Agreement may differ, with the specific terms to be determined by each Participating Jurisdiction and the Manufacturer.

Notwithstanding the foregoing, a proposed Listing Agreement between any Participating Jurisdiction and the Manufacturer is subject to the approvals which may be required by the Participating Jurisdiction. The failure of a Participating Jurisdiction to enter into a Listing Agreement with the Manufacturer does not provide either the Participating Jurisdiction or the Manufacturer with a cause of action.

The agreement by the Manufacturer and by the Participating Jurisdictions to the terms and conditions set out in this LOI shall not be construed as agreement by any party to any terms other than those specifically set out herein.

The Manufacturer will not undertake any communications respecting the reimbursement of the Drug Product by any Participating Jurisdiction before that Participating Jurisdiction has made a public announcement about the reimbursement status of the Drug Product.

Please indicate your agreement by signing the enclosed copies of this LOI and returning two (2) copies to the lead jurisdiction. One (1) fully executed original copy will then be returned to the Manufacturer.

Sincerely,

[F/P/T Signatory]

[Role]

[Department]

[Ministry]

[Manufacturer Signatory]

[Role]

[Manufacturer]

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Date

**APPENDIX “A”**

**1.0 SUPPLY OF DRUG PRODUCT(S)**

1.1 In accordance with each Participating Jurisdiction’s policies and processes, the Manufacturer will supply the Drug Products to each Participating Jurisdiction in quantities that are sufficient to allow all pharmacies to dispense the Drug Product in each Participating Jurisdiction.

**2.0 REIMBURSEMENT UNDER PUBLIC DRUG PLAN**

2.1 Pursuant to the terms and conditions of the public drug plan in each Participating Jurisdiction except Quebec, each Participating Jurisdiction will reimburse eligible claims made for the Drug Product for eligible patients in accordance with the following clinical (Choose: pan-Canadian Oncology Drug Review (pCODR) OR Common Drug Review (CDR)) criteria (the “Criteria”):

- [Insert CDR OR pCODR criteria wording unless alternate criteria has been expressly agreed to by pCPA]

2.2 For the Province of Quebec: The criteria will be according to the recommendation from l’Institut national d’excellence en santé et en services sociaux (INESSS).

**3.0 COVERAGE ADJUDICATION**

3.1 Adjudication of coverage eligibility will be determined by each Participating Jurisdiction.

**4.0 PRICING**

4.1 The List Price and the Net Price of the Drug Product will be as set out in the fifth and sixth columns of the table that follows, during the term of the Listing Agreement with the Participating Jurisdictions. For clarity, the List Price is the prevailing, per unit, ex-factory List Price of the Drug Product, as of the date of this Letter of Intent.

DIN	PRODUCT	GENERIC	STRENGTH	LIST PRICE	NET PRICE
				\$	\$

4.2 [Select applicable: The Manufacturer has the option of increasing the List Price of the Drug Product based on Patented Medicine Prices Review Board regulated price adjustments or Consumer Price Index (CPI) increases as allowed by each Participating Jurisdiction’s policies and processes, provided that the Net Price of the Drug Products remain in the sixth column of the table in section 4.1. For clarity, the Province of Quebec does not allow for price increases. OR The manufacturer shall maintain the List Prices presented in section 4.1 for the entire term of the Listing Agreement with the Participating Jurisdictions, including any subsequent renewal terms.]

**FIRST DOLLAR REBATE (Sample)**

4.3 For the purposes of this Letter of Intent and the eventual Listing Agreement between the Manufacturer and a Participating Jurisdiction:

“Accepted” is defined as where the dollar amount, for a claim that goes towards the coverage/reimbursement or accumulation towards the patient’s deductible or co-payment obligations, is greater than \$0.00.

4.4 During the effective period of the Listing Agreement with each Participating Jurisdiction, the Manufacturer shall pay to the Participating Jurisdiction, for each unit of the Drug Product that is Accepted by the Participating Jurisdiction under its public drug plan, a quarterly, semi-annual, or annual rebate calculated in accordance with the following formula:

$$R = Q \times (LP - NP) \times \left(\frac{MP}{LP}\right)$$

Where:

- R = the dollar amount of the rebate payment
- Q = total number of units of the Drug Product Accepted by the Participating Jurisdiction as described in Section n.n. Unit definition: (select tablet, capsule, vial, syringe).
- LP = the prevailing, per unit, ex-factory List Price of the Drug Product, at the time of dispense
- NP = net price, as defined in the n<sup>th</sup> column of the table in Section n.n  
= \$
- MP = maximum reimbursement price for a given dosage, including allowable markup but excluding dispensing fee

## 5.0 INCREMENTAL REBATE (Sample)

5.1 In addition to the rebate described in section 4.4, the Manufacturer will provide an additional rebate to each Participating Jurisdiction in the event that the Annual Expenditure for the Drug Product exceeds the Jurisdiction’s (cap type) Threshold (choose: defined in the following table OR of \$amt), in an Expenditure Year. For clarity, an Expenditure Year is the twelve (12) month period immediately following the effective date of the Listing Agreement for the Drug Product between a Participating Jurisdiction and the Manufacturer, and each twelve (12) month period thereafter.

Participating Jurisdiction	(cap type) Thresholds		
	Year 1	Year 2	Year 3
British Columbia			
Alberta			
Saskatchewan			
Manitoba			
Ontario			
Quebec			
New Brunswick			
Nova Scotia			
Newfoundland and Labrador			
Prince Edward Island			
Yukon			
Nunavut			
Northwest Territories			
Correctional Services Canada			
Veterans Affairs Canada			
Non-Insured Health Benefits			

5.2 For each Expenditure Year during the effective period of the Listing Agreement with each Participating Jurisdiction, the incremental product rebate will be calculated in accordance with the following formula:

(Insert needed rebate equation here)

Where:

(Insert table of terms here)

5.3 Prior to the end of the third Expenditure Year, Participating Jurisdictions may give notice to the Manufacturer that they wish to re-establish the thresholds beyond those values outlined in section n.n. Upon receiving such notice, the Manufacturer and the Participating Jurisdiction shall review and mutually agree to values for the thresholds for Year 4 and beyond. If revised thresholds are not established at the end of the third Expenditure Year, the Year 3 thresholds will be maintained for Year 4 and beyond.

## 6.0 REVIEW OF DATA

6.1 The Manufacturer will be provided the opportunity to review aggregate data used in rebate calculations, related only to the Drug Product, relied upon by each of the Participating Jurisdictions, if requested. Should any discrepancies be identified by the Manufacturer with respect to the amount of rebate the Manufacturer must pay, the Manufacturer shall have the opportunity to make representation to the Participating Jurisdictions regarding any required adjustment.

## 7.0 PROVISION OF CLINICAL DATA BY MANUFACTURER

7.1 The Manufacturer will provide to the Participating Jurisdictions all significant clinical data relating to efficacy of the Drug Product (“Data”) within thirty (30) days of that Data becoming available to the Manufacturer and being capable of disclosure by the Manufacturer under applicable law. In any case, where Data raises issues concerning patient safety, the

Manufacturer will provide that Data to the Participating Jurisdictions immediately once it become capable of disclosure under applicable law.

## **8.0 CONFIDENTIALITY**

- 8.1 Except as required by law, the Letter of Intent, [Select applicable: Appendix "A", Appendix "B", and Appendix "C"] (together the "Letter of Intent") and all information obtained through the negotiations related to this Letter of Intent shall be maintained in confidence by the Manufacturer and Participating Jurisdictions and shall not be disclosed to any third party, including but not limited to any other manufacturer, or any non-participating public or private drug benefit plans.
- 8.2 Except as required by law, any Listing Agreement between the Manufacturer and a Participating Jurisdiction implementing the terms of this Letter of Intent shall be maintained in confidence by the Manufacturer and the Participating Jurisdictions and shall not be disclosed to any third party, including any non-participating public or private drug benefit plan.
- 8.3 The parties acknowledge and agree that any confidential pricing, financial and scientific information submitted by the Manufacturer to the Participating Jurisdictions in connection with this Letter of Intent has been supplied in confidence and that any disclosure would reasonably be expected to result in commercial harm to the Manufacturer.
- 8.4 Notwithstanding the above, the Manufacturer acknowledges that the Participating Jurisdictions are subject to the provisions of their respective provincial freedom of information and protection of privacy legislation, and are required to comply with said legislation and with any orders that may be made by the freedom of information and protection of privacy commissioner, or equivalent office, within their respective jurisdictions.
- 8.5 The Participating Jurisdictions and/or the pCPA office may publicly announce that this LOI has been agreed to by the Participating Jurisdictions and the Manufacturer. The publication may identify the Drug Product and the reimbursement criteria described in this LOI, but will not disclose any financial or pricing information contained in the LOI other than the transparent list price for the Drug Product.
- 8.6 The Manufacturer will not undertake any communications respecting the reimbursement of the Drug Product by any Participating Jurisdiction before the Participating Jurisdiction has made a public announcement about the reimbursement status of the Drug Product.

## **9. TERM AND RENEGOTIATION**

- 9.1 The term of the Listing Agreement shall be determined by the Participating Jurisdiction.
- 9.2 The Participating Jurisdictions, via the pan-Canadian Pharmaceutical Alliance, may re-negotiate the terms of this agreement with the Manufacturer if there are significant market changes or if Drug Product expenditure significantly exceeds the Participating Jurisdictions' budget impact.

## **10. LOI AMENDMENT TO INCLUDE NEW JURISDICTIONS**

- 10.1 Should any pCPA member jurisdiction that is not listed as a Participating Jurisdiction in this LOI (the “New Jurisdiction”) wish to fund the Drug Product at a later date, the lead jurisdiction, on behalf of the Participating Jurisdictions, and the Manufacturer will either extend the material terms specified in this agreement, or extend the material terms specified in this agreement with less restrictive clinical criteria at the request of the New Jurisdiction, or extend the material terms of this agreement insofar as they align with the clinical criteria set forth by INESSS if Quebec is the New Jurisdiction..
- 10.2 The New Jurisdiction may then enter into its own Product Listing Agreement (PLA) with the Manufacturer. This process will be managed through the pCPA Office, and a formal letter of notification to the Manufacturer will serve as an amendment to the LOI to add the New Jurisdiction as a “Participating Jurisdiction” in the LOI.
- 10.3 For clarity, pCPA member jurisdictions include: British Columbia, Alberta, Saskatchewan, Manitoba, Ontario, Quebec, New Brunswick, Nova Scotia, Prince Edward Island, Newfoundland & Labrador, Yukon, Northwest Territories, Nunavut, Non-Insured Health Benefits (NIHB), Correctional Services of Canada (CSC) and Veterans Affairs Canada (VAC).

**11. PATIENT ACCESS PROGRAM (if applicable)**

- 11.1 The Manufacturer will continue to enroll new patients into their existing [program name] until six (6) months post LOI or until individual jurisdictional listing, whichever is sooner.
- 11.2 Jurisdictions should be responsible for the transfer of existing patients who meet provincial listing criteria upon listing or 6 months following the LOI, whichever is later.
- 11.3 The Manufacturer acknowledges and agrees that currently enrolled Patients who do not meet the Reimbursement Criteria of a Participating Jurisdiction will remain enrolled in the [program name].

**[END OF APPENDIX “A”]**