CORRESPONDENCE SUBMITTED TO SUPPORT TESTIMONY OF MATTHEW HERDER BEFORE THE HOUSE OF COMMONS' STANDING COMMITTEE ON HEALTH

MAY 2, 2023

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D. Correspondence showing that the Minister of Health and/or members of his office and Health Canada met with representatives of the pharmaceutical industry on multiple occasions between October 2022 and December 2022

    1. Email showing the results from the search of the lobbying registry, listing a minimum of 13 meetings between Health Canada officials and industry*

        *Nb. Only one of the companies (Johnson&Johnson) that met with the Minister and/or other officials manufacturers children's Tylenol and/or other analgesics. None of the other companies manufacture such medicines. This is an important fact because it has been suggested that the shortage of such medicines—rather than the proposed PMPRB guidelines—is why the Minister met with industry repeatedly during the fall of 2022.

E. Correspondence showing that pharmaceutical lobbying firms were aware that one or more people (in addition to the Acting Chairperson) were leaving the PMPRB before news of the resignations of Matthew Herder and Douglas Clark were made public

    1. Tweet posted by @PMPRB_Watch* indicating that "PMPRB types" are departing 333 Laurier Avenue (where PMPRB's offices are located), February 21, 2023

        *Nb. The identity of the person who operates the @PMPRB_Watch is not publicly know. However, it is believed to be operated by William Dempster, the CEO of 3SixtyPublic Affairs Inc., a consulting firm that also repeatedly met with Health Canada officials repeatedly during the fall of 2022.

    2. Tweet posted by @cmrherder (Matthew Herder's Twitter account) with his letter of resignation, February 23, 2023

F. Correspondence showing that the current Executive Director of the Office of Pharmaceutical Management Strategies (Michelle Boudreau) previously worked for the pharmaceutical industry as well as the PMPRB

    1. Powerpoint presentation by Michelle Boudreau in her role as Executive Director of the PMPRB, June 11, 2012
    2. Printout of Lobbyist Registration for "Rx&D, Canada's Research-Based Pharmaceutical Companies"* showing that Michelle Boudreau was employed as a lobbyist for that organization

        *Nb. Rx&D, Canada's Research-Based Pharmaceutical Companies, has changed the name of its organization to "Innovative Medicines Canada."

    3. Printout of list of public offices health by Michelle Boudreau prior to 2014 from the lobbyist registry website

A1

URGENT - Emergency Board meeting

Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>
Tue 2022-11-29 1:36 PM

To: C Kobernick <carolynkobernick@gmail.com>;Ingrid Sketris <Ingrid.Sketris@Dal.Ca>;Matthew Herder <Matthew.Herder@Dal.Ca>;Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>

IiJ 4 attachments (429 KB)

22-112870-971 - Appendix A - Letter - Signed by MIN.pdf; Letter to aChairperson from Min 2022 11 28 translated.docx; 20221128_LTR_Dr. Mélanie Bourassa Forcier_PMPRB.pdf; Acting Chairperson Letter to IMC 2022 11 21 Final.pdf;

Hello Board members,

I hope you have been well. Please find attached correspondence sent to the Acting Chairperson regarding the proposed guidelines and the consultation process. The correspondence is from the Minister of Health and the President of IMC. I am providing an unofficial translation of the Minister's letter to Melanie for your ease of reference. I am also attaching a copy of Melanie's outgoing letter to IMC.

After consultation with Isabel, it was determined that an urgent Board meeting should be held to canvas your views on the attached letters.

Melanie has indicated that she is available Thursday at 16:00 EST. Could you please indicate by return email at your earliest convenience if you are available to meet at that time for an hour to ninety minutes?

Once you have confirmed your availability, I will send out a request for a Teams meeting.

Take care,

Sherri Wilson
Director / Directrice
Board Secretariat / Secrétariat du Conseil
Patented Medicine Prices Review Board / Conseil d'examen du prix des médicaments brevetés
Government of Canada / Gouvernement du Canada
sherri.wilson@pmRrb-ceRJ:I&g_. Cell: 613-850-1278

B1

Re: A/Chairperson request for decision

Mélanie Bourassa Forcier <Melanie.Bourassa.Forcier@USherbrooke.ca>
Fri 2022-12-02 11:17 AM

To: Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>

Cc: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>;C Kobernick <carolynkobernick@gmail.com>;Ingrid Sketris <Ingrid.Sketris@dal.ca>;Matthew Herder <Matthew.Herder@dal.ca>

Hello

I've noted the position of the members that is not consistent with mine and I cannot endorse it.

I will obviously not sign any letter dictated to me.

Thank you

> On Dec. 2, 2022, at 10:10 a.m., Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca> wrote:
>
> Hello Melanie
>
> Here are the key messages that the other three Board members wish for me to convey to you, in response to your email request.
>
> - That the consultation period that is open until December 5, 2022 simply run its course.
> - That any discussion and subsequent Board decisions around next steps for the guideline process occur at the quarterly meeting of the Board on December 13, 2022, in person at the PMPRB office in Ottawa. Further there is no need to communicate anything further to DM Lucas about the Board's plans/intentions until after the Board meets on December 13, 2022.
> - That a meeting not be scheduled with IMC on December 5, 2022.
>
> The Board members will also be expecting to see a draft letter to IMC's Pam Fralick early next week. The purpose of that letter will be to acknowledge Ms. Fralick's incoming letter and indicate that the PMPRB is open to meet with IMC on a recurring basis as is proposed in Ms. Fralick's incoming letter, with meetings starting in the new year.
>
> Please let me know if there is anything further you require of me at this time.
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> Best regards,
>
> **Sherri Wilson**
> Director / Directrice
> Board Secretariat / Secrétariat du Conseil
> Patented Medicine Prices Review Board / Conseil d'examen du prix des médicaments brevetés
> Government of Canada / Gouvernement du Canada

sherri.wilson@pmprb-cepmb.gc.ca, Cell: 613-850-1278

From: Sherri Wilson
Sent: December 1, 2022 10:22 AM
To: C Kobernick <carolynkobernick@gmail.com>; Matthew Herder <Matthew.Herder@Dal.Ca>; Ingrid Sketris <Ingrid.Sketris@Dal.Ca>
Cc: Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>; Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>
Subject: A/Chairperson request for decision

Hello Board members

Please see the request from the Acting Chairperson below, which she asked me to forward to you.

I am also attaching a letter sent by the Acting Chairperson to the Minister of Health yesterday afternoon and a courtesy translation of that letter for your ease of reference.

I will be sending a Teams invite shortly for an in-camera Board meeting at 10:30.

Best regards,

Sherri Wilson
Director / Directrice
Board Secretariat / Secrétariat du Conseil
Patented Medicine Prices Review Board / Conseil d'examen du prix des médicaments brevetés
Government of Canada / Gouvernement du Canada
sherri.wilson@pmprb-cepmb.gc.ca, Cell: 613-850-1278

Dear Board Members

I took the time to think about your decision. This decision is to propose a meeting with IMC on December 13 and to end the consultation period for the guidelines on the scheduled date, which is December 5, 2022 (which is in itself a decision to do nothing with this regards).

Morally and professionally speaking, it will be impossible for me to support this decision (to do nothing). Yesterday, I assured Deputy Minister Lucas that it was essential for me to take the time to meet with the industry in order to better understand their misunderstandings related to the guidelines. Meeting with the industry after the end of the consultation period would have the effect of sending the message that our discussions of the 13th will not be taken into consideration in the modification of the guidelines. Legally speaking, I feel that in order to comply with the principles of administrative justice, we must give all stakeholders the chance to meet us in this process. Taking into account the comments of the industry after the consultation period would have the effect of favouring one stakeholder over another. Even if this is ok on a legal standpoint, I considering that this is problematic on a political standpoint.

Considering the above, two options are available to us:

1- Meet with IMC before the end of the consultation period (so before December 5); Or
2- Suspend or extend the consultation period until we meet with IMC.

To me, these options do not represent any risk, whereas the one you have chosen has several. I understand that many of you are exhausted, a feeling that I do not share because I joined the PMPRB later in the reform process. Nevertheless, it is important that feelings do not influence the rationality of our decisions.

The two options that I propose do not in any way jeopardize the implementation date of the guidelines. We will determine what we want to do about this after our meeting with IMC.

Please let me know your position before 10:00 a.m. so that the Minister is informed before his meeting with IMC: option 1, option 2 or if you wish to go ahead with your yesterday's decision (do nothing about the end date of consultations and meet with IMC on the 13th).

If this is the case, unfortunately, I will not support it as previously mentioned (this is not a decision from the Chairperson anyway). I will inform the Minister and, necessarily, I will have to think about my place within the Board because it is essential for me, in the development of public policies, to take the time to listen to and consider the actors. As I said yesterday, it is not just about informing and receiving comments, it is about collaborating in identifying the elements that allow us to better achieve our objectives. If the Minister decides to get rid of the PMPRB we will not achieve our objectives.

We can talk about this if you are available this morning. Thank you
Melanie

Mélanie Bourassa Forcier, LL.L., LL.M., M.Sc., PhD
Full Professor
Director of Law and Health Policy Master's Programs
Co-lead, Law and Life Sciences Program
Faculty of Law, University of Sherbrooke
Fellow, CIRAND
Associate, CSBE
Acting Chairperson, PMPRB

B2

Re: A/Chairperson request for decision

Mélanie Bourassa Forcier <Melanie.Bourassa.Forcier@USherbrooke.ca>
Fri 2022-12-02 11:17 AM

To: Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>

Cc: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>;C Kobernick <carolynkobernick@gmail.com>;Ingrid Sketris <Ingrid.Sketris@Dal.Ca>;Matthew Herder <Matthew.Herder@Dal.Ca>

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> Please let me know if there is anything further you require of me at this time.
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> Best regards,
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> **Sherri Wilson**
> Director / Directrice
> Board Secretariat / Secrétariat du Conseil
> Patented Medicine Prices Review Board / Conseil d'examen du prix des médicaments brevetés
> Government of Canada/ Gouvernement du Canada

sherri.wilson@QmQrb-ceQmb.gc.ca, Cell: 613-850-1278

From: Sherri Wilson
Sent: December 1, 2022 10:22 AM
To: C Kobernick <carolynkobernick@gmail.com>; Matthew Herder <Matthew.Herder@Dal.Ca>; Ingrid Sketris <Ingrid.Sketris@Dal.Ca>
Cc: Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>; Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>
Subject: A/Chairperson request for decision

Hello Board members

Please see the request from the Acting Chairperson below, which she asked me to forward to you.

1 am also attaching a letter sent by the Acting Chairperson to the Minister of Health yesterday afternoon and a courtesy translation of that letter for your ease of reference.

1 will be sending a Teams invite shortly for an in-camera Board meeting at 10:30.

Best regards,

Sherri Wilson
Director / Directrice
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Government of Canada / Gouvernement du Canada
sherri.wilson@QmQrb-ceQmb.gc.ca, Cell: 613-850-1278

Dear Board Members

I took the time to think about your decision. This decision is to propose a meeting with IMC on December 13 and to end the consultation period for the guidelines on the scheduled date, which is December 5, 2022 (which is in itself a decision to do nothing with this regards).

Morally and professionally speaking, it will be impossible for me to sign any letter addressed to the Minister or IMC informing them of your decision. Yesterday, I assured the Deputy Minister Lucas that it was essential for me to take the time to meet with the industry in order to better understand their misunderstandings related to the guidelines. Meeting with the industry after the end of the consultation period would have the effect of sending the message that our discussions of the 13th will not be taken into consideration in the modification of the guidelines. Legally speaking, I feel that in order to comply with the principles of administrative justice, we must give all stakeholders the chance to meet us in this process. Taking into account the comments of the industry after the consultation period would have the effect of favouring one stakeholder over another. Even if this is ok on a legal standpoint, I considering that this is problematic on a political standpoint.

Considering the above, two options are available to us:

3- Meet with MNC before the end of the consultation period (so before December 5); Or
4- Suspend or extend the consultation period until we meet with IMC.

To me, these options do not represent any risk, whereas the one you have chosen has several. I understand that many of you are out of breath, a feeling that I do not share because I joined the PMPRB later in the reform process. Nevertheless, it is important that feelings do not influence the rationality of our decisions.

The two options that I propose do not in any way jeopardize the implementation date of the

guidelines. We will determine what we want to do about this after our meeting with IMC.

Please let me know your position before 11:00 a.m. so that the Minister is informed before his meeting with IMC: option 1, option 2 or if you wish to go ahead with your yesterday's decision. If this is the case, unfortunately, I will not support it (this is not a decision from the president anyway). I will inform the Minister and, necessarily, I will have to think about my place within the Board because it is essential for me, in the development of public policies, to take the time to listen to and consider the actors. As I said yesterday, it is not just about informing and receiving comments, it is about collaborating in identifying the elements that allow us to better achieve our objectives. If the Minister decides to get rid of the PMPRB we will not achieve our objectives.

We can talk about this is you are available this morning. If not, please let me know your position.

Thank you
Melanie

Mélanie Bourassa Forcier, LL.L., LL.M., M.Sc., PhD
Full Professor
Director of Law and Health Policy Master's Programs
Co-lead, Law and Life Sciences Program
Faculty of Law, University of Sherbrooke
Fellow, CIRAND
Associate, CSBE
Acting Chairperson, PMPRB

B3

Re: Decision by the Acting Chairperson on the consultation period

Matthew Herder <Matthew.Herder@Dal.Ca>
Fri 2022-12-02 3:16 PM
To: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>;Ingrid Sketris <Ingrid.Sketris@Dal.Ca>;C Kobernick <carolynkobernick@gmail.com>
Cc: Douglas Clark <douglas.clark@pmprb-cepmb.gc.ca>;Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>;Isabel Jaen Raasch <isabel.jaenraasch@pmprb-cepmb.gc.ca>

The power to make guidelines, and the obligation to consult in the course of doing so, is explicitly vested in "the Board" under s. 96(4) and 96(5), of the Act, respectively.

1 would argue that the decision to suspend or extend consultations therefore rests with the Board as a whole. While the Chair (or Acting Chair) has authority over the conduct of the Board generally and the management of its internal affairs pursuant to s. 93(2), the explicit focus on guideline-making in a separate section militates in favour of guideline-making as being a whole Board responsibility.

Perhaps the regs add further clarity, but I think there's a solid basis for this interpretation in the Act itself. The provisions are cut and pasted below for others to see.

//m.

Chairperson and Vice-chairperson

93 (1) The Governor in Council shall designate one of the members of the Board to be Chairperson of the Board and one of the members to be Vice-chairperson of the Board.

Marginal note:Duties of Chairperson

(2) The Chairperson is the chief executive officer of the Board and has supervision over and direction of the work of the Board, including

- **(a)** the apportionment of the work among the members thereof and the assignment of members to deal with matters before the Board and to sit at hearings of the Board and to preside at hearings or other proceedings; and
- **(b)** generally, the conduct of the work of the Board, the management of its internal affairs and the duties of its staff.

General powers, etc.

96 (1) The Board has, with respect to the attendance, swearing and examination of witnesses, the production and inspection of documents, the enforcement of its orders and other matters necessary or proper for the due exercise of its jurisdiction, all such powers, rights and privileges as are vested in a superior court.

***

(4) Subject to subsection (5), the Board may issue guidelines with respect to any matter within its jurisdiction but such guidelines are not binding on the Board or any rights holder or former rights holder.

Consultation

(5) Before the Board issues any guidelines, it shall consult with the Minister, the provincial ministers of the Crown responsible for health and such representatives of consumer groups and representatives of the pharmaceutical industry as the Minister may designate for the purpose.

//m.

Matthew Herder, JSM LLM
CIHR-PHAC Chair in Applied Public Health
Director, Health Law Institute, Schulich School of Law
Associate Professor, Department of Pharmacology
Faculties of Medicine and Law, Dalhousie University
Email: Matthew.Herder@Dal.ca
Twitter: @cmrherder

From: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>
Sent: December 2, 2022 3:07 PM
To: Ingrid Sketris <Ingrid.Sketris@Dal.Ca>; C Kobernick <carolynkobernick@gmail.com>; Matthew Herder <Matthew.Herder@Dal.Ca>
Cc: Douglas Clark <douglas.clark@pmprb-cepmb.gc.ca>; Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>; Isabel Jaen Raasch <isabel.jaenraasch@pmprb-cepmb.gc.ca>
Subject: Re: A/Chairperson's decision on consultation period

Dear Board member,

As for me, I am referring to the Patent Act (93(2) PA). Please tell me which legislative provision you are relying on. I am cc'ing Isabel, PMPRB counsel.

Thank you
Mélanie Bourassa Forcier, Acting Chairperson

From: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>
Sent: December 2, 2022 12:59 pm
TO: Ingrid Sketris <Ingrid.Sketris@Dal.Ca>; C Kobernick <carolynkobernick@gmail.com>; Matthew Herder <Matthew.Herder@Dal.Ca>
Cc : Douglas Clark <douglas.clark@pmprb-cepmb.gc.ca>; Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>
Subject: A/Chairperson's decision on consultation period

Dear Board members,

As I mentioned earlier, I have noted your desire to end the consultation period on the guidelines on the scheduled date, December 5.

As you know, it is essential for me to take more time to better understand the misunderstandings of the stakeholders affected by our future guidelines.

Considering this situation and considering the fact that under the Act, I am responsible for the conduct of the work of the Board, I have decided to suspend the consultation period to allow us to meet with the stakeholders who have expressed misunderstandings to date and to hear their proposals.

I would like this decision to be made public today. Sherri: please send me the announcement of this decision once it is online. Please also (1) prepare a letter for IMC advising them of this and to propose a meeting on December 13 in our offices (with Doug and/or Tanya) and (2) advise Mr. Lucas of this decision.

Thank you and I am counting on your cooperation.

Mélanie Bourassa Forcier, A/Chairperson

B4

RE: PRIVILEGED - regarding your request for legal advice on the Code of Conduct for Board Members

Douglas Clark <douglas.clark@pmprb-cepmb.gc.ca>
Mon 2022-12-05 9:20 AM

To: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>;Isabel Jaen Raasch <isabel.jaenraasch@pmprb-cepmb.gc.ca>

Cc: Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>;IngridSketris <Ingrid.Sketris@Dal.Ca>;C Kobernick <carolynkobernick@gmail.com>;Matthew Herder <Matthew.Herder@Dal.Ca>

As General Counsel, Isabel and her team don't take positions. They provide their best legal advice and opinions based on the facts before them.

Like Isabel, you too are part of the Board. It sounds like the opinion you want is one that you should seek in your capacity as a private citizen, not as acting Chair.

As for your other question about dissidence which you sent to us at 10:02pm last night, as Isabel stated, she will address it when she finishes answering the other outstanding questions.

This barrage of ever burgeoning requests is taking a toll on staff. For their personal well being, I have instructed them not to respond to any further emails from you until the Board meets at 2pm.

Thank you for your understanding,

Doug

From: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>
Sent: December 5, 2022 7:05 AM
To: Isabel Jaen Raasch <isabel.jaenraasch@pmprb-cepmb.gc.ca>
Cc: Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>; Douglas Clark <douglas.clark@pmprb-cepmb.gc.ca>; Ingrid Sketris <Ingrid.Sketris@Dal.Ca>; C Kobernick <carolynkobernick@gmail.com>; Matthew Herder <Matthew.Herder@Dal.Ca>
Subject: Re: PRIVILEGED - regarding your request for legal advice on the Code of Conduct for Board Members

Isabel,

I realize that the issue surrounding the legality of one or more members of the Board publicly dissenting with a Board decision seems to be missing.

Thank you!
Have a good day!
Mélanie

From: Melanie Bourassa Forcier <melanie.forcier@RmRrb-ceJ;1mb.gc.ca>
Sent: December 5, 2022 06:55
TO: Isabel Jaen Raasch <isabel.jaenraasch@RmJ;1rb-ceJ;1mb.gc.ca>
Cc : Sherri Wilson <Sherri.Wilson@12mwb-ceJ;1mb.gc.ca>; Douglas Clark <douglas.clark@gmgrb-ceRmb.gc.ca>; Ingrid Sketris <!Dgrid.Sketris@Dal.Ca>; C Kobernick <carolynkobernick@gmail.com>; Matthew Herder <Matthew.Herder@Dal.Ca>
Subject: Re: PRIVILEGED - regarding your request for legal advice on the Code of Conduct for Board Members

Thank you Isabel,

In fact, the opinion being sought is supposed to be independent. The staff are necessarily unable to provide this independent opinion as they are part of the Board.

I nevertheless have noted your position.

I will wait for an answer to the other questions before the Board meets so we can proceed in accordance with the applicable standards.

Matthew, Ingrid and Carolyn: I'm in a meeting this afternoon. How about we meet at 4 p.m. Could you please block that time off pending Isabel's response?

My sincere thanks,
Mélanie

From: Isabel Jaen Raasch <isabel.jaenraasch@pmgrb-cegmb.gc.ca>
Sent: December 5, 2022 02:11
TO: Melanie Bourassa Forcier <melanie.forcier@pmwb-cegmb.gc.ca>
Cc: Sherri Wilson <Sherri.Wilson@rmrnrtxerunb.gc.ca>; Douglas Clark <douglas.clark@rurrnrtxellli)b.gc.ca>; Ingrid Sketris <Ingrid.Sketris@Dal.Ca>; C Kobernick <carolv.nkobernick@gmail.com>; Matthew Herder <Matthew.Herder@Dal.Ca>
Subject: RE: PRIVILEGED - regarding your request for legal advice on the Code of Conduct for Board

Members

Dear Board members,

Legal Services is currently working on providing you with a memorandum relating to the question I endeavoured to respond to in my email below (Dec. 4, 16:43) asap. That memorandum will also address the specific question in bullet point 1 of the acting Chair's email below. 1 understand that these questions are important and want to assure you that they are being given the utmost attention as we do our best to address them in a comprehensive and timely manner.

Regarding the other questions in that email, 1 can respond as follows:

- Does the acting Chairperson have the authority to request an external and independent legal opinion?

As indicated by Doug previously, under s. 4 of the Government Contract Regulations (htt12s://laws-lois.justice.gc.ca/eng/Regulations/SOR-87-402/index.html), contracts for the performance of legal services (i.e. contracts with outside contractors) can only be entered into only by or under the authority of the Minister of Justice. Pursuant to a sub-delegation of the authority in s. 4 of the GCR from the Minister of Justice to the acting Chairperson of the PMPRB, the acting Chairperson may only retain outside counsel for the PMPRB for hearings or to provide expert legal opinions should the PMPRB's internal Legal Services Unit not have the expertise and/or capacity. In my view, at this time we have the expertise and capacity to provide legal opinions on the matters that have been referred to us.

- Is it consistent with the rules and obligations of the Board for its members to meet without all members having been convened and able to participate in the deliberations leading to a decision or confirmation of a decision?

We will be addressing this question once we have finished addressing the one we are currently working on and may come back to request further details on the question at that time.

- Can discussions and deliberations of Board members take place with staff other than the Board Secretary or does this violate the confidentiality obligations of Board members?

We will be addressing this question once we have finished addressing the one we are currently working on and may come back to request further details on the question at that time

Best Regards,
Isabel
Isabel Jaen Raasch
General Counsel and Director of Legal Services
PMPRB

From: Melanie Bourassa Forcier <melanie.forcier@.pmprb-cepmb.gc.ca>
Sent: December 4, 2022 10:02 PM
To: Isabel Jaen Raasch <isabel.jaenraasch@Rmwb-ceRmb.gc.ca>
Cc: Sherri Wilson <Sherri.Wilson@pmRf'.b:ceJm)b.gc.ca>; Douglas Clark <douglas.clark@pmR[b-ceJm)b.gc.ca>; Ingrid Sketris <.I.Dgrid.Sketris@Dal.Ca>; C Kobernick <carolv.nkobernick@gmail.com>; Matthew Herder

<Matthew.Herder@Oal.Ca>
Subject: Re: PRIVILEGED - regarding your request for legal advice on the Code of Conduct for Board Members

Thank you Isabel

It's appreciated that you responded on a Sunday. I'm sorry about the situation. Specifically, I would appreciate it if you could tell us about the legality of the following:

- Does a Board member, including its acting Chairperson, contravene any obligation, such as their obligation of confidentiality, by publicly dissenting with a Board decision?
- Does the acting Chairperson have the authority to request an external and independent legal opinion?
- Is it consistent with the rules and obligations of the Board for its members to meet without all members having been convened and able to participate in the deliberations leading to a decision or confirmation of a decision?
- Can discussions and deliberations of Board members take place with staff other than the Board Secretary or does this violate the confidentiality obligations of Board members?

Thank you very much and have a good evening,
Mélanie

From: Isabel Jaen Raasch <isabel.jaenraasch@pmprb-cepmb.gc.ca>
Sent: December 4, 2022 16:43
TO: Melanie Bourassa Forcier <melanie.forcier@Rmwb-ceRmb.gc.ca>; Matthew.Herder@Oal.Ca <Matthew.Herder@Oal.Ca>; Ingrid.Sketris@Oal.Ca <Ingrid.Sketris@Dal.Ca>; carolv.nkobernick@gmail.com <carolv.nkobernick@gmail.com>
Cc: Sherri Wilson <Sherri.Wilson@ITTDITTb:œRfDb.gc.ca>; Douglas Clark <douglas.clark@ITTDITTb:œRfDb.gc.ca>
Subject: PRIVILEGED - regarding your request for legal advice on the Code of Conduct for Board Members

Dear Board members,

Thank you for reaching out to me on this new issue. I will prepare a memorandum of legal advice on the issue of the obligations of confidentiality relating to Board discussions on the proposed guidelines asap. I will be sending the memorandum to your PMPRB email accounts.

From: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>
Sent: December 4, 2022 12:38 PM

To: Isabel Jaen Raasch <isabel.jaenraasch@.pmprb-cepmb.gc.ca>
Subject: RE: A/Chairperson's decision on consultation period - PRIVILEGED

I thought you had been cc'd. Thank you for letting us know how things are going.

Sorry Isabel for this situation. Truly sorry.

Mélanie

From: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>
Sent: December 4, 2022 12:23
TO: Matthew Herder <Matthew.Herder@Dal.Ca>; Ingrid Sketris <Ingrid.Sketris@Dal.Ca>; Carolyn Kobernick (carolynkobernick@gmail.com) <carolynkobernick@gmail.com>
Cc : Sherri Wilson <Sherri.Wilson@RITHlli):Çe!}lnl).gc.ca>; Douglas Clark <douglas.clark@rum>r:b-ce!)lnl).gc.ca>
Subject: Re: A/Chairperson's decision on consultation period - PRIVILEGED

Thank you Matthew

Interesting, especially given the fact that you have frequently told us that your dissent should be noted if we were to go ahead with certain decisions.

Isabel: please let me know if my duty of confidentiality is an issue here. I did not see this at all as a problem in terms of compromising the confidentiality of our discussions, confidentiality that is particularly indispensable to us as members during hearings. However, for me, transparency was at stake. I will obviously follow your advice and of course, if my duty of confidentiality is an issue, I will respect it.

Now I will wait and see if we can meet so I can correct the information you received about me that is incorrect and to confirm your decision.

Thank you. I'm going to take a break from reading since for some unknown reason I have been significantly attacked over the past few days simply because I do not share your interpretation of our duty to consult. The personal attacks against me are affecting the very integrity of the Board. Although it may not appear obvious to you, I am human and the things being said about me simply because I wanted to extend the discussion period are deeply hurtful.

Thank you
Mélanie

From: Matthew Herder <Matthew.Herder@Dal.Ca>
Sent: December 4, 2022 11:47
TO: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>; Ingrid Sketris <Ingrid.Sketris@Dal.Ca>; Carolyn Kobernick (carolynkobernick@gmail.com) <carolynkobernick@gmail.com>
Cc: Sherri Wilson <Sherri.Wilson@ru:rmrb-ce!)lnl).gc.ca>; Douglas Clark <douglas.clark@w:rnrb-ce!)lnl).gc.ca>
Subject: Re: A/Chairperson's decision on consultation period - PRIVILEGED

Good morning everyone,

Thanks for ensuring that we're ail in the loop, Doug. I hope that continues to be the case. I

wanted to pickup on two points from the exchange below.

First, in principle I agree that it is important to ensure that both the Department of Health (including the Minister) and other stakeholders have an adequate opportunity to respond to our proposed guidelines. However, I think it is critical to note that they've both being given multiple opportunities during the consultation period to do so but until this past week refrained. As noted previously, Doug has reached out to and/or met with them on multiple occasions. IMC has also not yet provided a submission with their feedback although they have indicated that they will do so by the deadline of the 5th unless we decide to suspend or delay the consulations. In these circumstances, the claim that the consultation has been inadequate is specious in my view.

Second, I'm alarmed by the Acting Chair's suggestion that, were we to proceed as the majority of the Board intends and conclude the consultation tomorrow as planned, that she would communicate her dissent to IMC and the Minster. This would seem to be in direct violation of our obligations of confidentiality as expressed in the Board's Code of Conduct. Perhaps Isabel can weigh in on that point, as I understand that the Acting Chair is suggesting she will proceed in that fashion unless we agree to suspend or extend the consultation. Whether it violates the Code or not, this puts myself, Ingrid and Carolyn under significant pressure to agree with a course of action that I (and I understand the other two Board members) do not support.

Matthew

Matthew Herder, JSM LLM
CIHR-PHAC Chair in Applied Public Health
Director, Health Law Institute, Schulich School of Law
Associate Professer, Department of Pharmacology
Faculties of Medicine and Law, Dalhousie University
Email: Matthew.Herder@Dal.ca
Twitter: @cmrherder

From: Melanie Bourassa Forcier <melanie.forcier@Rmwb-ceRmb.gc.ca>
Sent: December 4, 2022 11:46 AM
To: Ingrid Sketris <J.l]grid.Sketris@Dal.Ca>; Matthew Herder <Matthew.Herder@Dal.Ca>; Carolyn Kobernick (carolv.nkobernick@gmail.com) <carolv.nkobernick@gmail.com>
Cc: Sherri Wilson <Sherri.Wilson@wprbj:e()fTlb.gc.ca>; Douglas Clark <douglas.clark@Rfilprb:-œ()fTlb.gc.ca>
Subject: Re: A/Chairperson's decision on consultation period - PRIVILEGED

Dear Board Members,

The last week has been particularly difficult. We are experiencing a significant conflict that must be resolved in order to ensure the survival, integrity and proper conduct of business for the PMPRB. Also, we must never lose sight of our mandate, which is to ensure the protection of Canadian consumers.

I want us to have a meeting tomorrow morning before 10:00 a.m. (members only). I would like to take advantage of this meeting to rectify the information that has been communicated to you and which represents a direct attack on my reputation and my integrity.

I have indicated to you that it is important to me that we adequately fulfill our obligations under Section 96(5) of the Patent Act.

Within the consultation period we received two requests, one from IMC and one from a Minister of Health. As I told you, we cannot ignore them. We must meet with IMC either on December 5 (within the consultation period) or at a later date. In the latter situation, this implies extending the consultation period in order to be fair to all citizens and not favour the industry.

Failure to act on these requests, moving forward with the end of the consultation period on the scheduled date of December 5, sends a message that we have a preconceived idea of the adequacy of our guidelines and this immediately affects the impartial character of our institution.

Taking the time to meet the actors does not oblige us to anything with regard to either the timing of the implementation of the guidelines or the content of our guidelines.

If we can't meet tomorrow and I don't hear from you by 5 p.m. tonight, I'm going to assume that you want to go ahead with your decision not to consider the requests made by IMC and the Minister, requests made before 5 December.

I have to respond to these requests. I will therefore respond to IMC and to the Minister of Health by informing them of your decision. I will, on the other hand, indicate that I am dissenting in this decision which seems to me contrary to the respect of section 96 (5) but that I was informed that I did not have a veto on this subject.

I note that the staff does not wish to positively respond to my request for an external and independent legal advice. Thank you for this answer. It is noted.

Thanks
Mélanie

From: Douglas Clark <douglas.clark@P.mP.rb-ceP.mb.gc.ca>
Sent: December 4, 2022 10:30
TO: Melanie Bourassa Forcier <melanie.forcier@P.mP.rb-ceP.mb.gc.ca>; Isabel Jaen Raasch <isabel.jaenraasch@P.mP.rb-ceP.mb.gc.ca>
Cc: Sherri Wilson <Sherri.Wilson@P.mP.rb-ceP.mb.gc.ca>; Matthew Herder <Matthew.Herder@Dal.Ca>; Carolyn Kobernick (carolv.nkobernick@gmail.com) <carolv.nkobernick@gmail.com>; Ingrid Sketris <I!Jgrid.Sketris@Dal.Ca>
Subject: RE: A/Chairperson's decision on consultation period - PRIVILEGED

I am bringing the rest of the Board in our your latest email to staff. I think it is critically important at this stage that any communication between the acting Chair and staff include the entirety of the Board. Quite frankly, Sherri, Isabel and I are not comfortable communicating with you otherwise.

As matters stand, based on the legal opinion provided by our General Council on December 2nd, the record should reflect that the Board has decided not to suspend the consultations. There are no grounds for seeking an outside legal opinion on the same matter and doing so would be contrary to our subdelegated authority from the Department of Justice and our obligation to spend public monies responsibly.

Ali of our communications on this matter to date have been internal to the PMPRB, not public, and therefore cannot possibly constitute defamation.

I am sad that it has come to this but there are steps to be followed within government in situations such as this and I will take them if necessary to protect myself and staff from wrongdoing.

Doug

From: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>
Sent: December 4, 2022 8:23 AM
To: Douglas Clark <douglas.clark@pmprb-cepmb.gc.ca>; Isabel Jaen Raasch <isabel.jaenraasch@pmprb-cepmb.gc.ca>
Cc: Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>
Subject: Re: A/Chairperson's decision on consultation period - PRIVILEGED

Doug,

1 - Judicial review or other similar remedy:

Your position is an interesting one. It is in fact doubtful that the Minister would request a judicial review given the PMPRB structure. However, it's impossible for him not to have an avenue available to compel us to perform our duties properly. The PMPRB structure being particularly legal, the use of such a review could prove unusual.

Judicial review will be open to the industry, that much is certain.

I imagine that the government is currently weighing their options. The refusal to extend the consultation period goes directly against the request by the Minister and the Deputy Minister. This, I'm not comfortable with.

2 – Public funds

For several years now, the PMPRB has come up with reforms that resulted in extremely costly litigation. We

lost several of these cases. I don't want any more litigation. Seeking a legal opinion that will take 4 hours to prepare is nothing compared to the cost of legal action that could result from the Board's emotional decision.

I don't understand why the members have such a problem with extending the consultation period.

As I've mentioned, the point is precisely to avoid putting ourselves in a posture of confrontation. The point is also to give all stakeholders, not just IMC, a chance to be heard. This flies in the face of the principles of fundamental justice.

3 suspension versus extension

One or the other. The reason I'm not opting for extension is that we do not yet have an agreement. Extension gives the stakeholders more time to be heard.

4 Concept of consultation

I have already published papers about consultation processes. Contemporary doctrine calls for much more comprehensive processes than those currently conducted by Health Canada. We are in a situation where our vision of the consultation is subject to legal action.

Damage to my reputation and defamation:

Regarding your mental health. I'm quite saddened to read that my actions this past week, because they are not in line with what you want, have affected your mental health. From my perspective, it had particularly been affected by various legal actions against the PMPRB and successive suspensions of reform proposals by the government. This is completely understandable.

Last week has certainly been difficult. It's been very tough mentally for me too, as I'm having to deal with insubordination and attacks on my reputation. My words are being twisted and I am being smeared.

That said, it is essential for me as A/Chairperson to ensure that we act rationally and avoid future legal action that is damaging, both personally and for the organization. My mandate as a member is to avoid excessive pricing of patented medicines on the market. My mandate as Chairperson is to ensure the organization's integrity.

On the instructions to Sherri: excuse me? Circumvent the Access to Information Act? Unbelievable.

I intend to take steps to stop the smears against me. This is what I asked Sherri: please arrange a meeting with the Minister. I didn't want to send a letter, as I found it highly problematic that the Minister wrote me a letter, which I shared with you, and you agreed with it.

Sherri has, on multiple occasions, refused to request this meeting with the Minister.

You prepared a letter for the Minister, a highly aggressive letter in which you committed to not put the directives in place on the scheduled date.

I deleted that passage, which was inconsistent with the very authority granted to the members.

I told Sherri that sending such a letter would be subject to an ATIP request and that it would send a message to the public of a lack of openness to the government that I certainly did not want to send as a message. I therefore edited the letter you had prepared for me, specifically to ensure that the public message was consistent with what I was morally comfortable with.

I wish to point out the many times you asked me to take messages via Teams in order to circumvent ATIP. I found that highly problematic.

Not to mention that you and Sherri told the members more than once that I had made a commitment to the Deputy Minister when you know very well that this is incorrect. You know very well that I told the Deputy Minister that I was open to extending the discussion period to take the time to understand stakeholder misunderstandings. You know very well that I said that I didn't know what the Board's position would be. I also informed you by text, a copy of which I've kept.

At first I thought it was your lack of understanding of French but then reading your email I realize that this is a clear attempt to portray me as a Chairperson without integrity.

I finally realize, further to the Minister's letter, that I was not provided with the full picture. I wonder whether this is a case of obstruction.

I did not add the members to this email in order to exercise a bit of judgment. Never did I harm you personally and what you are doing in your email has me looking into what needs to be done to stop the harm to my reputation and defamation.

thank you

From: Douglas Clark <douglas.clark@Rm12rb-ce12mb.gc.ca>
Sent: December 3, 2022 19:08
TO: Melanie Bourassa Forcier <melanie.forcier@12m12rb-ce12mb.gc.ca>; Matthew Herder <Matthew.Herder@Dal.Ca>; C Kobernick <carolv.nkobernick@gmail.com>; Isabel Jaen Raasch <isabel.jaenraasch@RmQrb-ceRmb.gc.ca>
Cc: Ingrid Sketris <Ingrid.Sketris@Dal.Ca>; Sherri Wilson <Sherri.Wilson@12m12rb-ce12mb.gc.ca>
Subject: RE: A/Chairperson's decision on consultation period - PRIVILEGED

Mélanie, as public servants one of our foremost duties is to be responsible stewards of public funds. One of the consequences of that duty in the present context is that the PMPRB only has subdelegated authority from the DoJ to retain experts or outside counsel where we lack the capacity or expertise to perform the required work in-house. The legal opinion you have described is a relatively straightforward one and we have both the ability and capacity to provide it by internal means. Indeed, our General Counsel provided the key components of it yesterday on very short notice despite health issues in her family that she normally otherwise would have attended to.

As for the legal risks you are concerned about, one doesn't have to be a lawyer to know that it is a legal impossibility for the government to judicially review itself. As a government body, when the PMPRB's decision making is judicially reviewed in Federal Court, it is represented by the Attorney General. The AG cannot be both applicant and respondent to a case. The risk of the Minister judicially reviewing the PMPRB for failing to consult with him is therefore zero. Furthermore, as you know already, at your direction, I personally sought a meeting on the draft guidelines with the Minister and/or his office on multiple occasions, through calls, emails and texts, none of which were returned. Your request to the Minister to meet to discuss the Guidelines in your letter to him of November 30th has likewise gone unanswered. The PMPRB simply cannot be faulted for failing to meet with the Minister on this matter.

In terms of the other part of the legal opinion you are seeking on the scope of the Board's duty to consult on its Guidelines under s.96(5), this can also easily be provided in house in short order, as opposed to the weeks it would take to retain and instruct outside counsel for this same purpose. In my preliminary view, given that the Guidelines have no force of law and are non-binding on patentees and the Board, I would think the procedural fairness/natural justice standards would be mid-range at best. There is no doubt in my mind that they have been met in this instance, as we have followed the same protocol as the previous two rounds of consultations on proposed new Guidelines in 2020. It seems to me that what you are arguing for is further consultation, not a suspension, and I do agree that a case can be made for that given the feedback we have received to date.

However, that is a decision the Board should only make after being fully briefed at their upcoming meeting on December 13.

It goes without saying that the core of your responsibilities as A/Chairperson is to protect consumers from excessive pricing. Achieving this priority requires you to protect both the board members, the staff, and the integrity of the organization. When you told the DM that you were open to the suspension and that we should be more receptive, you lent legitimacy to the industry's false allegations against us (which you previously claimed to find offensive) and threw the members and staff to the wolves for reasons that totally escape me. In your email to me of November 1, you denied committing the Board to suspending consultations because, when you told the DM that you were open to it, you then said that you had to speak with the Board. In what universe does that leave open the possibility for the Board to take a different decision without revealing that the other Board members do not share your opinion? Now that the Board has decided not to suspend consultations, you have exposed your colleagues' confidential opinions to the outside world and made them vulnerable to retaliation for political reasons.

I have never seen the head of an organization demonstrate such a lack of judgment and engage in such questionable ethical behaviour in so short a time. Your instructions to Sherri to try to circumvent access to information legislation in your efforts to communicate with the Minister is just one of so many examples from last week. Your inability to disclose to the other Board members the existence of your letter to the Minister or what you actually said to the DM are others.

On a personal level, outside professional settings, I appreciate you very much, but being the executive director under your recent leadership has taken a considerable toll on my mental health, for all the above reasons.

Doug

From: Melanie Bourassa Forcier <melanie.forcier@Rmwb-ceRmb.gc.ca>
Sent: December 3, 2022 3:58 PM
To: Matthew Herder <Matthew.Herder@Dal.Ca>; C Kobernick <carolynkobernick@gmail.com>; Isabel Jaen Raasch <isabel.jaenraasch@pmprb-cepmb.gc.ca>
Cc: Ingrid Sketris <Ingrid.Sketris@Dal.Ca>; Douglas Clark <douglas.clark@pmprb-cepmb.gc.ca>; Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>
Subject: Re: A/Chairperson's decision on consultation period - PRIVILEGED Matthew,

As A/Chairperson, I have the authority to seek an independent, outside legal opinion regardless of the time it takes to be produced in order to maintain the integrity of the Board and to try to avoid getting bogged down in legal action for an extension of a few days of consultation.

My concern regarding the consultations is that two groups involved, both the Minister and the pharmaceutical industry, have said that they were not sufficiently consulted.

The Board members were cc'ed in the interests of transparency.

As for the other paragraphs of your email, I consider them borderline defamatory, and I do not intend to get into an email exchange with you. I will simply repeat that I told the Deputy Minister that it was important for me to take time to meet with the stakeholders, but I did not know what the Board's decision would be, so I would inform him of this decision. Perhaps that was not understood because I wrote in French. As for my response and my position on the industry, you have it in the letter to IMC.

[1]Sherri·and/or Isabelle, **please provide me with the procedure for seeking a legal opinion rapidly.**

Mélanie

From: Matthew Herder <Matthew.Herder@Dal.Ca>
Sent: December 3, 2022 14:46
TO: Melanie Bourassa Forcier <melanie.forcier@12m12rb-ce12mb.gc.ca>; C Kobernick <carolv.nkobernick@gmail.com>; Isabel Jaen Raasch <isabel.jaenraasch@12m12rb-ce12mb.gc.ca>
Cc: Ingrid Sketris <I.Jgrid.Sketris@Dal.Ca>; Douglas Clark <douglas.clark@12m12rb-ce12mb.gc.ca>; Sherri Wilson <Sherri.Wilson@12m12rb-ce12mb.gc.ca>
Subject: Re: A/Chairperson's decision on consultation period - PRIVILEGED

Dear Melanie,

I suspect it will be very difficult to obtain independent legal advice between now and the close of business on Monday.

In any event, in light of your message, I'm left with more questions. In my view it is critically important for the Board as a whole to have a full an accurate account of what has transpired in recent days. Below I outline a series of questions that remain in my mind.

First, you indicate that you proposed to the members of the Board that we suspend our consultations. Did you or did you not indicate to the Deputy Minister -- *prior to speaking with myself or other members of the Board* -- that we would suspend our consultations? If not, what precisely did you endeavour to do in that meeting? : I never indicated to the Minister that I was going to suspend or extend the consultation period.

Second, you indicate that the Minister was not adequately consulted. Beyond the letter from the Minister, what is your basis for suggesting this? My understanding is that officials in Health Canada, including the Deputy Minister, have long been informed and aware of our consultations. They have chosen not to engage with us in recent weeks and months. If consultation on the part of the Board was lacking, why were you not concerned about the adequacy of consultations until this past week?

Third, I continue to be surprised by your stated intention to proceed in a direction that is contrary to the advice of senior staff, contrary to the views of the other members of the Board, and contrary to legal advice we have received. As such, I feel it is necessary to ask for further information about the communication between you and a member of the private sector whom you referred to earlier this week as your "friend". Who is this person? What is their position exactly? When and how often have you met with this person? Were any other members of the PMPRB, such as senior staff, present? If so, who was present? Has this person, or other persons in the private sector, assisted in developing the positions you've taken in the course of the last 1-2 weeks?

I am genuinely sorry to be raising these questions. But I feel compelled to do so in light of this turn of events.

Matthew

Matthew Herder, JSM LLM
CIHR-PHAC Chair in Applied Public Health

Director, Health Law Institute, Schulich School of Law
Associate Professor, Department of Pharmacology
Faculties of Medicine and Law, Dalhousie University
Email: Matthew.Herder@Dal.ca
Twitter: @cmrherder

From: Melanie Bourassa Forcier <melanie.forcier@gmgrb-cegmb.gc.ca>
Sent: December 3, 2022 2:57 PM
To: C Kobernick <carolynkobernick@gmail.com>; Isabel Jaen Raasch <isabel.jaenraasch@gmgrb-cegmb.gc.ca>
Cc: Ingrid Sketris <I.ogrid.Sketris@Dal.Ca>; Matthew Herder <Matthew.Herder@Dal.Ca>; Douglas Clark <douglas.clark@gmgrb-cegmb.gc.ca>; Sherri Wilson <Sherri.Wilson@gmgrb-cegmb.gc.ca>
Subject: Re: A/Chairperson's decision on consultation period - PRIVILEGED

Thank you Isabel.

According to subsection 96(5) of the *Patent Act*, the Board is to consult with the Minister and representatives of the pharmaceutical industry.

In his letter of November 28, 2022, the Minister clearly indicated that the Board's consultation process did not respect his right to be consulted under this subsection, nor the right of the pharmaceutical industry, which has clearly expressed misunderstanding about some aspects of our draft guidelines.

Failure to properly fulfill our obligations under the Act, which means holding a proper consultation period allowing us to hear and appreciate the issues raised by all the players, exposes us in my opinion to an application for judicial review by the department, which has informed us that they have not been adequately consulted. Furthermore, the letter I sent to the department, the one drafted for the most part by Doug and the staff (except for the last paragraph, which I wrote), clearly indicates that we did not meet with departmental officials.

The failure to extend (or suspend) the consultation period but then agree to meet with the industry after this period about our guidelines also exposes us, in my opinion, to a challenge that the rules of procedural fairness were not followed with respect to the other players.

That is why I proposed to the Board members to extend or suspend the consultation period in order to comply with our legal obligations. My understanding of the doctrine is that a consultation process must be meaningful, not simply one involving a transfer of information and a compilation of responses.

Section 93 of the *Patent Act* includes a non-exhaustive list of the Chairperson's responsibilities, given the use of the word "including." The Chairperson's duties also include overseeing the conduct of the work of the Board.

Subsection 96(5) of the *Patent Act* includes an obligation for the Board. This is a prescriptive provision. This section does not confer decision-making authority on the Board as a whole with respect to the administrative conduct of consultations. In my view, this is a responsibility of the Chairperson.

For a matter of a few days or even weeks, the Board is exposing itself to significant legal risks if it were to (1) end the consultation period on December 5, while some stakeholders believe they have not been sufficiently consulted and (2) meet with the industry following this consultation, thereby directly violating the rules of equity and fundamental justice. For this reason, if the Board truly wishes to maintain its position, it would be wise to seek an outside legal opinion.

I appreciate that we are currently experiencing an unpleasant and difficult conflict, but to ensure that we conduct our affairs properly in compliance with the legislation applicable to us, I believe it is important to seek an outside opinion prior to the end of the consultation period.

Given my legal responsibility (93(2)) with regard to the duties of Board staff, Isabelle, I would appreciate it if you could inform me of the process for seeking an independent, outside legal opinion on whether or not subsection 93(2) PA takes precedence over subsection 96(5) PA as well as on the scope of the Board's duty to consult under subsection 96(5) PA. The correspondence with both IMC and the department will need to be shared.

I am aware that time is short, but we cannot take legal risks.

Thank you
Mélanie

From: C Kobernick <carolynkobernick@gmail.com>
Sent: 3 décembre 2022 09:29
TO: Isabel Jaen Raasch <isabel.jaenraasch@P.mP.rb-ceP.mb.gc.ca>
Cc: Melanie Bourassa Forcier <melanie.forcier@P.mP.rb-ceP.mb.gc.ca>; Ingrid Sketris <!.!Jgrid.Sketris@Dal.Ca>; Matthew Herder <Matthew.Herder@Dal.Ca>; Douglas Clark <douglas.clark@P.mP.rb-ceP.mb.gc.ca>; Sherri Wilson <Sherri.Wilson@RmP.rb-ceP.mb.gc.ca>
Subject: Re: A/Chairperson's decision on consultation period - PRIVILEGED

Thank you Isabel for your legal advice. It is very timely and helpful.

Carolyn
647 987-8555

On Dec 2, 2022, at 6:12 PM, Isabel Jaen Raasch <isabel.jaenraasch@P.mRrb-ceP.mb.gc.ca> wrote:

As per your request please find the attached privileged memorandum.

From: Melanie Bourassa Forcier <melanie.forcier@RmRrb-ceP.mb.gc.ca>
Sent: December 2, 2022 4:59 PM
To: Isabel Jaen Raasch <isabel.jaenraasch@P.mRrb-ceRmb.gc.ca>; Ingrid Sketris <Ingrid.Sketris@Dal.Ca>; C Kobernick <carolynkobernick@gmail.com>; Matthew Herder <Matthew.Herder@Dal.Ca>
Cc: Douglas Clark <douglas.clark@P.mRrb-ceP.mb.gc.ca>; Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>
Subject: Re: A/Chairperson's decision on consultation period - PRIVILEGED

Thank you Isabel. I appreciate.

Mélanie

From: Isabel Jaen Raasch <isabel.jaenraasch@RmRrb-ceP.mb.gc.ca>
Sent: December 2, 2022 14:16
TO: Melanie Bourassa Forcier <melanie.forcier@Rmwb-ceRmb.gc.ca>; Ingrid Sketris <!.IJgrid.Sketris@Dal.Ca>; C Kobernick <carolynkobernick@gmail.com>; Matthew Herder <Matthew.Herder@Dal.Ca>
Cc: Douglas Clark <douglas.clark@pmprb-cepmb.gc.ca>; Sherri Wilson <Sherri.Wilson@RmRrb-ceP.mb.gc.ca>
Subject: RE: A/Chairperson's decision on consultation period - PRIVILEGED

Thank you for reaching out to me on this discussion. I take this to mean that you are requesting legal advice on the matter of whether s. 93(2) of the Patent Act supersedes s. 96 of the Patent Act. As such, I will prepare a memorandum of legal advice asap.

Isabel

From: Melanie Bourassa Forcier <melanie.forcier@Rmwb-ceRmb.gc.ca>
Sent: December 2, 2022 2:07 PM
To: Ingrid Sketris <!.IJgrid.Sketris@Dal.Ca>; C Kobernick <carolynkobernick@gmail.com>; Matthew Herder <Matthew.Herder@Dal.Ca>
Cc: Douglas Clark <douglas.clark@pmprb-cepmb.gc.ca>; Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>; Isabel Jaen Raasch <isabel.jaenraasch@RmRrb-ceP.mb.gc.ca>
Subject: Re: A/Chairperson's decision on consultation period

Dear Board member,

As for me, I am referring to the Patent Act (93(2) PA). Please tell me which legislative provision you are relying on. I am cc'ing Isabel, PMPRB counsel.

Thank you
Mélanie Bourassa Forcier, Acting Chairperson

From: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>
Sent: December 2, 2022 12:59
TO: Ingrid Sketris <Ingrid.Sketris@Dal.Ca>; C Kobernick <carolv.nkobernick@gmail.com>; Matthew Herder <Matthew.Herder@Dal.Ca>
Cc : Douglas Clark <douglas.clark@pmprb-cepmb.gc.ca>; Sherri Wilson <Sherri.Wilson@Rmwb-ceRmb.gc.ca>
Subject: A/Chairperson's decision on consultation period

Dear Board members,

As I mentioned earlier, I have noted your desire to end the consultation period on the guidelines on the scheduled date, December 5.

As you know, it is essential for me to take more time to better understand the misunderstandings of the stakeholders affected by our future guidelines.

Considering this situation and considering the fact that under the Act, I am responsible for the conduct of the work of the Board, I have decided to suspend the consultation period to allow us to meet with the stakeholders who have expressed misunderstandings to date and to hear their proposals.

I would like this decision to be made public today. Sherri: please send me the announcement of this decision once it is online. Please also (1) prepare a letter for IMC advising them of this and to propose a meeting on December 13 in our offices (with Doug and/or Tanya) and (2) advise Mr. Lucas of this decision.

Thank you and I am counting on your cooperation.

Mélanie Bourassa Forcier, A/Chairperson
<PRIVILEGED preliminary memo to Board re. s 93 and 96 Dec 2_2022.docx>

B5

Re: Health Canada's submission on PMPRB guidelines consultation

Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>
Mon 2022-12-05 1:29 PM
To: Matthew Herder <Matthew.Herder@Dal.Ca>;Ingrid Sketris <Ingrid.Sketris@Dal.Ca>;C Kobernick <carolynkobernick@gmail.com>

Hi

1. I'm not sure what to referring to when you mention that we have to be more transparent...could you please specify?
4.1 don't see how taking the time to meet ait stakeholders sends a negative message to patients and consumers...On the contrary, I think that it sends the message that we take the required time to make sure that our guidelines will stand any judicial challenge
3. Request made by the minister: Eric says in his email: "We sent this submission via the PMPRB portal earlier this morning." I suppose that this is thus public (or will be soon - I might be wrong)

My understanding, from our past meetings, is that our deliberations had to be confidential, no staff being present.

If you want to discuss next steps, following your (and the one of other board members - Carolyn and Ingrid) decision if it stays the same, I do not think that today is a good day. I think that both the staff and I have to take a step back. There is not reason to rush such meeting.

Mel

From: Matthew Herder <Matthew.Herder@Dal.Ca>
Sent: December 5, 2022 12:16
TO: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>; Ingrid Sketris <Ingrid.Sketris@Dal.Ca>; C Kobernick <carolynkobernick@gmail.com>
Subject: Re: Health Canada's submission on PMPRB guidelines consultation

Hi again,

I'll leave it to Carolyn and Ingrid to respond about whether they are comfortable meeting with only Sherri this afternoon. I will go with what the majority of the Board decides in terms of whether to meet or not. Personally, I think other staff should be present as a major part of the challenge we now find ourselves in derives from the limited or non-transparent information sharing. I would feel more comfortable if everything is more transparent within the Board + with staff moving forward. Again, though I will defer to the majority about whether to proceed with Sherri and no other staff this afternoon.

For the record, I do *not* think dialogue with industry is impossible. We have tried to have that dialogue repeatedly throughout the pandemic, including during these most recent consultations. And we may still

decide tare-open consultations rather than implement the guidelines on January 1st. I remain open to that possibility, which is why I want to meet on the 13th after having the opportunity to review and reflect upon submissions from all stakeholders. I really think we are losing sight of what I think of as our main stakeholder, namely patients and consumers of patented medicines more broadly.

I appreciate that saying nothing sends a message. But we can relay to Eric and others at Health that we plan to assess and decide next steps on the 13th. The same can be communicated to IMC. But we have to bear in mind that, suspending or extending the consultations also potentially sends a message to patients that we are failing to fulfil our consumer protection mandate.

Last, can you clarify what you mean when you say that the letter of the Minister is "now available to the public"? Do you mean that it could be public, if someone was to ATIP it? Or that it has been publicly released already in some way?

Thank you,
Matthew

Matthew Herder, JSM LLM
CIHR-PHAC Chair in Applied Public Health
Director, Health Law Institute, Schulich School of Law
Associate Professer, Department of Pharmacology
Faculties of Medicine and Law, Dalhousie University
Email: Matthew.Herder@Dal.ca
Twitter: @cmrherder

From: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>
Sent: December 5, 2022 12:58 PM
To: Matthew Herder <Matthew.Herder@Dal.Ca>; Ingrid Sketris <Ingrid.Sketris@Dal.Ca>; C Kobernick <carolynkobernick@gmail.com>
Subject: Re: Health Canada's submission on PMPRB guidelines consultation

Hello Matthew

Thank you for your answer. For the past few days I have been facing personal attacks and people questioning my judgment, my independence and my impartiality because it seems important to me to respond positively to the requests of the Minister of Health and of IMC, which is to take more time to hear the stakeholders, this, in order to properly fulfill our obligation to consult.

To do otherwise, to continue by being silent following these demands, sends, in my opinion, a message of confrontation with which I am not comfortable. To do otherwise, to go against the minister's request which is now available to the public, makes me extremely uncomfortable.

We could indeed do nothing and resume consultations later. lt's all in the message we want to send. Do nothing, say nothing sends out the message that I'm not comfortable with. Taking the time to hear and

understand the different perspectives has always been extremely important to me.

I can clearly see that many consider that a dialogue is impossible with the industry. On the other hand, I believe that our mandate, as members of the PMPRB, is nevertheless to be open to this dialogue and to not assume that we have fulfilled our obligations. Once again, this does not commit us to anything as to when our guidelines will be implemented or as to the content of the guidelines.

Now, I admit that I hesitate to hold the meeting if your decision is firm. I think we are at a point where the staff and I need to take a step back.

If you are prepared to re-discuss your decision (Matthew, Carolyn and Ingrid) taken yesterday morning, then I believe that these are "board's deliberations" which must be confidential. At most Sherri can be present.

I am sincerely affected by the scale of the crisis, all of this because I expressed my difference in interpretation of our obligation to consult.

Considering all this, I would appreciate it if each of you could let me know if you would like this meeting at 2:00 p_m.

Thanks
Melanie

From: Matthew Herder <Matthew.Herder@Dal.Ca>
Sent: December 5, 2022 11:09
TO: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>; Ingrid Sketris <Ingrid.Sketris@Dal.Ca>; C Kobernick <carolynkobernick@gmail.com>
Subject: Re: Health Canada's submission on PMPRB guidelines consultation

Thank you for this information, Melanie.

Part of why I think staff must be present if we meet later today is to have a better understanding of what our options will be once the consultation closes at the end of today. To my mind, it is entirely open to us to decide (after we meet on the 13th) to re-open the consultations if we think that is best. Staff can advise us about how that would work. I don't think we need to decide anything today, in part, because we - as a board - haven't yet been briefed on what all the concerns that stakeholders have raised are.

That statement in the letter from Eric stands out to me. How does Health know what these questions are? We haven't yet received any submission from IMC yet.

I continue to think we should look at the submissions that have been submitted in detail, hear from staff, and discuss in depth next week.

Sincerely,

Matthew

Get Outlook for iOS

From: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>
Sent: Monday, December 5, 2022 11:59:22 AM
To: Ingrid Sketris <Ingrid.Sketris@Dal.Ca>; Matthew Herder <Matthew.Herder@Dal.Ca>; C Kobernick <carolynkobernick@gmail.com>
Subject: RE: Health Canada's submission on PMPRB guidelines consultation

FYI.

Mélanie

From: Belair, Eric (HC/SC) <Eric.Belair@hc-sc.gc.ca>
Sent: December 5, 2022 10:28
TO: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>; Douglas Clark <douglas.clark@pmprb-cepmb.gc.ca>
Subject: RE: Health Canada's submission on PMPRB guidelines consultation

Please use this version (we removed "draft" from the document title).

Eric Bélair
Associate Assistant Deputy Minister / Sous-ministre adjoint délégué
Strategic Policy Branch/ Direction générale de la politique stratégique
Health Canada/ Santé Canada
343-552-1733
eric.belair@hc-sc.gc.ca

From: Belair, Eric (HC/SC)
Sent: 2022-12-05 10:02 AM
To: melanie.forcier@pmprb-cepmb.gc.ca; Douglas Clark <douglas.clark@pmprb-cepmb.gc.ca>
Subject: Health Canada's submission on PMPRB guidelines consultation

Hello Mélanie and Doug,

Attached please see a courtesy copy of Health Canada's submission on the PMPRB consultations on the guidelines. We sent this submission via the PMPRB portal earlier this morning.

Regards,

Eric

Eric Bélair
Associate Assistant Deputy Minister / Sous-ministre adjoint délégué
Strategic Policy Branch/ Direction générale de la politique stratégique
Health Canada/ Santé Canada
343-552-1733
eric.belair@hc-sc.gc.ca

C1

Fw: PRIVILEGED - regarding your request for legal advice on confidentiality and dissent

Matthew Herder <Matthew.Herder@Dal.Ca>
Mon 2022-12-19 11:53 AM
To: sherri.wilson@pmprb-cepmb.gc.ca <Sherri.Wilson@pmprb-cepmb.gc.ca>

Matthew Herder, JSM LLM
CIHR-PHAC Chair in Applied Public Health
Director, Health Law Institute, Schulich School of Law
Associate Professor, Department of Pharmacology
Faculties of Medicine and Law, Dalhousie University
Email: Matthew.Herder@Dal.ca
Twitter: @cmrherder

From: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>
Sent: December 5, 2022 3:37 PM
To: Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>
Cc: Matthew Herder <Matthew.Herder@Dal.Ca>; Ingrid Sketris <Ingrid.Sketris@Dal.Ca>; Matthew Herder <matthew.herder@pmprb-cepmb.gc.ca>; Carolyn Kobernick <carolyn.kobernick@pmprb-cepmb.gc.ca>; Ingrid Sketris <ingrid.sketris@pmprb-cepmb.gc.ca>
Subject: Re: PRIVILEGED - regarding your request for legal advice on confidentiality and dissent

Dear Sherri

My understanding is that Mattew is not available after 4 and, on my side, I'm not available between 2h30 and 4.

I need to know if Carolyn and Ingrid decide to go against the minister's demand submitted this morning on our website. If the answer is no then we'll have to inform the public that our consultations are either suspended to extended. Mat confirms his yesterday's decision not to extend the consultation period.

As for the rest of the crisis we can adress it in a meeting later this week or next week.

Thank you very much
Mélanie

From: Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>
Sent: December 5, 2022 14:29
TO: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>
Cc: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>; Matthew Herder <Matthew.Herder@Dal.Ca>; Ingrid Sketris <Ingrid.Sketris@Dal.Ca>; Matthew Herder <matthew.herder@pmprb-cepmb.gc.ca>; Carolyn Kobernick <carolyn.kobernick@pmprb-cepmb.gc.ca>; Ingrid Sketris <ingrid.sketris@pmprb-

cepmb.gc.ca>; Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>
Subject: RE: PRIVILEGED - regarding your request for legal advice on confidentiality and dissent

Dear Melanie,

In light of the Board members requesting time to review the latest legal opinion provided earlier today, would you like me to schedule a meeting with yourself and the other Board members later today or another day this week?

Please advise and I will send out the Teams invitation.

Best regards,

Sherri Wilson
Director / Directrice
Board Secretariat / Secrétariat du Conseil
Patented Medicine Prices Review Board/ Conseil d'examen du prix des médicaments brevetés
Government of Canada / Gouvernement du Canada
sherri.wilson@Q!l!P-J:Q l2ffi.Q9 , Cell: 613-850-1278

From: C Kobernick <carolynkobernick@gmail.com>
Sent: December 5, 2022 1:56 PM
To: Isabel Jaen Raasch <isabel.jaenraasch@pmprb-cepmb.gc.ca>
Cc: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>; Matthew Herder <Matthew.Herder@Dal.Ca>; Ingrid Sketris <Ingrid.Sketris@Dal.Ca>; Matthew Herder <matthew.herder@pmprb-cepmb.gc.ca>; Carolyn Kobernick <carolyn.kobernick@pmprb-cepmb.gc.ca>; Ingrid Sketris <ingrid.sketris@pmprb-cepmb.gc.ca>; Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>; Douglas Clark <douglas.clark@pmprb-cepmb.gc.ca>
Subject: Re: PRIVILEGED - regarding your request for legal advice on confidentiality and dissent

Thank you very much Isabel. This is very helpful. I would like to take some time to review this opinion, as do Matt and Ingrid.

Regards,

Carolyn
647 987-8555

D1

Fwd: lobbying registry

.. ·;.corn>

Wed 2023-05-03 10:14 PM

To: Matthew Herder <Matthew.Herder@dal.ca>

Here you go. You have to really pay attention not to double count meetings. I count 13 meetings between industry and the Minister or his office but Don seems to think there are 15, so am not sure about my math. That doesn't include all the other meetings with Health Canada officials.

---------- Forwarded message ---------

Oin>

Date: Fri, Apr 14, 2023 at 10:38AM
Subject: lobbying registry
To:

Lobbying activity: pharma and HC between October and December 2022, pharma industry groups at the top (there was also lobbying activity by individual pharma companies, namely GSK, Abbvie, Hoffman La Roche, and Janssen and Johnson&Johnson, but it is harder to assume that it is PMPRB-related although it could be, so I've added it at the bottom:

Innovative Medicines Canada / Médicaments novateurs Canada
In-house Organization
Designated Public Office Holders:
- **Sandenga Yeba,** Senior Policy Advisor, Minister's Office | Health Canada (HC)
- **Jean-Sebastien Bock,** Director of Policy, Office of the Minister of Health | Health Canada (HC)
- **Jamie Kippen,** Chief of Staff to the Minister | Health Canada (HC)

Communication Date: **2022-12-01**

Life Sciences Ontario
Consultant: **Philip Delistoyanov, 3Sixty Public Affairs**
Designated Public Office Holders:
- **Sandenga Yeba,** Senior Policy Advisor, Minister's Office | Health Canada (HC)

Communication Date: **2022-11-18**

Life Sciences Ontario (LSO)
In-house Corporation
Designated Public Office Holders:
- **Sandenga Yeba,** Senior Policy Advisor, Minister's Office | Health Canada (HC)

Communication Date: **2022-11-18**

Life Sciences Ontario
Consultant: **WILLIAM DEMPSTER, 3Sixty Public Affairs Inc.**
Designated Public Office Holders:
- **Sandenga Yeba,** Senior Policy Advisor, Minister's Office | Health Canada (HC)

Communication Date: **2022-11-18**

Life Sciences Ontario

Consultant: **WILLIAM DEMPSTER, 3Sixty Public Affairs Inc.**
Designated Public Office Holders:

- **Michelle Boudreau,** Executive Director, Office of Pharmaceutical Management Strategies | Health Canada (HC)
- **Samir Khan,** Director, Office of Pharmaceutical Management Strategies | Health Canada (HC)

Communication Date: **2022-11-04**

Life Sciences Ontario (LSO)

In-house Corporation
Designated Public Office Holders:

- **Michelle Boudreau,** Executive Director, Office of Pharmaceutical Management Strategies | Health Canada (HC)
- **Samir Khan,** Director, Office of Pharmaceutical Management Strategies | Health Canada (HC)

Communication Date: **2022-11-04**

Life Sciences Ontario

Consultant: **Philip Delistoyanov, 3Sixty Public Affairs**
Designated Public Office Holders:

- **Michelle Boudreau,** Executive Director, Office of Pharmaceutical Management Strategies | Health Canada (HC)
- **Samir Khan,** Director, Office of Pharmaceutical Management Strategies | Health Canada (HC)

Communication Date: **2022-11-04**

Innovative Medicines Canada / Médicaments novateurs Canada

In-house Organization
Designated Public Office Holders:

- **Stephen Lucas,** Deputy Minister of Health | Health Canada (HC)

Communication Date: **2022-10-21**

Pharma companies:

GlaxoSmithKline

In-house Corporation
Designated Public Office Holders:

- **Sandenga Yeba,** Senior Policy Advisor, Minister's Office | Health Canada (HC)
- **Jean-Sebastien Bock,** Director of Policy, Office of the Minister of Health | Health Canada (HC)

Communication Date: **2022-12-01**

GlaxoSmithKline Inc.

Consultant: **John Delacourt, Counsel Public Affairs**
Designated Public Office Holders:

- **Sandenga Yeba,** Senior Policy Advisor, Minister's Office | Health Canada (HC)
- **Jean-Sebastien Bock**, Director of Policy, Office of the Minister of Health | Health Canada (HC)

Communication Date: **2022-12-01**

GlaxoSmithKline Inc.

Consultant: **Sheamus Murphy, Counsel Public Affairs Inc.**
Designated Public Office Holders:

- **Jean-Sebastien Bock,** Director of Policy, Office of the Minister of Health | Health Canada (HC)
- **Sandenga Yeba,** Senior Policy Advisor, Minister's Office | Health Canada (HC)

Communication Date: **2022-12-01**

Hoffmann-La Roche Limited

In-house Corporation
Designated Public Office Holders:

- **Sandenga Yeba,** Senior Policy Advisor, Minister's Office | Health Canada (HC)

Communication Date: **2022-12-01**

AbbVîe Corporation

In-house Corporation
Designated Public Office Holders:

- **Michelle Boudreau,** Executive Director, Office of Pharmaceutical Management Strategies | Health Canada (HC)
- **Eric Belair,** Associate Assistant Deputy Minister, Strategic Policy Branch | Health Canada (HC)

Communication Date: **2022-11-30**

GlaxoSmithKlîne Consumer Healthcare ULC

Consultant: **Ashley Brambles, Edelman Global Advisory / Ashley M Brambles**
Designated Public Office Holders:

- **Jamie Kippen,** Chief of Staff, Minister's Office | Health Canada (HC)
- **Sandenga Yeba,** Senior Policy Advisor, Minister's Office | Health Canada (HC)

Communication Date: **2022-11-23**

Johnson & Johnson Inc.

In-house Corporation
Designated Public Office Holders:

- **Eric Costen,** Senior Assistant Deputy Minister, Strategic Policy Branch ! Innovation, Science and Economie Development Canada (ISED)
- **Eric Belair,** Associate Deputy Minister | Health Canada (HC)

Communication Date: **2022-11-22**

Janssen Inc.

In-house Corporation
Designated Public Office Holders:

- **Eric Belair,** Associate Assistant Deputy Minister, Strategic Policy Branch | Health Canada (HC)
- **Eric Costen,** Senior Assistant Deputy Minister ! Innovation, Science and Economie Development Canada (ISED)

Communication Date: **2022-11-22**

AstraZeneca Canada Inc.

In-house Corporation
Designated Public Office Holders:

- **Sandenga Yeba,** Senior Policy Advisor, Minister's Office | Health Canada (HC)

Communication Date: **2022-11-18**

GlaxoSmithKline Consumer Healthcare ULC
Consultant: **Ashley Brambles, Edelman Global Advisory / Ashley M Brambles**
Designated Public Office Holders:

- **Sandenga Yeba,** Senior Policy Advisor, Minister's Office | Health Canada (HC)
- **Jamie Kippen,** Chief of Staff to the Minister, Minister's Office | Health Canada (HC)

Communication Date: **2022-11-18**

Johnson & Johnson Inc.
In-house Corporation
Designated Public Office Holders:

- **Stefania Trombetti,** Assistant Deputy Minister, Regulatory Operations and Enforcement | Health Canada (HC)

Communication Date: **2022-11-17**

Johnson & Johnson Inc.
In-house Corporation
Designated Public Office Holders:

- **Stephen Lucas,** Deputy Minister | Health Canada (HC)
- **Jean-Yves Duclos,** Minister of Health | Health Canada (HC)

Communication Date: **2022-11-17**

Johnson & Johnson Inc.
In-house Corporation
Designated Public Office Holders:

- **Stefania Trombetti,** Assistant Deputy Minister, Regulatory Operations and Enforcement | Health Canada (HC)

Communication Date: **2022-11-16**

Johnson & Johnson Inc.
In-house Corporation
Designated Public Office Holders:

- **Jean-Yves Duclos,** Minister of Health | Health Canada (HC)

Communication Date: **2022-11-16**

Johnson & Johnson Inc.
In-house Corporation
Designated Public Office Holders:

- **Jamie Kippen,** Chief of Staff, Minister's Office | Health Canada (HC)

Communication Date: **2022-11-16**

Johnson & Johnson Inc.
In-house Corporation
Designated Public Office Holders:

- **Stefania Trombetti,** Assistant Deputy Minister, Regulatory Operations and Enforcement | Health Canada (HC)

Communication Date: **2022-11-16**

Johnson & Johnson Inc.
In-house Corporation
Designated Public Office Holders:

- **Jean-Yves Duclos,** Minister of Health | Health Canada (HC)

Communication Date: **2022-11-16**

Johnson & Johnson Inc.
In-house Corporation
Designated Public Office Holders:

- **Jamie Kippen,** Chief of Staff, Minister's Office | Health Canada (HC)

Communication Date: **2022-11-16**

AbbVie Corporation
In-house Corporation
Designated Public Office Holders:

- **Michelle Mujoomdar**, Director, Specialty Pharmaceuticals, Office of Pharmaceutical Management Strategies | Health Canada (HC)
- **Michelle Boudreau,** Executive Director, Office of Pharmaceutical Management Strategies | Health Canada (HC)
- **Samir Khan,** Director, Policy Division | Health Canada (HC)
- **Daniel MacDonald,** Director | Health Canada (HC)

Communication Date: **2022-11-07**

Johnson & Johnson Inc.
In-house Corporation
Designated Public Office Holders:

- **Jean-Yves Duclos**, Minister of Health | Health Canada (HC)
- **Stephen Lucas,** Deputy Minister | Health Canada (HC)

Communication Date: **2022-11-03**

GlaxoSmithKline Consumer Healthcare ULC
Consultant: **Pierre Cyr, Edelman Global Advisory** .
Designated Public Office Holders:

- **Jamie Kippen,** Chief of Staff, Minister's Office | Health Canada (HC)

Communication Date: **2022-11-02**

GlaxoSmithKline
In-house Corporation
Designated Public Office Holders:

- **Susan Fitzpatrick**, Head of the Canada Drug Agency Transition Office | Health Canada (HC)

Communication Date: **2022-10-27**

AbbVie Corporation

In-house Corporation
Designated Public Office Holders:

- **Sandenga Yeba,** Senior Policy Advisor, Minister's Office | Health Canada (HC)

Communication Date: **2022-10-26**

GlaxoSmithKline Consumer Healthcare ULC

Consultant: **Ashley Brambles, Edelman Global Affairs / Ashley M Brambles**
Designated Public Office Holders:

- **Jamie Kippen,** Chief of Staff, Minister's Office | Health Canada (HC)

Communication Date: **2022-10-24**

GlaxoSmithKline Consumer Healthcare ULC

Consultant: **Pierre Cyr, Edelman Global Advisory**
Designated Public Office Holders:

- **Jamie Kippen,** Chief of Staff, Minister's Office | Health Canada (HC)

Communication Date: **2022-10-24**

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Thread

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PMPRBWatch
@PMPRB_Watch

The snow is falling up in Ottawa. Are some #PMPRB types now finding themselves out in the snow? Is anyone close to 333 Laurier Avenue West to advise if one or more folks have left the building with bankers' boxes?

3:15 PM· Feb 21, 2023 · **1,125** Views

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Tweet your reply **Rcply**

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PMPRB Watch @PMPRB_Watch · Feb 24
canada.ca/en/patented-me...

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beth Vanstone @bethdenniss · Feb 21
lnquiringminds need to know!!

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Thread

Q

Matthew Herder
@cmrherder

0

On Monday I resigned from the PMPRB, Canada's drug pricing regulator. Here's why:

B

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10:22 AM· Feb 23, 2023 · **274K** Views

1lr1 View Tweet analytics

0 t1

Tweet your reply

Reply

Matthew Herder@cmrherder · Feb 24

Thanks everyone for the support. Vou can access a copy of my resignation letter here:

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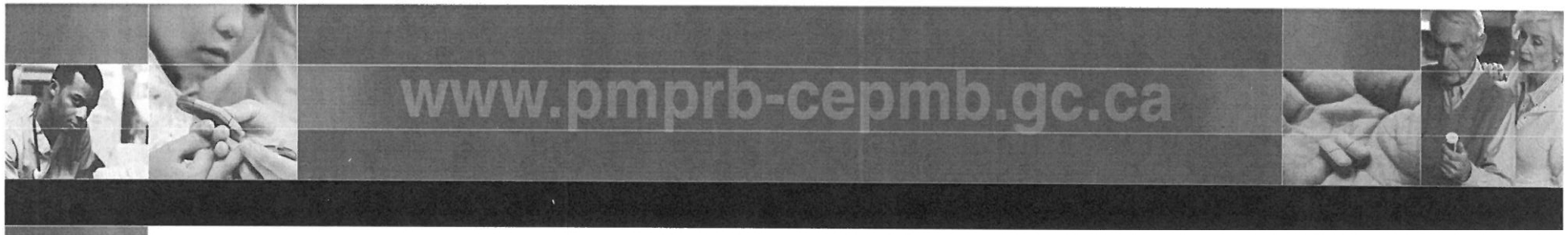
Patented Medicine Prices Review Board

Conseil d'examen du prix des médicaments brevetés

Canada



Patented Medicines Prices Review Board (PMPRB):

25 Years of Experience

Michelle Boudreau, Executive Director

Pricing and Reimbursement

Toronto, Ontario

June11,2012

Outline

- Overview of the PMPRB
- **PMPRB Price Tests**
- Canada Compared to the World
- Changes and Clarifications to Guidelines Since 2010
- Guidelines Monitoring and Evaluation Plan
- Regulatory Statistics
- Update on Hearings
- Looking Forward
- Annex

Overview of the PMPRB

- **Established in 1987 as consumer protection pillar via amendments to *Patent Act***
- **The PMPRB is an independent quasi-judicial body with a dual mandate:**
  - ***Regulatory:*** To ensure that prices charged by patentees for patented medicines sold in Canada are not excessive
  - ***Reporting:*** To report on pharmaceutical trends of all medicines and on R&D spending by pharmaceutical patentees
- **Jurisdiction**
  - Regulate prices patentees charge (i.e. factory-gate price) for patented drug products sold in Canada, to wholesalers, hospitals or pharmacies, for human and veterinary use

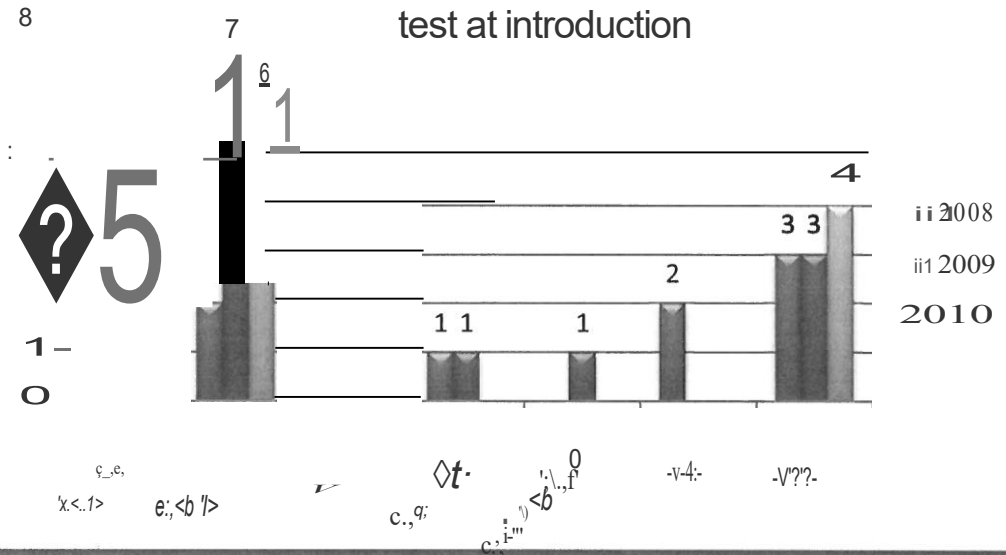
PMPRB Price Tests - Therapeutic Level

- **Blend of Therapeutic Improvement and International Reference Pricing**
- **Recognize incremental pharmaceutical innovation**
  - At introduction, price premium aligned with degree of therapeutic improvement:
    - Four new levels of therapeutic improvement:
      1) Breakthrough - Median of International Price Comparison (MIPC)
      2) Substantial Improvement - Higher of top of Therapeutic Glass Comparison (TCC) and the MIPC
      3) Moderate Improvement - Higher of mid-point between top of TCC test and the MIP, and top of TCC *(primary & secondary factors app/y here)*
      4) SlighUNo Improvement - Top of TCC
  - **After introduction, monitor Average Transaction Price (ATP) relative to Non-Excessive Average Price (NEAP), subject to CPI based limit**

PMPRB Price Tests - International Referencing

- **Reference pricing at introduction and for existing drugs based on 7 comparator COUntries** - France, Germany, Italy, Sweden, Switzerland, UK, and US
  - Policy changes in these countries could impact prices in Canada
- **Over last three years, Germany has most often been the highest referenced price for PMPRB price tests, followed by US**
  - Recent cost containment measures by refêrence countries may lead to lower prices in Canada (e.g., Germany)

Frequency in setting Highest International Price Comparison test at introduction



Changes/Clarifications to Guidelines since 2010

Issue	Change/Clarification	When Change Made
Triggering Investigation	• Eliminated 5% investigation trigger at national level for existing patented drug products	May 2012
Offset Excess Revenues	• Replaced 3-year period to offset *de minimus* excess revenue with a VCU with requirement to offset in a timely manner	May 2012
Any Market	• Clarified that Any Market Price Review would not be applied retroactively	April 2012
DIP Methodology	• Pilot administration of the DIP methodology with streamlined processes developed with a working group • Recommendations of DIP working group accepted	April 2011 / February 2012
Existing drug products subsequently sold by another patentee	• Patented DINs acquired and sold by persons other than the initial patentee are bound to the Guidelines, and continue to be treated as an existing drug product (no change from earlier Guidelines)	January 2011

Changes/Clarifications to Guidelines since 2010 {cont'd)

Issue	Change/Clarification	When Change Made
Offset of Excess Revenue	▪ Clarified that prices of existing patented drug products are reviewed on an annual basis. Therefore, for Jan-June period: 1) Existing drug products will not be initially identified as "Does Not Trigger" 2) Board Staff will not calculate any offset	October 2010
Policy on Use of Non-Patented Comparator Drug Products in Price Tests	▪ price of relevant non-patented drug products included in the price tests, unless Board Staff conclude the price of the medicine is excessive, based on absence of competition or other market conditions	October 2010
1nternational Therapeutic Class Comparison Test (ITCC)	▪ Missing text inserted and description of ITCC test updated	April 2010

Guidelines Monitoring and Evaluation Plan (GMEP)

- **GMEP monitors and evaluates the application and impact of major changes to the Guidelines on an ongoing basis**
  - Ensures Guidelines remain relevant and effective
  - Addresses expectations of stakeholders
  - Uses bath qualitative and quantitative indicators
  - Allows Staff to provide annuai updates to the Board

Guidelines Monitoring and Evaluation Plan (GMEP) (cont'd)

Guideline Changes	Rationale for Change	Observations*
Overall Implementation		▪ Ongoing monitoring, evaluation, and resolution of issues ▪ Proactive outreach and education
New Levels of Therapeutic Improvement	▪ Recognizing incremental therapeutic innovation	▪ 19% of new drug products classified as *Moderate Improvement* ▪ (8 drug products based on seconda ctors)
Overall Restructuring of Price Tests	▪ Price premium to reflect therapeutic value	▪ 15% of new drug products classified as *Moderate Improvement* priced at premium (i.e. above what would have been allowed under old Guidelines)
DIP Methodology	▪ Avoid creating disincentives for offering benefits	▪ Since pilot, 58 successful DIP applications ▪ 45 Simple DIP applications ▪ 13 Regular DIP applications

*Results based on 2010 review

Guidelines Monitoring and Evaluation Plan {GMEP) {cont'd)

Guideline Changes	Rationale for Change	Observations
Wholesaler Exemption	▪ Recognizing the nature of generic drug product prices and rebates	▪ No cases where wholesaler Maximum Average Potential Price (MAPP) exceeded national MAPP ▪ 62 reviews completed. ▪ 60cases where Wholesaler Average Transaction Price (W-ATP) < Highest International Price Comparison Test (HIPC) ▪ 2 cases where HIPC could not be conducted
Use of Public Prices	▪ Ensure fair and predictable application of the Guidelines ▪ Achieve greater transparency	▪ 19 new drug products where Therapeutic Class Comparison (TCC) test conducted ▪ 11 cases public price of pivotai comparator < National Non-Excessive Average Price (N-NEAP) ▪ 6 cases pivotai comparator not patented ▪ AQPP and RAMQ most frequently cited sources
Any Market	▪ Ensuring that no sub-national market is paying excessive prices	▪ Monitoring only ▪ Will apply only ta drugs sold on or after January 2010 ▪ Applied at intro, and when investigation triggered

Regulatory Statistics

	2011	2010
New Drug Products Introduced	109	68
Number of Investigations	69	87

- Between 2000 and 2009, average of 86 new p tented drug products/year
- Of the 109 new drug products introduced in 2011:
  - 79% within Guidelines
  - 13% under investigation
  - 8% outside of Guidelines but do not trigger an investigation

Regulatory Statistics: Voluntary Compliance Undertakings and Board Orders - 2008-2012

Year	# VCUs	# Board Orders	Payments of Excess Revenues
2008	6	1	$25.5M
2009	10	1	$37.3M
2010	12	3	$13.2M
2011	9	1	$0.9M
2012 (May 31)	6	1	$12.1M

Update on Hearings

- **Matters before the Board**
  - Ongoing
    - Apotex Inc. (Failure to File)
    - Apo-Salvent CFC
  - Decisions pending
    - *Sandoz Inc.* (Failure to File)
    - *Pentace/ and Quadracel* (reconsideration of the reasons on remedy)
- **Matters before the Federal Court - Judicial Review**
  - *ratiopharm Inc.; ratio-Sa/butamol HFA; Copaxone Redetermination*
- **Matter decided by the Supreme Court of Canada in 2011**
  - *Celgene Corporation* (sale of Thalomid under Special Access Program)

Looking Forward

- **Ongoing engagement and outreach with stakeholders**
- **Continued focus on consumer protection while not creating disincentives to innovation/approaches that benefit consumers/payers**
- **Board adopted two priorities for 2012/13:**
  - alternate dispute resolution ("ADR") ta further enhance compliance
  - reducing regulatory burden
- **PMPRB response to recently conducted program evaluation**
- **Continuing engagement with int'l organizations/regulators**
- **Commitment to Guidelines that are responsive to a changing environment**

Thank you.

Merci.

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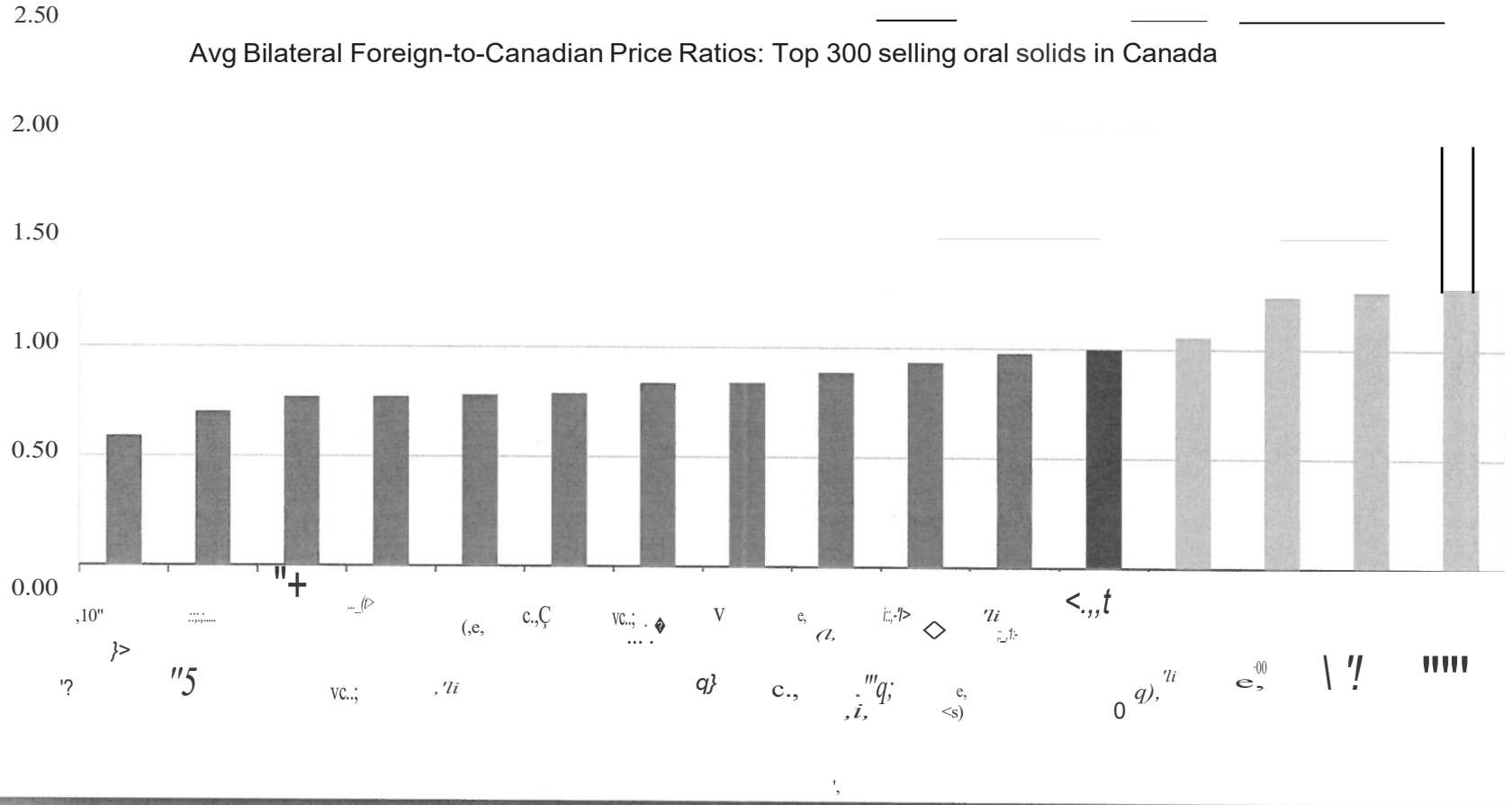
Twitter: **@PMPRB_CEPMB**

Annex

Pharmaceutical Trends Data

Canada Compared to the World

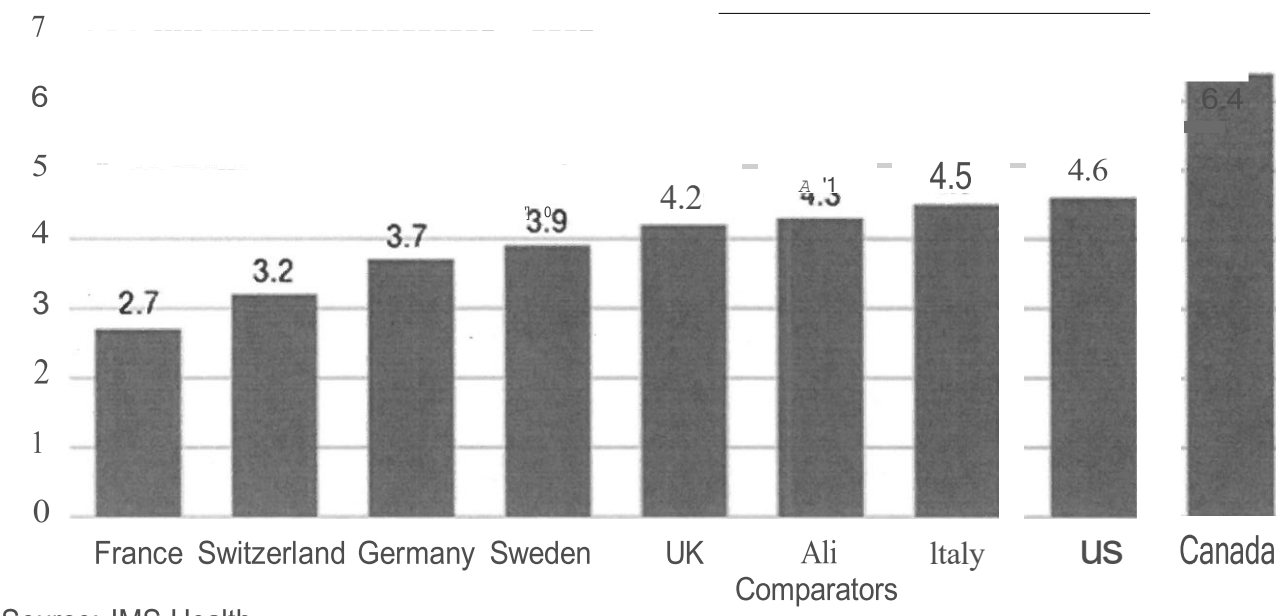
- **Canadian prices in 2010 comparatively higher than a number of OECD countries**



Canada Compared to the World {cont'd)

- **Growth in drug sales outpacing comparator countries**

Figure 15 Average Rate of Growth, Drug Sales, at Constant 2010 Market Exchange Rates by Country, 2005-2010

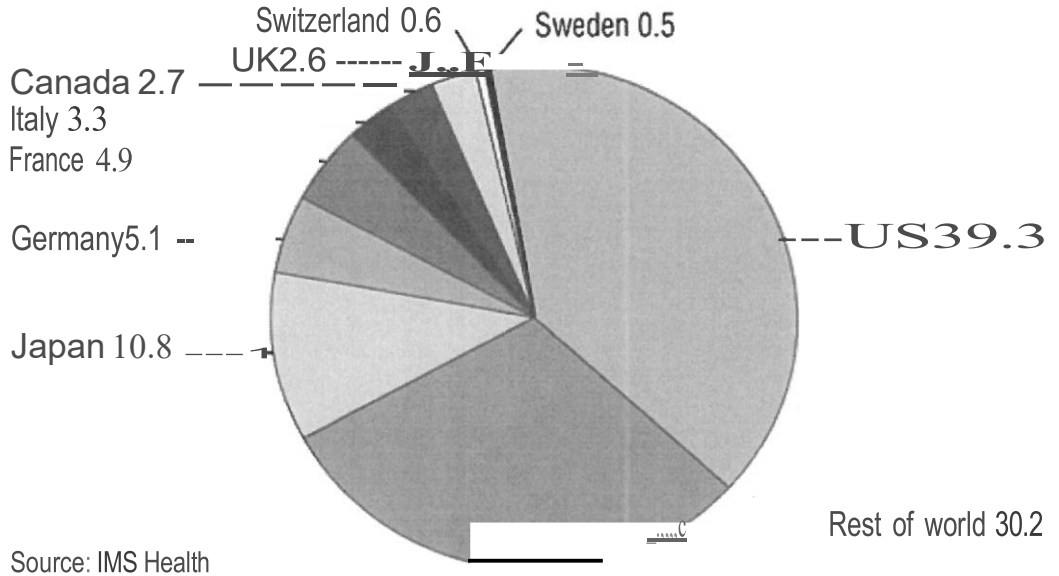


Source: IMS Health

Canada Compared to the World (cont'd)

- **In 2005 and 2010, Canadian drug sales accounted for 2.4% and 2.7%, respectively, of the global market**

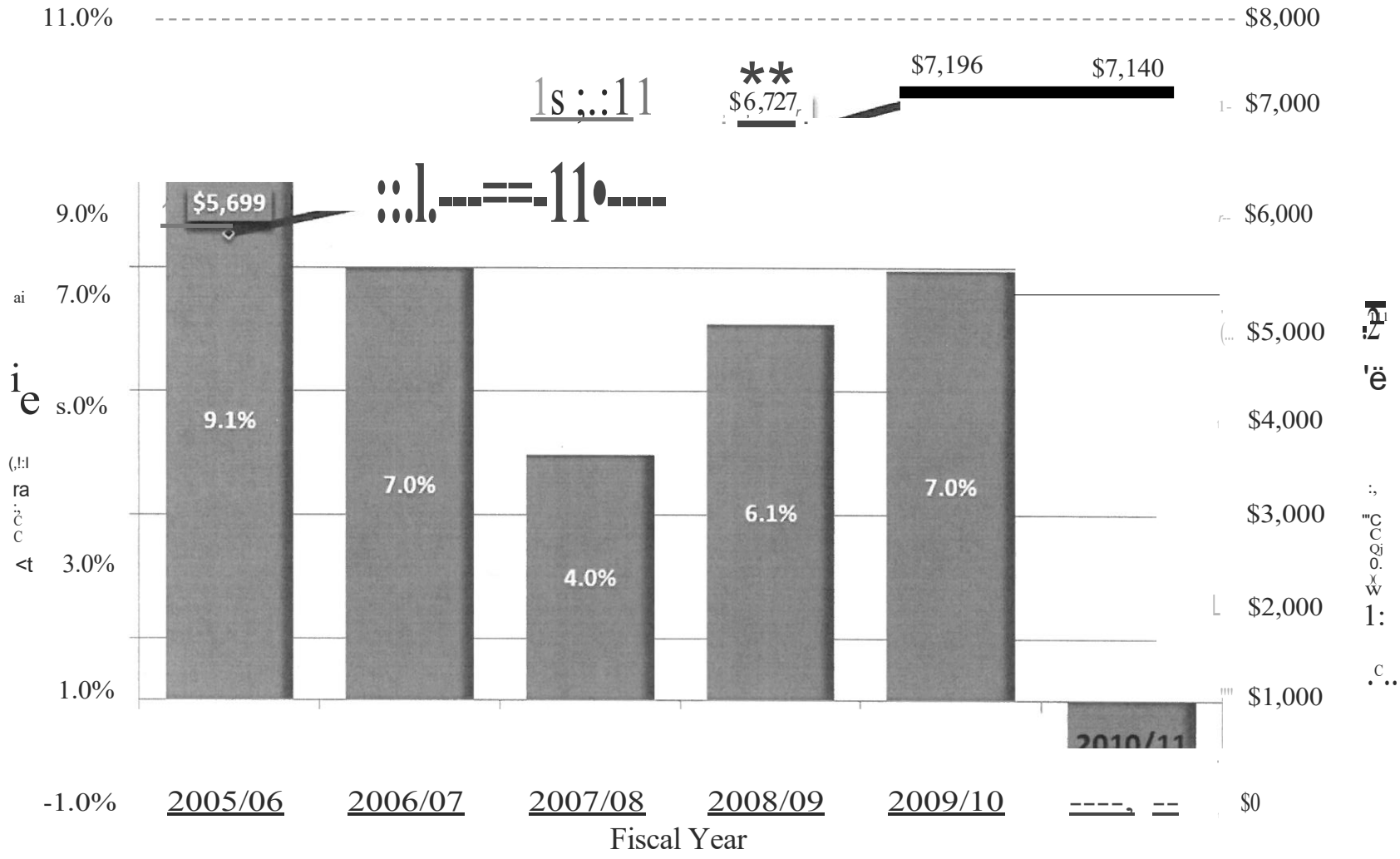
Figure 13 Distribution of Drug Sales Among Major National Markets, 2010



Source: IMS Health

- **Small, but a growing market**

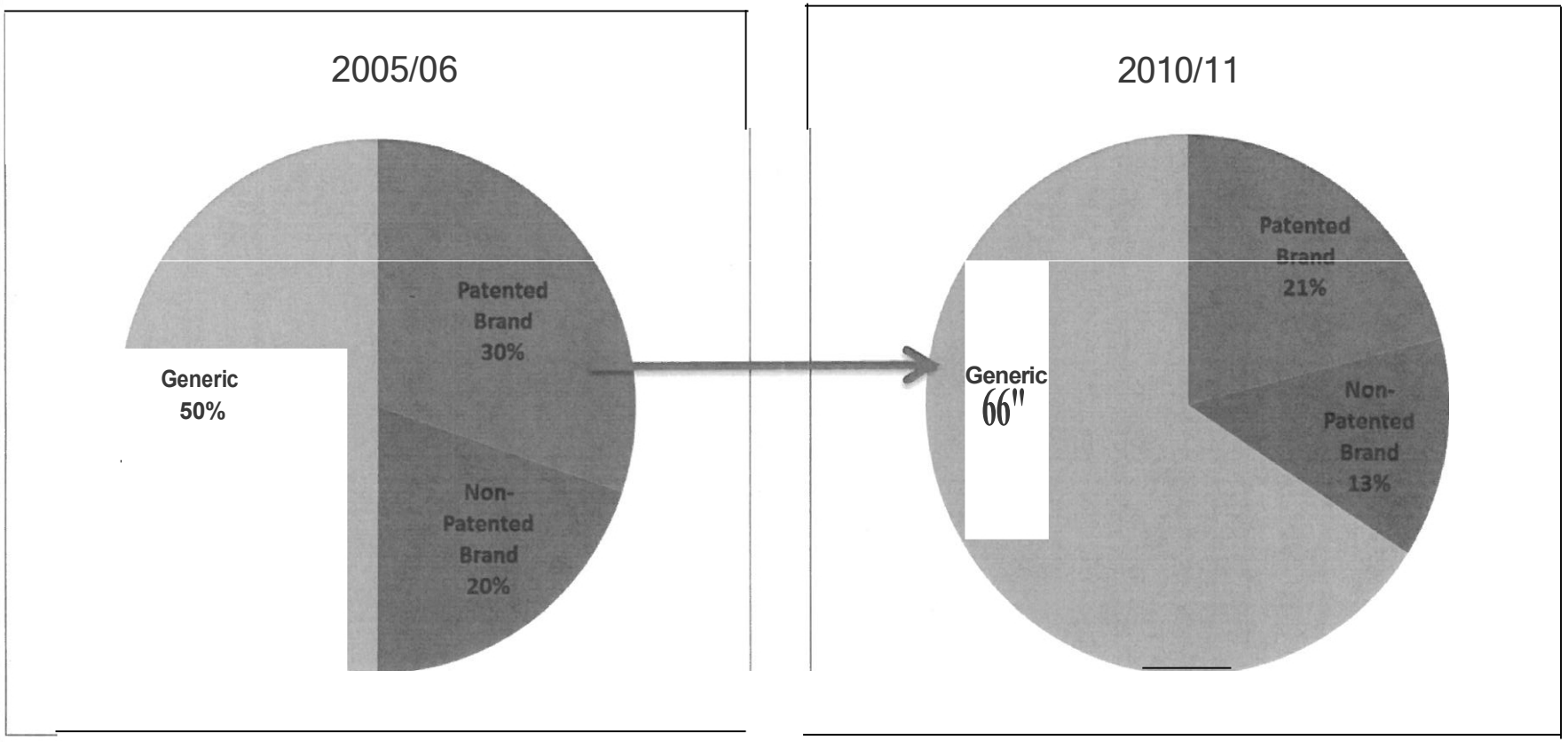
Canadian Public Drug Plan Spending* on Prescription Drugs Rates of Growth and Annual Totals, 2005/06 to 2010/11



plan spending on the prescription, which includes the drug, dispensing fee and markup.

*The government share of spending on prescription drugs by nine public drug plans participating in NPDUIS. The totals are

Shift in Shares of Total Prescriptions* by Market Segment, 2005/06 to 2010/11



*Totals are for nine public drug plans participating in NPDUIS.

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Registry of Lobbyists

(§] Registration - In-house Organization

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Innovative Medicines Canada / Médicaments novateurs Canada / Pamela Fralick, President

Registration Information

In-house Organization name: **Innovative Medicines Canada/ Médicaments novateurs Canada**

Previous in-house organization names

Responsible Officer Name: **Pamela Fralick, President** G

Resl:Jonsible Officer Change History

Initial registration start date: **2004-08-19**

Registration status: **Active**

Registration Number: **782797-371**

Associated Communications

Total Number of Communication Reports: **856**

Monthly communication reports in the last 6 months: *n*

« < **Registration versions:** 41 of 102: 2015-03-12 to 2015-10-15 **v** > »

Version 41 of 102 (2015-03-12 to 2015-10-15}

T **Lobbying Information**

Subject Matters

- Aboriginal Affairs
- Agriculture

- Arts and Culture
- Broadcasting
- Constitutional Issues
- Consumer Issues
- Defence
- Education
- Employment and Training
- Energy
- Environment
- Financial Institutions
- Fisheries
- Forestry
- Government Procurement
- Health
- Immigration
- Industry
- Infrastructure
- Intellectual Property
- Internai Trade
- International Relations
- International Trade
- Justice and Law Enforcement
- Labour
- Mining
- Regional Development
- Science and Technology
- Small Business
- Sports
- Taxation and Finance
- Telecommunications
- Tourism
- Transportation

Subject Matter Details

Legislative Proposai, Bill or Resolution

- Annual federal Budgets and Budget updates as it relates to the biopharmaceutical industry
- Canada's Food and Consumer Safety Action Plan as it relates to the regulation and protection of biopharmaceutical products
- Incarne Tax Act as it relates to biopharmaceutical products
- Patent Act as it relates to reporting requirements and pricing guidelines, and the protection of intellectual property in biopharmaceutical products

Legislative Proposai, Bill or Resolution, Regulation

- Canadian Environmental Protection Act and Regulations in respect of modern, science-based regulations to reflect rapidly changing new technologies
- Food and Drugs Act and Regulations and the Import and Export Permits Act with respect to cross-border trade as it relates to the export of Canadian biopharmaceuticals

Policies or Program

- Anti-Counterfeit Trade Agreement (ACTA) as it concerns counterfeit drugs
- Canada's Access to Medicines Regime with respect to ensuring that the program allows for the delivery of timely access to needed medicines to the developing world supported by a business climate in Canada that continues to encourage research into further treatment and prevention of disease
- Canada-United States Regulatory Cooperation Council (RCC) initiatives related to the regulation of biopharmaceutical products
- Canadian Institutes of Health Research (CIHR) Clinical Research Initiative as it relates to public/private research and development partnerships
- Common Drug Review Policies as it relates to reimbursement recommendation decision-making process and framework
- Establish accountability with the federally financed Canadian Agency for Drugs and Technologies in Health (CADTH)
- Free trade treaty agreement as they relate to the North American Free Trade Agreement (NAFTA) and free trade negotiations as it relates to India, the European Union, Japan, MERCOSUR and the Trans-Pacifie Partnership
- Pharmaceutical pricing policy issues arising from the jurisdiction of the Patended Medicines Prices Review Board (PMPRB)
- Scientific Research and Educational Design (SR&ED) Tax Credit in respect of updating the system and increasing the expenditure limit for refundable credits
- Subsequent Entry Biologies (SEBs) as it relates to Regulations, Policies, or Guidelines being developed by Health Canada, specifically the Draft Guidance Document on SEBs, the Notices of Changes to Health Canada's Guidance Documents on Data Protection and Patented Medicines Regulations (Notice of Compliance) Regulations
- The government's Science and Technology strategy as it relates to the biopharmaceutical industry
- World Health Organization (WHO) issues concerning pharmaceuticals as it relates to Counterfeits, Access to Medicines, and the Intergovernmental Working Group (IGWG)
- World Intellectual Property Organization (WIPO) issues concerning the protection of and access to intellectual property
- World Trade Organization (WTO) issues concerning the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) with respect to the protection of data, Access to Medicines, and TRIPs "flexibility"

Regulation

- Food and Drug Regulations as it relates to data protection and the regulation and protection of biopharmaceutical products
- Health Canada's Regulatory Roadmap for Health Products and Food as it relates to the biopharmaceutical industry
- New Substances Notification Regulations as it relates to the biopharmaceutical industry
- Patented Medicines (Notice of Compliance) Regulations as it relates to the regulation of intellectual property for biopharmaceutical products
- Patented Medicines (Notice of Compliance) Regulations with respect to ensuring that patent rights are respected and are internationally competitive
- Patented Medicines Regulations as it relates to the regulation and protection of biopharmaceutical products
- Smart Regulations as it relates to the biopharmaceutical industry

Communication Techniques

- Written communication
- Oral communication
- Grass-roots communication

Government Institutions

- Agriculture and Agri-Food Canada (AAFC)
- Canada Revenue Agency (CRA)
- Canadian Institutes of Health Research (CIHR)
- Canadian International Trade Tribunal (CITT)
- Competition Tribunal (CT)
- Employment and Social Development Canada (ESDC)
- Environment Canada
- Finance Canada (FIN)
- Fisheries and Oceans Canada (DFO)
- Foreign Affairs, Trade and Development Canada
- Health Canada (HC)
- House of Commons
- Industry Canada
- Justice Canada (JC)
- Members of the House of Commons
- National Research Council (NRC)
- Natural Resources Canada (NRCan)
- Natural Sciences and Engineering Research Council (NSERC)
- Office of the Information and Privacy Commissioner (OIPC)
- Patented Medicine Prices Review Board (PMPRB)
- Prime Minister's Office (PMO)
- Privy Council Office (PCO)

- Public Health Agency of Canada (PHACY · ,·,,,.. t•·.
- Public Works and Government Services Canada
- Senate of Canada
- Solicitor General Canada (SGC)
- Statistics Canada (StatCan)
- Treasury Board Of Canada Secretariat (TBS)
- Veterans Affairs Canada (VAC)

,.. **In-house Organization Details**

Description of the organization's activities

Canada's Research-Based Pharmaceutical Companies (Rx&D) is the association of leading research-based pharmaceutical companies dedicated to improving the health of Canadians through the discovery and development of new medicines and vaccines. Our community represents the men and women working for more than 50 member companies which invest more than $1 billion in research and development each year to fuel Canada's knowledge-based economy, contributing over $3 billion to the Canadian economy. Guided by our Code of Ethical Practices, our membership is committed to working in partnership with governments, private payers, healthcare professionals and stakeholders in a highly ethical manner.

Responsible officer name and position during the period of this registration

RUSSELL WILLIAMS, PRESIDENT

Organization's membership or classes of membership

(a) Full Membership: Full membership is open to innovative pharmaceutical Persans which research, develop, manufacture and/or distribute pharmaceutical prescription preparations under their own labels in Canada. (b) Biopharmaceutical Membership: Biopharmaceutical membership is open to Persans who are engaged, in research and development of pharmaceutical products and/or biopharmaceutical health care products with the aim of producing, manufacturing or distributing the same under its own label. (c) Medical Research Affiliate Membership: Medical research affiliate membership is open to non-profit organizations engaged in research which have a relationship or are connected with hospitals, universities, research institutes, recognized health/disease organizations, or divisions or units thereof, whose membership, in the determination of the Board, would be consistent with the abjects of the Association and would enhance the ability of the Association to attain such abjects, and who are engaged in health research. (d) Associate Membership: Associate membership is open to Persans who do not qualify under any of the foregoing membership categories and whose membership, in the determination of the Board, would be consistent with the abjects of the Association and would enhance the ability of the Association to attain such abjects. Without limiting the generality of the foregoing, Associate Members may include contract research organizations, contract

manufacturing organ-izations and clinical research organizations who supply goods and/or services to Full Members or Biopharmaceutical Members and other stakeholder groups which are appropriate in the determination of the Board.

Government funding

No government funding was received during the last completed financial year.

In-house Organization Contact Information

Address:
55 Metcalfe St.
Suite 1220
Ottawa, ON K1P 6L5
Canada

Telephone number: 613-236-0455 Ext. 425
Fax number: 613-236-6756

,.. **Lobbyists Details**

Lobbyists employed by the organization

- **Michelle Boudreau,** Vice President, Private Markets | Public offices held
- **Sarah E Douglas,** Manager of Media Relations | Public offices held
- **Declan Hamill,** Chief of Staff and Vice President, Legal Affairs | Public offices held
- **Keith McIntosh,** Executive Director, Scientific & Regulatory Affairs | No public offices held
- **Isabelle Robillard,** A/Vice President, Public Affairs | Public offices held
- **Hugh Scott,** Executive Director, Strategic Alliances | Public offices held
- **Brett Skinner,** Executive Director, Health and Economie Policy | Public offices held
- **Russell Williams,** President | No public offices held

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2023-03-30

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Registration - In-house Orga·nrzation

Public offices held: Michelle Boudreau

List of Public Offices Held

Position	Period Held	Last Date Designated Public Office Held
Executive Director Patented Medicine Prices Review Board, Executive Director's Office	2010 to 2013	Not a designated office
Executive Advisor Health Canada, Deputy Minister's Office	2008 to 2008	Not a designated office
Director General Health Canada, Natural Health Products Directorate	2008to 2010	Not a designated office
Director Health Canada, Litigation Secretariat	2007 to 2007	Not a designated office
Acting Associate Director General Health Canada, Inspectorate	2005 to 2006	Not a designated office
Legal Counsel Department of Justice, Health Canada Legal Services	1999 to 2005	Not a designated office
Legal Policy Analyst Industry Canada, Intellectual Property	1998 to 1999	Not a designated office
Policy Analyst Canadian Heritage, Copyright Policy	1996 to 1998	Not a designated office

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