March 28, 2018

Re: Your request for access to information under Part II of the Access to Information and Protection of Privacy Act [Our File #: HCS/030/2018]

On March 8, 2018, the Department of Health and Community Services (the Department) received your request for access to the following records:

‘‘??? Copies of all repayment agreements between the province of Newfoundland and Labrador and the federal government that were entered into pursuant to section 103 of the Patent Act. This section reads: 'The Minister may enter into agreements with any province respecting the distribution of, and may pay to that province out of the Consolidated Revenue Fund, amounts received or collected by the Receiver General under section 83 or 84 or in respect of an undertaking given by a patentee or former patentee that is accepted by the Board in lieu of holding a hearing or making an order under section 83, less any costs incurred in relation to the collection and distribution of those amounts.'

??? Copies of any reports or similar documents produced since January 1, 2013 and dealing with one or more of the following topics: (i) the effects of provincial laws and regulations on drug prices, (ii) impact (on prices or otherwise) of Product Listing Agreements for drugs, or (iii) the impact (on prices or otherwise) of the pan-Canadian Pharmaceutical Alliance.

??? All communications from the province of Newfoundland and Labrador to the federal government or to a federal entity regarding proposed amendments to the Patented Medicines Regulations, SOR 94-688. The amendments in question were published on December 2, 2017 in the Canada Gazette, along with a Regulatory Impact Analysis Statement.

??? Any response from the province of Newfoundland and Labrador or a provincial entity of Newfoundland and Labrador to any of the following three consultations:  


??? Proposed amendments to the Patented Medicines Regulations Consultation - closed June 2017.

??? Consultation following the publication of the proposed text of the amendments to the Patented Medicines Regulations in the Canada Gazette, Part I - closed February 2018’’.

I am pleased to inform you that a decision has been made by John G. Abbott, Deputy Minister for the Department, to provide access to some of the requested information. Access to the remaining information contained within the records, has been refused in accordance with the following
exceptions to disclosure, as specified in the Access to Information and Protection of Privacy Act (the Act):

Pages 6 – 12:
Section 29(1)(a) – Policy Advice or Recommendations
29. (1) The head of a public body may refuse to disclose to an applicant information that would reveal
(a) advice, proposals, recommendations, analyses or policy options developed by or for a public body or minister;

Pages 126 – 130:
Section 34 - Disclosure Harmful to Intergovernmental Relations or Negotiations
s. 34 (1) The head of a public body may refuse to disclose information to an applicant if the disclosure could reasonably be expected to
(a) harm the conduct by the government of the province of relations between that government and the following or their agencies:
(i) the government of Canada or a province.

Section 40- Disclosure Harmful to Personal Privacy
40. (1) The head of a public body shall refuse to disclose personal information to an applicant where the disclosure would be an unreasonable invasion of a third party’s personal privacy.

Please be advised that you may ask the Information and Privacy Commissioner to review the processing of your access request, as set out in section 42 of the Access to Information and Protection of Privacy Act (the Act). A request to the Commissioner must be made in writing within 15 business days of the date of this letter or within a longer period that may be allowed by the Commissioner.

The address and contact information of the Information and Privacy Commissioner is as follows:
Office of the Information and Privacy Commissioner
2 Canada Drive
P. O. Box 13004, Stn. A
St. John’s, NL A1B 3V8
Telephone: (709) 729-6309
Toll-Free: 1-877-729-6309
Facsimile: (709) 729-6500

You may also appeal directly to the Supreme Court Trial Division within 15 business days after you receive the decision of the public body, pursuant to section 52 of the Act.

Please be advised that responsive records will be published following a 72 hour period after the response is sent electronically to you or five business days in the case where records are mailed to you. It is the goal to have the responsive records posted to the Completed Access to Information Requests website within one business day following the applicable period of time. Please note that requests for personal information will not be posted online.
If you have any further questions, please contact the undersigned by telephone at 709-729-7010 or by email at MichaelCook@gov.nl.ca.

Sincerely,

[Signature]

Michael Cook
ATIPP Coordinator
/Enclosures
Policy Advice or Recommendations

29.  (1) The head of a public body may refuse to disclose to an applicant information that would reveal

   (a) advice, proposals, recommendations, analyses or policy options developed by or for a public body or minister;

   (b) the contents of a formal research report or audit report that in the opinion of the head of the public body is incomplete and in respect of which a request or order for completion has been made by the head within 65 business days of delivery of the report; or

   (c) draft legislation or regulations.

(2) The head of a public body shall not refuse to disclose under subsection (1)

   (a) factual material;

   (b) a public opinion poll;

   (c) a statistical survey;

   (d) an appraisal;

   (e) an environmental impact statement or similar information;

   (f) a final report or final audit on the performance or efficiency of a public body or on any of its programs or policies;

   (g) a consumer test report or a report of a test carried out on a product to test equipment of the public body;

   (h) a feasibility or technical study, including a cost estimate, relating to a policy or project of the public body;

   (i) a report on the results of field research undertaken before a policy proposal is formulated;

   (j) a report of an external task force, committee, council or similar body that has been established to consider a matter and make a report or recommendations to a public body;

   (k) a plan or proposal to establish a new program or to change a program, if the plan or proposal has been approved or rejected by the head of the public body;
(l) information that the head of the public body has cited publicly as the basis for making a decision or formulating a policy; or

(m) a decision, including reasons, that is made in the exercise of a discretionary power or an adjudicative function and that affects the rights of the applicant.

(3) Subsection (1) does not apply to information in a record that has been in existence for 15 years or more.
Disclosure Harmful to Intergovernmental Relations or Negotiations

34. (1) The head of a public body may refuse to disclose information to an applicant if the disclosure could reasonably be expected to

(a) harm the conduct by the government of the province of relations between that government and the following or their agencies:

(i) the government of Canada or a province,

(ii) the council of a local government body,

(iii) the government of a foreign state,

(iv) an international organization of states, or

(v) the Nunatsiavut Government; or

(b) reveal information received in confidence from a government, council or organization listed in paragraph (a) or their agencies.

(2) The head of a public body shall not disclose information referred to in subsection (1) without the consent of

(a) the Attorney General, for law enforcement information; or

(b) the Lieutenant-Governor in Council, for any other type of information.

(3) Subsection (1) does not apply to information that is in a record that has been in existence for 15 years or more unless the information is law enforcement information.
Disclosure harmful to personal privacy

40. (1) The head of a public body shall refuse to disclose personal information to an applicant where the disclosure would be an unreasonable invasion of a third party's personal privacy.

(2) A disclosure of personal information is not an unreasonable invasion of a third party's personal privacy where

(a) the applicant is the individual to whom the information relates;

(b) the third party to whom the information relates has, in writing, consented to or requested the disclosure;

(c) there are compelling circumstances affecting a person’s health or safety and notice of disclosure is given in the form appropriate in the circumstances to the third party to whom the information relates;

(d) an Act or regulation of the province or of Canada authorizes the disclosure;

(e) the disclosure is for a research or statistical purpose and is in accordance with section 70;

(f) the information is about a third party's position, functions or remuneration as an officer, employee or member of a public body or as a member of a minister's staff;

(g) the disclosure reveals financial and other details of a contract to supply goods or services to a public body;

(h) the disclosure reveals the opinions or views of a third party given in the course of performing services for a public body, except where they are given in respect of another individual;

(i) public access to the information is provided under the Financial Administration Act;

(j) the information is about expenses incurred by a third party while travelling at the expense of a public body;

(k) the disclosure reveals details of a licence, permit or a similar discretionary benefit granted to a third party by a public body, not including personal information supplied in support of the application for the benefit;

(l) the disclosure reveals details of a discretionary benefit of a financial nature granted to a third party by a public body, not including
(i) personal information that is supplied in support of the application for the benefit, or

(ii) personal information that relates to eligibility for income and employment support under the Income and Employment Support Act or to the determination of income or employment support levels; or

(m) the disclosure is not contrary to the public interest as described in subsection (3) and reveals only the following personal information about a third party:

(i) attendance at or participation in a public event or activity related to a public body, including a graduation ceremony, sporting event, cultural program or club, or field trip, or

(ii) receipt of an honour or award granted by or through a public body.

(3) The disclosure of personal information under paragraph (2)(m) is an unreasonable invasion of personal privacy where the third party whom the information is about has requested that the information not be disclosed.

(4) A disclosure of personal information is presumed to be an unreasonable invasion of a third party's personal privacy where

(a) the personal information relates to a medical, psychiatric or psychological history, diagnosis, condition, treatment or evaluation;

(b) the personal information is an identifiable part of a law enforcement record, except to the extent that the disclosure is necessary to dispose of the law enforcement matter or to continue an investigation;

(c) the personal information relates to employment or educational history;

(d) the personal information was collected on a tax return or gathered for the purpose of collecting a tax;

(e) the personal information consists of an individual's bank account information or credit card information;

(f) the personal information consists of personal recommendations or evaluations, character references or personnel evaluations;

(g) the personal information consists of the third party's name where

(i) it appears with other personal information about the third party, or

(ii) the disclosure of the name itself would reveal personal information about the third party; or
(h) the personal information indicates the third party’s racial or ethnic origin or religious or political beliefs or associations.

(5) In determining under subsections (1) and (4) whether a disclosure of personal information constitutes an unreasonable invasion of a third party’s personal privacy, the head of a public body shall consider all the relevant circumstances, including whether

(a) the disclosure is desirable for the purpose of subjecting the activities of the province or a public body to public scrutiny;

(b) the disclosure is likely to promote public health and safety or the protection of the environment;

(c) the personal information is relevant to a fair determination of the applicant’s rights;

(d) the disclosure will assist in researching or validating the claims, disputes or grievances of aboriginal people;

(e) the third party will be exposed unfairly to financial or other harm;

(f) the personal information has been supplied in confidence;

(g) the personal information is likely to be inaccurate or unreliable;

(h) the disclosure may unfairly damage the reputation of a person referred to in the record requested by the applicant;

(i) the personal information was originally provided to the applicant; and

(j) the information is about a deceased person and, if so, whether the length of time the person has been deceased indicates the disclosure is not an unreasonable invasion of the deceased person’s personal privacy.
42. (1) A person who makes a request under this Act for access to a record or for correction of personal information may file a complaint with the commissioner respecting a decision, act or failure to act of the head of the public body that relates to the request.

(2) A complaint under subsection (1) shall be filed in writing not later than 15 business days

(a) after the applicant is notified of the decision of the head of the public body, or the date of the act or failure to act; or

(b) after the date the head of the public body is considered to have refused the request under subsection 16 (2).

(3) A third party informed under section 19 of a decision of the head of a public body to grant access to a record or part of a record in response to a request may file a complaint with the commissioner respecting that decision.

(4) A complaint under subsection (3) shall be filed in writing not later than 15 business days after the third party is informed of the decision of the head of the public body.

(5) The commissioner may allow a longer time period for the filing of a complaint under this section.

(6) A person or third party who has appealed directly to the Trial Division under subsection 52 (1) or 53 (1) shall not file a complaint with the commissioner.

(7) The commissioner shall refuse to investigate a complaint where an appeal has been commenced in the Trial Division.

(8) A complaint shall not be filed under this section with respect to

(a) a request that is disregarded under section 21;

(b) a decision respecting an extension of time under section 23;

(c) a variation of a procedure under section 24; or

(d) an estimate of costs or a decision not to waive a cost under section 26.

(9) The commissioner shall provide a copy of the complaint to the head of the public body concerned.
Direct appeal to Trial Division by an applicant

52. (1) Where an applicant has made a request to a public body for access to a record or correction of personal information and has not filed a complaint with the commissioner under section 42, the applicant may appeal the decision, act or failure to act of the head of the public body that relates to the request directly to the Trial Division.

(2) An appeal shall be commenced under subsection (1) not later than 15 business days

(a) after the applicant is notified of the decision of the head of the public body, or the date of the act or failure to act; or

(b) after the date the head of the public body is considered to have refused the request under subsection 16 (2).

(3) Where an applicant has filed a complaint with the commissioner under section 42 and the commissioner has refused to investigate the complaint, the applicant may commence an appeal in the Trial Division of the decision, act or failure to act of the head of the public body that relates to the request for access to a record or for correction of personal information.

(4) An appeal shall be commenced under subsection (3) not later than 15 business days after the applicant is notified of the commissioner’s refusal under subsection 45 (2).
Potential copyright material

If you wish to obtain a copy please contact the ATIPP Office at (709) 729-7072 or atippoffice@gov.nl.ca.
Good evening,

Yesterday, June 28th, 2017, was the last day for stakeholders’ submissions regarding the Patented Medicines Pricing Review Board (PMPRB) and Patented Medicines Regulations consultation. For your information, please find attached the submission document for this consultation from Innovative Medicines Canada.

At your convenience, myself and representatives from Innovative Medicines Canada would be more than happy to meet with you and your teams to review this document in more detail. In the meantime, if you have any comments, questions, or concerns please let me know and I will have those comments addressed.

Thank you,

Bobby

ROBERT (BOBBY) E. SUTHERLAND
Director, Atlantic Canada
Directeur, Canada Atlantique

Innovative Medicines Canada
 Médicaments Novateurs Canada

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1220-55 rue Metcalfe St., Ottawa, ON, K1P 6L5
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Bringing Research to Life
Pour Donner Vie À la recherche

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NL Position Note
PT Health Ministers Meeting
December 14, 2017

Agenda Item: pCPA VCU Funding Disbursement

Issue & Purpose:

- s. 29(1)(a)

Suggested Speaking Points:

- We are supportive of the proposed distribution model, which will see the disbursement of VCU funds based partially on equal distribution and partially on population.

- We will use our portion of the VCU funding to fund a full time position dedicated to enhancing pCPA activity.

- We are eager to increase its capacity to participate in the work of the pCPA.

Background:

pCPA VCU Funding

- Deputy Ministers of Health have previously approved the use of VCU funding, at $50M over 10 years, to support enhanced pCPA activity (Appendix A).

- $30M (of the $50M) has been recently released from the federal government to Ontario (on behalf of the participating jurisdictions) to provide stability of funding for the pCPA Office. This $30M in funding provides, $3M per year to support salary and benefits of existing staff, staffing expansion, as well as funding for procurement of contracted expertise, web-site & communications, information technology (video conferencing/webinars/etc.), learning and development, operations, and travel.

- The remaining approved $20M, $2M per year, is to provide jurisdictional capacity. The methodology detailed in the initial proposal was $150,000 per FTE for 14 FTEs (one for each participating jurisdiction). The net new FTE capacity could be used by each jurisdiction in whatever manner was determined appropriate to support of the collective pCPA effort. The proposed methodology for disbursement was not approved as part of the original approval.
The pCPA Governing Council reviewed this matter at its October 2017 meeting and continues to support the disbursement of the $20M amongst the jurisdictions for capacity and a revised disbursement methodology is proposed.

Proposed Methodology

- [s. 29(1)(a) s. 34(1)(a)(i)]

**Provincial/Territorial/Federal position:**
- All P/Ts except Quebec are supportive of the proposed approach. Quebec supports a per population approach to distribution.

**NL Assessment/Position:**
- [s. 29(1)(a)]
- NL is an active member of the pCPA and finds value in its objectives.

**Prepared/Approved by:** M. Mullins/J. O’Dea

**December 12, 2017**
Appendix A

Expanded Resourcing for pCPA Activity

1. Sustain current pCPA activities
   - The pCPA Office was launched in September 2015 and currently employs five staff members. The total annual budget is $1.5M.
   - Through the existing MoU, participating jurisdictions contribute an annual amount towards the pCPA Office annual operating budget. The existing MoU sets out the budget and allocations for three fiscal years (with an end date of March 31, 2019).
   - VCU funds are being used to enhance the current $1.5M annual pCPA Office budget and replace the annual contribution made by participating jurisdictions; thereby providing a sustainable funding source for the pCPA collective for the next 10 years.

2. Expand pCPA capacity
   - The pCPA Office provides central coordination for negotiation activities across jurisdictions.
   - $1.5M in new funding will be used to expand the pCPA capacity and will be invested in three areas:
     - Staff – includes additional staff in the pCPA Office to advance the development of common strategies and policies related to negotiations and to provide central coordination and support for communications and analytics;
     - Services – includes targeted activities that can be ‘contracted out’ to provide focused deliverables (e.g. the negotiation for the next generics framework);
     - Support – includes providing training to strengthen skills of pCPA staff and resources within participating jurisdictions to improve negotiation best practices and support for operational and logistical considerations to allow effective pan-Canadian functioning (i.e. in person meetings of pCPA Executive Committee).

3. Additional resources for participating jurisdictions
   - While the pCPA Office supports central coordination amongst participating jurisdictions, individual jurisdictions continue to lead negotiations with manufacturers, on behalf of the collective group. As such, the success of the pCPA relies on the ability of participating jurisdictions to support pCPA activities.
   - Funding was proposed for fourteen new dedicated ‘pCPA-liaison’ staff in the F/P/Ts, to increase the capacity within participating jurisdictions to support the pCPA’s ability to reach timely decisions and complete successful negotiations.
OCT 05 2017

Dr. Bob Bell  
Deputy Minister of Health and Long-Term Care  
Province of Ontario  
80 Grosvenor Street  
10th Floor, Hepburn Block  
Queen’s Park  
Toronto, Ontario M7A 1R3

Dear Dr. Bell:

Subject: Agreement on Statutory Payment to Ontario for enhancement of the pan-Canadian Pharmaceutical Alliance (pCPA)

I am writing in follow up to the February 24, 2017, Federal-Provincial-Territorial (F/P/T) Conference of Deputy Ministers of Health discussion on the strategic investment of Voluntary Compliance Undertaking funds (i.e., funds paid to the Government of Canada by drug patent holders through Voluntary Compliance Undertakings, Board Orders, and other settlements reached by the Patented Medicine Prices Review Board) to strengthen the pCPA.

As you are aware, last spring, the then federal Minister, the Honourable Jane Philpott, approved the distribution of $50 million to the province of Ontario in lieu of contributions to and from individual provinces and territories (P/Ts) to support the ten-year proposal endorsed by the F/P/T Deputy Ministers for the pCPA. The $50 million will be provided in two installments: $30 million immediately, and the remaining $20 million in a second installment later this year.

As set out in that proposal (enclosed), the first installment of $30 million is allocated to fund the pCPA Office’s operating budget of $3 million per year for 10 years. The $3 million would replace the $1.5 million per year previously contributed by the P/Ts and provide an additional $1.5 million per year to significantly enhance the pCPA’s negotiating and policy capacity, and assure its sustainability. The second installment of $20 million is intended to enhance the capacity of individual P/T jurisdictions to participate in the pCPA processes.

Ontario is accepting the $50 million on behalf of all P/Ts participating in the pCPA. As a result, Ontario is accountable to these P/Ts for the proper expenditure of the $50 million. Health Canada understands that the pCPA Office is required to report on all
pCPA Office expenditures to the P/Ts in accordance with the Memorandum of Understanding (MOU) respecting the pCPA, and that this MOU is currently being amended to include additional terms and conditions regarding the use, management, and accounting for the $50 million. It is my understanding that the Ontario Ministry of Health and Long-Term Care has agreed to accept $30 million at this time, to enhance the capacity of the pCPA Office.

The distribution of these funds is approved under the statutory authority set out in section 103 of the Patent Act, which allows the federal Minister of Health to enter into an agreement with a province for the disbursement of excess revenues collected from drug patent holders.

In order to formalize this agreement, and allow Health Canada to initiate the payment of $30 million, I would ask that you indicate your concurrence by signing, dating, and returning a copy of this letter within 30 days of receipt.

The allocation of the remaining $20 million, for enhanced capacity in individual jurisdictions, is still subject to discussions with the P/Ts, with details to be worked out in the near-term. Following confirmation of these details, a further disbursement of $20 million will be made under section 103 of the Patent Act.

Thank you in advance for your response. I am confident that with this investment we can build on the success of the pCPA to make further progress in improving the affordability of prescription medicines for the Canadian health care system.

Yours sincerely,

Simon Kennedy

Enclosure

c.c. P/T Deputy Ministers responsible for Health
I concur: ______

Dr. Bob Bell  
Deputy Minister  
Ontario Ministry of Health and Long Term Care

Date

Please return a signed copy of this letter to the postal address below:

Mr. Luke Carter  
Director  
Federal-Provincial-Territorial Relations Division  
Strategic Policy Branch  
Health Canada  
Brooke Claxton Building  
Tunney’s Pasture, P.L. 0909D  
70 Colombine Driveway  
Ottawa, Ontario  K1A 0K9