pan-CANADIAN PHARMACEUTICAL ALLIANCE

Memorandum of Understanding
Effective as of April 1, 2016

BETWEEN:

HER MAJESTY THE QUEEN IN RIGHT OF BRITISH COLUMBIA, as represented by the Deputy Minister of Health;

AND:

HER MAJESTY THE QUEEN IN RIGHT OF ALBERTA, as represented by the Deputy Minister of Health;

AND:

HER MAJESTY THE QUEEN IN RIGHT OF SASKATCHEWAN, as represented by the Deputy Minister of Health;

AND:

HER MAJESTY THE QUEEN IN RIGHT OF MANITOBA, as represented by the Deputy Minister of Health, Healthy Living and Seniors;

AND:

HER MAJESTY THE QUEEN IN RIGHT OF ONTARIO, as represented by the Deputy Minister of Health and Long-Term Care;

AND:

THE GOVERNMENT OF QUEBEC, represented by the Minister responsible for Canadian Relations and the Canadian Francophonie, acting through the Associate Secretary General for Canadian Intergovernmental Affairs, and the Minister of Health and Social Services, acting through the Deputy Minister of Health and Social Services;

AND:

HER MAJESTY THE QUEEN IN RIGHT OF NEW BRUNSWICK, as represented by the Deputy Minister of Health;

AND:

HER MAJESTY THE QUEEN IN RIGHT OF NOVA SCOTIA, as represented by the Deputy Minister of Health and Wellness;
AND:

HER MAJESTY THE QUEEN IN RIGHT OF NEWFOUNDLAND AND LABRADOR, as represented by the Deputy Minister of Health and Community Services and the Deputy Minister of Intergovernmental Affairs;

AND:

HER MAJESTY THE QUEEN IN RIGHT OF PRINCE EDWARD ISLAND, as represented by the Deputy Minister of Health and Wellness;

AND:

HER MAJESTY THE QUEEN IN RIGHT OF YUKON, as represented by the Deputy Minister of Health and Social Services;

AND:

HER MAJESTY THE QUEEN IN RIGHT OF NORTHWEST TERRITORIES, as represented by the Deputy Minister of Health and Social Services;

AND

HER MAJESTY THE QUEEN IN RIGHT OF NUNAVUT, as represented by the Deputy Minister of Health

(collectively the “Parties”)

PREAMBLE

WHEREAS the Premiers of Canada at a meeting of the Council of the Federation in August 2010 directed Provincial-Territorial Health Ministers to work towards a pan-Canadian pricing alliance, which has evolved since its inception and now aims to conduct joint negotiations for brand drugs to increase access to clinically and cost effective drug treatment options, improve consistency of drug funding decisions, achieve consistent and lower drug costs, and reduce duplication and improve use of resources;

AND WHEREAS the Premiers of Canada at a subsequent meeting of the Council of Federation in July 2012, established the Health Care Innovation Working Group (“HCIWG”) comprised of Co-Chair Premiers and Provincial-Territorial Health Ministers to focus on three priority areas, one of which relates to brand and generic pharmaceuticals;

AND WHEREAS the HCIWG formally established a pan-Canadian pricing alliance respecting brand drugs and expanded its mandate to include generic drug initiatives aimed at achieving better prices for generic drugs and improving consistency in generic drug pricing;
AND WHEREAS with these two mandates relating to brand drugs and generic drugs, a pan-Canadian Pharmaceutical Alliance (pCPA) was formed between the Parties;

AND WHEREAS the HCIWG selected the Deputy Ministers of Health in Ontario, Saskatchewan and Nova Scotia to lead the pCPA's pharmaceutical initiatives;

AND WHEREAS the Parties have agreed to establish a centralized office (the "pCPA Office") to provide leadership and operating support to Parties to facilitate the achievement of the pCPA's mandate and ensure that outcomes of pCPA initiatives are value-driven, clearly communicated, monitored and evaluated;

AND WHEREAS the Parties wish to enter into a Memorandum of Understanding to record their understandings regarding the governance and operation of the pCPA, the establishment and funding of the pCPA Office, the process for pCPA negotiations with drug manufacturers;

AND WHEREAS the Parties agree to use remaining funding from the National Pharmaceutical Strategy for pCPA functions prior to the annual funding contributions outlined herein;

NOW THEREFORE, the Parties intend as follows:

1.0 PURPOSE AND PRINCIPLES

1.1 The purposes of this MOU include:

a) To formalize and strengthen the pCPA governance and accountability framework and related processes to achieve the objectives of the pCPA;

b) To set out the mutual expectations of Parties to make consensus-based decisions within a collaborative interest based framework; and

c) To establish the pCPA Office including its governance and funding requirements.

1.2 The objectives of the pCPA are to provide value to the Canada's health care systems of the Parties and to improve patient care by negotiating drug funding collectively to:

a) Increase access to clinically effective and cost effective drug treatment options;

b) Improve consistency of drug funding decisions among Parties;

c) Achieve consistent and lower drug costs for Parties; and

d) Reduce duplication of effort and improve use of resources.
The pCPA process reflects the following guiding principles:

a) **Holistic**: considers value from multiple perspectives;

b) **Predictable**: there should be clear communication and application of processes, timelines, participation, as well as clarity around decision making processes and guidelines for early engagement;

c) **Consistent**: consideration of value should be applied consistently while recognizing the unique nature of each negotiation

d) **Transparent**: there should be timely and regular public reporting for the continuum of the process. There should be open dialogue amongst negotiating parties during individual negotiations, subject to any necessary confidentiality requirements.

e) **Efficient & Effective**: pCPA processes should (i) seek alignment with national or jurisdictional Health Technology Assessment review bodies, (ii) capitalize on expertise of involved parties, and (iii) be effective in supporting evidence-based decision making.

f) **Collaborative and representative**: there should be cross-jurisdictional engagement with patients, partners and stakeholders across the health care systems.

g) **Respectful**: pCPA process should recognize different perspectives and needs amongst stakeholders including differences in each Party’s legislative, regulatory institutions and policy frameworks.

h) **Ethical**: pCPA processes should reflect ethical principles such as validity, veracity and the autonomy of Parties with an understanding of the existing confidentiality requirements for individual negotiations.

i) **Value-driven**: pCPA should achieve value for the Canadian health care systems by increasing access to clinically effective and cost effective drug treatment options, improving consistency in drug funding decisions, and achieving consistent and lower drug costs;

j) **Evidence-informed**: pCPA decision making should be guided primarily by best available evidence; and

k) **Responsive**: pCPA activities should be routinely evaluated and appropriately modified to ensure continuous quality improvement, change and innovation to advance the mandate of the pCPA and the collective interests of the Parties.
1.4 Each Party understands that the pCPA is an interest-based collaboration and is committed to:

a) Fostering an atmosphere of trust and making significant efforts to collaborate with all Parties to ensure the objectives of the pCPA are met;
b) Continuing to build from experience to date and adapting quickly to change;
c) Capitalizing on the strengths, skills and capabilities of other Parties;
d) Recognizing that each Party currently has its own formulary, unique programs, issues, accountability frameworks (including legislative, regulatory and policy structures) and budgets, but each will still maintain an overall commitment to align with those of the pCPA wherever possible to achieve consistency with respect to drug funding decisions, as appropriate;
e) Recognizing that, within a collaborative interest based framework, jurisdictional cooperation is required to achieve joint goals;
f) Being transparent with other Parties about drug funding decisions even when the decisions may not align with those of other Parties;
g) Understanding each other's roles and responsibilities in the pCPA and being held accountable to those roles and responsibilities through the annual reporting process described in this MOU;
h) Providing the necessary financial resources to establish and maintain the pCPA Office, in accordance with this MOU;
i) Treating each other fairly and equitably keeping in mind the broader public purpose of the pCPA; and
j) Sharing funding and responsibility for the overall pCPA initiative and the strategic direction and oversight of the pCPA Office.

1.5 With respect to negotiations with manufacturers about patented (brand) drug products, each Party is also committed to:

a) Participating in the pCPA process when it believes a product can ultimately be listed within a reasonable timeframe in its jurisdiction;
b) Declaring at the outset of the pCPA processes, or when known/identified, if it anticipates any issues in its jurisdiction with respect to the funding of a drug product;
c) Engaging in open, honest and timely dialogue amongst all Parties;
d) Leading negotiations on behalf of the pCPA where it has available resources or using available resources to support negotiations; and
e) Actively engaging early and throughout a particular negotiation, or, if unable to do so, relying on the lead Party to continue the process in order to avoid delays in concluding negotiations.

1.6 With respect to the generic drug pricing initiatives, each Party is also committed to:

a) Respecting the spirit and intent of all pan-Canadian generic pricing initiatives, including the current tiered pricing framework for generic drugs established in 2013;

b) Participating in evaluations of pan-Canadian generic pricing initiatives; and

c) Considering any future pan-Canadian generic pricing framework that may be recommended for implementation by the pCPA.

1.7 Each Party is also committed to engaging in collective dialogue at the Governing Council table on related public drug programs issues of national importance, and to bring these issues to the attention of the HCIWG, the Council of the Federation, and PT Ministers of Health for their consideration, as appropriate.

2.0 GOVERNANCE OF THE pCPA

2.1 Principles: Each Party commits to the following principles of collaborative governance:

a) The governance structure and process set out in this MOU establishes the chains of authority, responsibility and communications required to empower particular people to make decisions, and it includes the policy, measurement and control mechanisms required to enable people to deliver on their roles and responsibilities.

b) The governance processes should be constructive, deliberative, and should utilize consensus-based decision making in the public interest for Canada’s healthcare systems.

2.2 Overall Structure: A visual representation of the pCPA’s governance structure is attached to this MOU as Appendix “A”.

2.3 Conference of PT Deputy Ministers of Health: The PT Deputy Ministers of Health from the Parties (collectively, the Conference of Deputy Ministers of Health) are responsible for overseeing the initiatives of the pCPA and may meet as required to facilitate discussions on issues relating to the pCPA. The Conference of Deputy Ministers of Health will receive progress reports on pCPA initiatives from the Governing Council annually, or as may otherwise be required or requested by the Conference of Deputy Ministers of Health. The Conference of Deputy Ministers of Health will provide a status report on pCPA initiatives to the Health Care Innovation Working Group (HCIWG) every two years, or as may otherwise be required or requested by the HCIWG or the Council of the Federation.
2.4 **Governing Council:** Each Party shall appoint one individual to be its representative at the Governing Council (collectively, the Governing Council shall consist of the representatives of the Parties). Each representative shall be responsible for the drug plan in his or her jurisdiction and must have the ability to allocate resources and facilitate decision-making in that jurisdiction. The Governing Council shall:

a) Establish a terms of reference and a chair/co-chair structure of the Governing Council;

b) Meet quarterly or on an as needed basis to provide strategic direction to the Steering Committee and, where necessary, to drug plan staff within Parties;

c) Provide executive level sponsorship within each respective Party;

d) Allocate sufficient resources to pCPA initiatives, including the establishment of an annual budget for the pCPA office;

e) Represent and communicate the interests of the pCPA initiatives within each respective Party;

f) Submit an annual report about the pCPA to the Conference of Deputy Ministers of Health respecting results achieved in the previous year and any additional pan-Canadian drug programs issues identified and discussed in accordance with section 1.7 of this MOU;

g) Recommend changes to this MOU to the Conference of Deputy Ministers of Health;

h) Assign additional functions and responsibilities to the Steering Committee, as may be necessary or appropriate; and

i) Carry out such other activities that may be assigned by the Conference of Deputy Ministers of Health.

2.5 **Steering Committee:** A set of representatives shall be selected by the Governing Council to form the Steering Committee, which at a minimum must include the co-leads of pCPA. In making this selection, the Governing Council may take into consideration other factors such as those organizations leading multiple negotiations. The Governing Council shall review the composition of the Steering Committee on an annual basis, and make adjustments as necessary. The members of the Steering Committee shall:

a) Establish a terms of reference;

b) Meet quarterly and on an as needed basis to carry out the functions of the Steering Committee;
c) Under the Governing Council’s direction, provide leadership and support to implement pCPA initiatives, including negotiations with manufacturers, issues management, speaking engagements on behalf of the pCPA, provide direction and assistance to Drug Plan Leads, provide direction to, and oversight and management of the pCPA Office, and carry out any additional functions that may be assigned by the Governing Council; and

d) Propose changes to this MOU to the Governing Council.

2.6 Drug Plan Leads: Each Party shall identify one or more Drug Plan Lead(s) for its Party. Such a person shall be an operational leader for the implementation of pCPA initiatives for a Party, and must have the requisite authority to fulfill this role. Each such person shall consider the direction provided by the Steering Committee and is responsible to their respective representative on the Governing Council. The Drug Plan Leads will work with the pCPA Office to determine day to day operational needs and carry out any additional functions that may be assigned by the Governing Council or Steering Committee.

3.0 pCPA Office

3.1 The Parties agree to the establishment of a pCPA Office, an administrative function, to help drive the collective pCPA success through achievement of value-driven, effectively communicated and evaluated outcomes and to provide leadership and operational excellence to Parties to collectively achieve the objectives of the pCPA. The pCPA Office is not a decision-making authority but provides administrative, analytical, negotiations, measurement, policy and communications support to Parties. The functions of the pCPA Office, subject to direction from the Steering Committee, include providing:

a) Leadership to the pCPA as the operational and public face of the pCPA process, and through policy development specific to negotiations and generic drug product initiatives;

b) Continued support for the Parties to advance negotiating capacity and expertise;

c) Negotiation, analytical and administrative support for Parties;

d) Centralized support for generics initiatives, including ongoing evaluation and management of related operational processes;

e) Manage development and implementation of future pan-Canadian generic pricing framework initiatives, as required;

f) Communications with external stakeholders and internal communications with Parties and, where applicable, cancer agencies;

g) Quality services through evaluation of ongoing value, identification of opportunities for process performance improvement, and education and skills development;
h) Support to the Parties of strategic linkages through such entities as Canadian Agency for Drugs and Technologies in Health, Patented Medicines Review Board and non-government organizations;

i) Standardization of products (such as templates) and processes;

j) Policy analysis, performance benchmarking, monitoring, and reporting; and

k) Administrative support to the pCPA Steering Committee and Governing Council including preparing and communicating records of decision to ensure the effective and timely information dissemination to and from various pCPA tables/discussions.

3.2 The pCPA Office shall be established as part of the public service of the Province of Ontario. Ontario shall be responsible for ensuring appropriate staffing, identifying a pCPA Office Manager, and providing office resources within the annual budget of the pCPA as approved by the Governing Council. Subject to any guidance provided by the Steering Committee and in consultation with other Parties, Ontario shall make all decisions respecting the hiring, performance management, discipline and termination of staff of the pCPA Office.

3.3 The pCPA Office shall have an operating budget for each fiscal year. The fiscal year that begins on April 1, 2016 and ends on March 31, 2017, will be the first full fiscal year in which the pCPA Office operates, and the budget shall be determined and allocated as detailed in Appendix "B".

For the following two fiscal years (April 1, 2017 to March 31, 2018 and April 1, 2018 to March 31, 2019) the budget and allocations set out in Appendix "B" continue to apply, but may be reviewed and revised by the Governing Council each fiscal year to ensure that they continue to reflect the responsibilities of the pCPA Office and the Parties.

In fiscal years subsequent to the fiscal year that ends on March 31, 2019, the Governing Council may establish a new budget and allocations.

If, in any fiscal year, the Governing Council cannot achieve consensus on a budget for the pCPA Office, the budget shall be referred to the Conference of Deputy Ministers of Health for a decision. Pending decisions on the budget for a subsequent fiscal year, the previous approved budget shall apply.

3.4 Each Party shall pay its respective funding contribution to Ontario by no later than April 30th of each year and/or on an ad hoc basis as determined by the Governing Council. All funding contributions received by Ontario (the "contribution fund") shall be kept and used to offset expenditures made by Ontario respecting the pCPA Office.

3.5 Ontario shall monitor the expenditure of the pCPA Office operating budget. If, in any fiscal year, Ontario believes that pCPA Office expenditures will exceed the approved operating budget for that year, Ontario will notify the Governing Council and seek approval of a revised operating budget for the fiscal year.
3.6 Ontario shall provide the Parties with a report by July 1st of each year of the previous fiscal year's expenditures in respect of the pCPA Office in accordance with the approved budget, and a summary of the contribution fund position. For clarity, the first report required under this section shall be provided by July 1, 2017 in respect of the fiscal year that commences on April 1, 2016 and ends on March 31, 2017. The expenses of the pCPA shall be spent and accounted for in accordance with the financial directives and accounting rules applicable to the expenditure of public funds by the Government of Ontario, including being subject to audit by the Auditor General of Ontario.

4.0 DISPUTE RESOLUTION

4.1 It is the intent of the Parties to resolve any dispute through consensus-based decision making within a collaborative interest based framework. Any dispute arising out of this MOU shall be first referred to the Steering Committee for resolution and approval of said resolution by the Governing Council. If a dispute cannot be resolved by the Steering Committee within 45 days of its referral, it shall be referred directly to the Governing Council for resolution.

5.0 CONFIDENTIALITY

5.1 All information collected, received or produced by the Parties, the Conference of Deputy Ministers of Health, the Governing Council, the Steering Committee, the Drug Plan Leads, the pCPA Office, and their respective officers, employees, agents, consultants and advisors respecting the pCPA and its initiatives shall be deemed to be confidential information ("Confidential Information"), unless that information (i) was in the public domain at the time of its receipt or collection, (ii) was independently developed without such confidential information or (iii) was received by or from a third party without breach of any confidentiality obligation.

5.2 Each Party shall maintain the confidentiality of Confidential Information subject to the law applicable to the Party (hereinafter "applicable law").

5.3 Each Party shall ensure that it only uses Confidential Information for the purposes of implementing pCPA initiatives in its jurisdiction, including making funding or listing decisions in its jurisdiction, subject to applicable law.

5.4 Each Party shall ensure that its respective officers, employees, agents, consultants and advisors comply with sections 5.2, 5.3 and 5.6.

5.5 Despite the foregoing, Parties may share Confidential Information with each other for the purposes of pCPA operations and initiatives and without the consent of any other Party, subject to applicable law.

5.6 Neither any Party nor the pCPA Office shall disclose Confidential Information to any third party except:
a) as required by applicable law. If a request for disclosure is made pursuant to applicable law, the recipient of the request shall forthwith notify the pCPA Office on behalf of all other Parties, of the request in order to permit other Parties to assist in maintaining the confidentiality of the Confidential Information;

b) to a manufacturer that has made a submission to the pCPA, but only if the Confidential Information disclosed relates to that manufacturer’s submission and the disclosure is for the purpose of negotiating or implementing funding terms for that manufacturer’s product;

c) in communications to the public respecting the mandate, governance and performance of the pCPA or the outcome of pCPA negotiations with drug manufacturers, but only to indicate whether those negotiations were successful in agreeing to fund a drug product for one or more indications; or

d) as may be approved by the Governing Council for the purposes of advancing pCPA activities and initiatives.

5.7 Any person making a submission to or in respect of a drug product under consideration by the pCPA shall be informed that information submitted in relation thereto shall be subject to the provisions of this Article 5.0.

5.8 The Parties acknowledge that:

a) the disclosure of Confidential Information could reasonably be expected to prejudice the conduct of pCPA initiatives and the economic interests of any Party; and

b) Confidential Information collected from a drug manufacturer for pCPA initiatives is supplied in confidence and, if disclosed, could reasonably be expected to result in competitive or commercial harm to the manufacturer and result in similar information no longer being supplied to any Party.

6.0 TERM, ADDING PARTIES, WITHDRAWAL AND TERMINATION

6.1 This MOU is effective as of April 1, 2016 and shall continue until it is terminated in accordance with its terms, assuming the signature of this MOU by all Parties set out above.

6.2 The MOU may be amended at any time to add one or more parties as Parties. The effect of adding a new party to this MOU on the governance structure, funding and any other matter shall be addressed by the Parties before a new party is added.

6.3 Any Party may withdraw from this MOU by providing at least one hundred and twenty (120) days prior written notice to the pCPA Office. The Parties shall promptly determine how to address the effect of such a withdrawal on the pCPA, including its governance structure and funding of the pCPA Office, and the withdrawing Party shall co-operate to ensure the smooth transition of the pCPA.
6.4 This MOU may be terminated with the unanimous consent of the Parties.

6.5 The MOU shall be reviewed by the Governing Council by no later than July 1, 2017. The Governing Council may specify the form, manner and timelines for this review.

6.6 Records documenting the addition or removal of a Party from the MOU, changes to the governance and structure of the pCPA, or changes to the funding of the pCPA Office shall be retained by Ontario in accordance with applicable laws and policies.

7.0 GENERAL

7.1 This MOU may only be amended by written agreement executed by all Parties as of the time of the amendment.

7.2 This MOU and any amendments may be executed in counterparts. Each signed copy shall be an original signed copy and together shall constitute one instrument.

7.3 Any notice required or permitted to be given under this MOU may be provided to the pCPA Office. Any notice shall be effective on delivery of the notice at the pCPA Office.
7.4 Each Party is responsible for ensuring that it has the necessary approvals to execute and amend this MOU, and to terminate its participation in this MOU.

SIGNATURES

HER MAJESTY THE QUEEN IN RIGHT OF BRITISH COLUMBIA,
As represented by the Deputy Minister of Health
Per: ____________________________
Date: ____________________________

HER MAJESTY THE QUEEN IN RIGHT OF ALBERTA,
As represented by the Deputy Minister of Health
Per: ____________________________
Date: ____________________________

HER MAJESTY THE QUEEN IN RIGHT OF SASKATCHEWAN,
As represented by the Deputy Minister of Health
Per: ____________________________
Date: ____________________________

HER MAJESTY THE QUEEN IN RIGHT OF MANITOBA,
As represented by the Deputy Minister of Health, Healthy Living and Seniors
Per: ____________________________
Date: ____________________________
HER MAJESTY THE QUEEN IN RIGHT OF ONTARIO,
As represented by the Deputy Minister of Health and Long-Term Care
Per: ___________________________
Date: __________________________

THE GOVERNMENT OF QUÉBEC,
As represented by the Deputy Minister of Health and Social Services
Per: ___________________________
Date: __________________________

As represented by the Associate General Secretary of Canadian Intergovernmental Affairs
Per: ___________________________
Date: __________________________

HER MAJESTY THE QUEEN IN RIGHT OF NEW BRUNSWICK,
As represented by the Deputy Minister of Health
Per: ___________________________
Date: __________________________

HER MAJESTY THE QUEEN IN RIGHT OF NOVA SCOTIA,
As represented by the Deputy Minister of Health and Wellness
Per: ___________________________
Date: __________________________
HER MAJESTY THE QUEEN IN RIGHT OF NEWFOUNDLAND AND LABRADOR,
As represented by the Deputy Minister of Health and Community Services
Per: ____________________________
Date: ___________________________

As represented by the Deputy Minister of Intergovernmental Affairs
Per: ____________________________
Date: ___________________________

HER MAJESTY THE QUEEN IN RIGHT OF PRINCE EDWARD ISLAND,
As represented by the Deputy Minister of Health and Wellness
Per: ____________________________
Date: ___________________________

HER MAJESTY THE QUEEN IN RIGHT OF YUKON,
As represented by the Deputy Minister of Health and Social Services
Per: ____________________________
Date: ___________________________

HER MAJESTY THE QUEEN IN RIGHT OF THE NORTHWEST TERRITORIES,
As represented by the Deputy Minister of Health and Social Services
Per: ____________________________
Date: ___________________________
HER MAJESTY THE QUEEN IN RIGHT OF NUNAVUT,

As represented by the Deputy Minister of Health

Per: _______________________________

Date: ____________________________
Appendix “A”

pCPA Governance Structure

Attached to and forming part of the MOU between the Parties made effective as of April 1, 2016.

Canada’s Premiers (Council of the Federation) → Health Care Innovation Working Group (HCIWG) → Conference of the PT Deputy Ministers of Health

pCPA

- pCPA Governing Council
- pCPA Steering Committee
- Drug Program/Cancer Agency Leads and Staff

Office of the pCPA
**Appendix “B”**

**pCPA Office Annual Budget**

Attached to and forming part of the MOU between the Parties made effective as of April 1, 2016.

Funding: For budget of $1.5M - 50% equal division, 50% per capita division.

<table>
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<th>Annual Budget:</th>
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<th>Total annual contribution by P/T</th>
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