RELEVANT CORRESPONDENCE TO SUPPORT THE TESTIMONY OF

MÉLANIE BOURASSA FORCIER

AS PART OF THE STUDY OF THE PATENTED MEDICINE PRICES REVIEW BOARD

SUBMISSION TO THE STANDING COMMITTEE ON HEALTH

8 MAY 2023

I. INTRODUCTORY REMARKS

This document is in response to the motion adopted by members of the Standing Committee on Health on 4 May 2022:

"That witnesses produce correspondence they consider relevant to support their testimony to the committee, in relation to the study of the Patented Medicine Prices Review Board, which shall be submitted to the clerk of the committee by Tuesday, May 9, 2023, at 4:00 p.m."

It picks up on the remarks made by witness Mélanie Bourassa Forcier, who testified in her capacity as a former member, vice-chairperson and acting chairperson of the Patented Medicine Prices Review Board (hereafter the "board").

It provides clarification following her testimony on 27 April 2023 as well as following the testimony of Mr. Matthew Herder, a former member of the board, and of Mr. Douglas Clark, the board's executive director, on 2 May 2023.

Some of the annexes do not have a date and some are based on her recollections. The witness made a request to obtain all the emails from the board to effectively buttress her remarks, and the request was turned down.

Some sections of the correspondence attached to this document were redacted because they were not relevant to the study of the Standing Committee on Health.

This document in its entirety is protected by parliamentary privilege and subject to immunity.

II. OPENING STATEMENT, 27 APRIL

Mr. Chair, members. Thank you for inviting me to appear before your today. My name is Mélanie Bourassa Forcier. I am a lawyer and a full professor in law at the Université de Sherbrooke. I have a Master's degree in international health policy, majoring in pharmaceutical economics and health economics from the London School of Economics and Political Science. In the course of my studies, I focused on several international models for the regulation of innovation and for controlling medicine prices.

I also have a doctorate in law, and my thesis was on Canada's pharmaceutical patents policy. The thesis studied the theory of rational choice and how this interest affected the formulation of public policy and the behaviour of interest groups. Also in my thesis, I addressed various innovative pharmaceutical industry policy strategies, which among other things made it possible to amend the *Patent Act* on two occasions.

As a professor, I give courses on pharmaceutical law and policy, on health systems governance and on accessibility challenges, particularly among Canada's Indigenous communities. As a researcher, I am directing several research projects, including one on the social responsibility of the pharmaceutical industry and equitable access to patented medicines and vaccines in a pandemic funded by the Social Sciences and Humanities Research Council (SSHRC). I have also worked on several occasions on governance, ethics and listening to stakeholders.

I was an ethics and regulatory commissioner for Quebec's Commissaire à la santé et au bien-être, an independent body that is part of Quebec's Ministère de la Santé. I am also a member of the Commission de l'éthique en science et en technologie du Québec.

I am here before you in my capacity as a former member, vice-chairperson and acting chairperson of the Patented Medicine Prices Review Board (PMPRB). I was appointed to this position by the Governor in Council in June 2019. I resigned on 5 December 2022.

I would like to use these few minutes available to me to give you my vision of the board and to make a few recommendations that we might discuss during the round of questions.

I believe that the board is a key organization.

Its impressive research division does thorough work. The studies from this division are an excellent source of information for the scientific community.

However, my view is that the board's quasi-judicial role should be completely separate from its operational role. Its members should only deal with the quasi-judicial sphere, which in turn should be limited to reviewing excessive prices for patented medicines.

The chairperson is the only person in contact with staff, the minister and the stakeholders, and ought not to sit during hearings.

The operational role of the board should be more flexible and allow for innovations in both policies and practices.

The PMPRB's mandate should also be clarified. Is its only mandate to control excessive pricing of patented medicines, or is its role to ensure accessibility to patented medicines for Canadians?

To ensure effective governance, a serious review of the internal operating rules is required. The board should establish clear and transparent operating procedures for itself. It should also, moreover, provide independent external protection and support for members appointed to the body.

With respect to guidelines, if the board were to keep its mandate as it is, its members should have timely access to the contents of submissions presented in consultations.

More comprehensively and broadly, in terms of innovation and accessibility to medicines, I recommend

- creating a registry that would monitor the rate of penetration of medicines in Canada as compared to other countries;

- reviewing the definition of research and development and to promote R & D being carried out in Canada;

- promoting innovations, with a capital "I";

- that the government maintain a public registry of innovations resulting from public funding, whether solely or in partnership with industry, and that it ensure that what it is funding becomes available in the Canadian market;

- that the federal government establish a fund that could provide independent financing for groups of patients.

Lastly, the consultation period subject to your study pertains to the quasi-judicial functions of this organization, as well as the rules and decisions of its members acting in that capacity. Although these members are bound by confidentiality requirements, I will make an effort to answer your questions to the best of my knowledge, with due regard to these requirements.

Thank you for your attention.

III. CLARIFICATION PERTAINING TO TESTIMONY

A. Ms. Mélanie Bourassa Forcier's testimony – 27 April 2023

Mr. Don Davis referred to a December 2021 briefing note. Since I did not have the document in my possession and I had not had an opportunity to review it ahead of the question period, I mistakenly assumed that Mr. Davis was referring to my letter to the minister dated 30 November 2022 (**Annex B**), which has wording that is very similar to the one referred to by Mr. Davis.

In any event, if I signed the note he was referring to, then I approved it. I still do not have the note in my possession.

B. Mr. Herder's testimony – 2 May 2023

Mr. Herder's evidence was largely based on hearsay and on assumptions, which appear not to have been substantiated, in particular when he said that former board officials contravene the *Conflict of Interest Act*, and I will therefore refrain from confirming or correcting most of his statement.

However, I would like to make a clarification and give a reminder pertaining to what appears to have been forgotten in evidence on 2 May 2023. As courts have affirmed multiple times, the federal government does not have jurisdiction to regulate medicine prices in a general manner. This is an area of provincial jurisdiction.

The sole constitutionally recognized mandate for the board is to intervene in excessive (and not unreasonable) pricing of patented medicines.

C. Mr. Clark's testimony – 2 May 2023

1. Role of the executive director, reporting structure and requests to meet with the minister

In his opening statement, Mr. Clark stated:

> *I want to first address the confusion from last week's testimony around the protocol for briefing the minister and who dialogues with whom between the PMPRB and Health Canada. Before doing so, I should point out that the PMPRB chairperson position is a part-time appointment and has always been occupied by persons residing outside of the National Capital Region and who juggle multiple other professional responsibilities. As such, in order for the PMPRB to operate effectively day to day, the executive director is often called upon to exercise functions that, based on a pedantic interpretation of the PMPRB's org chart and reporting structure, would normally fall to the chairperson.*
>
> *Accordingly, with the exception of the current minister, I have personally briefed every minister of Health on guidelines reform as far back as Minister Ambrose under the previous government, either on behalf of the chairperson or together. Some of these ministers I have briefed on this topic multiple times. To the best of my recollection, every such briefing was initiated and arranged by the deputy minister's office, often at the behest of the minister's office.*

(a) Role of the executive director and reporting structure

Section 96 of the *Patent Act* says that it is the responsibility of the board to issue its guidelines and hold its consultations.

The *Chairperson's Guidelines* say that only the chairperson is in contact with the minister.

Section 102 of the *Patent Act* provides that the minister may at any time convene a meeting of the chairperson and such members of the board as the chairperson may designate.

The board's organization chart does not make a link between the executive director and the minister.

(b) Different interpretations of applicable rules

The lack of internal operating rules has resulted in different interpretations regarding the role of the executive director. The Act, the *Chairperson's Guidelines* and the organization chart are clear. It would seem that practices have evolved internally, and that these practices are not perfectly aligned with the above-mentioned normative documents.

As the acting chairperson and as a member, I never saw the geographic distance as a limitation to my capacity to fulfil my roles and responsibilities. Moreover, for information, several members of the board often made the request to be more involved in the processes pertaining to the fulfillment of their obligations.

(c) Requests for meetings with the minister

As soon as I took office as acting chairperson in November 2021, I requested Ms. Sherri Wilson, the board's executive secretary, for a meeting with the minister. For some months, I had noticed some **tension in the relationship between Mr. Clark, the executive director, and the minister's office** due to multiple delays to the reform, which was originally sponsored by the government, and on which the board's personnel had worked tirelessly for years. Moreover, in his testimony, Mr. Clark confirmed that the board's team found the defeat pertaining to the reform psychologically difficult.

I felt that the lack of communication and support from the office of the minister was escalating the situation and I felt duty-bound, as the acting chairperson, to work towards improving the situation. It was my responsibility, as the acting chairperson, to discuss the situation with the minister. The executive director was also deeply affected by the multiple failures related to his work and to the work of his team.

I believed it was essential to re-establish dialogue. Moreover, I feel that the current situation is the outcome of this lack of dialogue that ought to have been managed several months before.

As I noted in my testimony on 27 April 2023, the board's executive secretary told me that I could not request a meeting with the minister, and that I had to be called by the minister. I therefore respected this chain of command.

(d) Requests to meet with the minister in relation to the guidelines

Nevertheless, on or about 18 November 2022, I reiterated my requests to meet with the minister in relation to the new proposed guidelines with the board staff.

On 18 November 2022 via a text message, I asked Mr. Clark directly for a meeting with the minister (**Annex C1)** after Innovative Medicines Canada (IMC) issued a negative release related to the proposed guidelines. I did not get any follow up from him on this matter.

On 21 November 2022, I made the same request with the board's executive secretary. I reiterated this request several times with her, up until 29 November 2022 **(Annex C2).**

On 29 November 2022, at 11:56 a.m., I told the executive director that I had a feeling the executive secretary had not followed up on my request to meet with the minister. [translation] "I have a feeling Sherri has not sent my request for a meeting with the minister. I've asked her several times. Know anything?" (**Annex C3).**

Mr. Clark responded on 29 November 2022 at 12:14 p.m.: [translation] "I've prepared a draft of your potential response to the minister. We need to talk before we do anything. The key thing going forward is to protect ourselves. The minister absolutely doesn't want to have anything to do with us (...) **there's no chance that the minister will meet with you. None."** (**Annex C3).**

I wrote back: [translation]: **"Pls let's ask him.** We'll see what he says."

Mr. Clark responded: [translation]: "Sherri will send you the draft shortly. We need to discuss it before we do anything." (**Annex C3**).

At the same time, **ten days after my initial request** to Mr. Clark, the executive director (18 November 2022), on 29 November 2022, at 11:59 a.m., I once again asked the board's executive secretary if she had sent my request to meet with the minister. [translation]: "Have you sent my request to meet with the minister? Please let me know" (**Annex C2**).

The same day, at 12:16 p.m., she finally responded: **I haven't because I am unsure how to make it happen, given that typically in the bureaucracy requests to meet with the Minister go through the Deputy Minister's office because we are required to follow the chain of command as public servants.**" (**Annex C2**).

On or about 29 November 2022, I received the draft letter to the minister, which had been dictated by the executive director and his team, and which, as I recall, still did not include my request to meet with the minister.

Again, based on my recollections, I added the second last paragraph to the draft letter, stating that I wished to meet with the minister (**Annex B**).

My changes triggered a strong response from Mr. Clark in an email in which he noted that "In any event, the Minister is not going to meet with you. He may try to fire you, but he has no cause to do so you are just trying to do your job to the best of your ability." (**Annex C4**).

I did not have access to the five requests to meet with the minister submitted to the Standing Committee on Health by Mr. Clark, the executive director, which he referred to multiple times throughout his testimony.

Unfortunately, I was never told about such requests.

However, I knew that he was making efforts to contact his counterparts in the minister's office, without any luck.

As mentioned, in light of this situation, the apparent conflict or absence of dialogue between the minister's office and Mr. Clark (**see annexes C3 and C4**), it was my responsibility as the acting chairperson to talk with the minister to ensure the good governance of the organization.

In addition, during a telephone conversation pertaining to my request to meet with the minister and regarding my letter dated 30 November 2022, I suggested to Mr. Clark that he meet with Mr. Lucas on his own, but that I would meet with the minister. At no time did he mention his attempts to talk with the minister directly.

Obviously, given my desire to meet with the minister upon coming into office, you will understand that I would have been mystified had I known that Mr. Clark, the executive director, wanted to meet with the minister directly. I have to say that his evidence came as a surprise.

2. Concept of "suspension" and division among members

Unfortunately, one word, "suspension", fueled, and I would go as far as to say, triggered an unprecedented crisis in the board.

Immediately upon receipt of the minister's letter dated 28 November 2022, Mr. Clark and the board's legal department were preoccupied with the term "suspension" and saw this as potential interference with the board's independence.

Upon receipt of the letter or shortly thereafter, Mr. Clerk, Mr. Herder, and the board's executive secretary in particular, constantly adopted a narrow, **out of context** interpretation of the term "suspension" mentioned by the minister in his letter dated 28 November 2022, and which I also referred to in our communication.

(a) Teams meeting with Mr. Lucas on 30 November 2022

On 30 November 2022, at 5:30 p.m., at the request of Mr. Lucas (and not as per my request to meet the minister), we had a Teams meeting that was also attended by Mr. Clark and Mr. Kippen from the minister's office.

Given that the board's staff was deeply concerned about the term "suspension" that the minister referred to in his letter dated 28 November 2022, during this meeting, I specifically asked Mr. Lucas what the term "suspension" meant. **Mr. Lucas then noted that the key thing was to take time to meet with stakeholders, whether that means suspending or extending. It was clear then that the minister's intention was to ask to take more time to meet with the stakeholders, regardless of the path preferred by the board. It was also clear that the term "suspension" that the letter was referring to did not amount to "halting" or "stopping" the board's consultation process.**

I then told Mr. Lucas that I personally had no objection, but I needed to consult members of the board. To be honest, I never considered that my colleagues could see this as problematic.

I was wrong.

When I told Mr. Lucas that I was going to consult with the other members, I received a text message from Mr. Clark telling me that [translation] "You better stop that" (**Annex E**).

To this day, I do not know if Mr. Clark wanted me to resign or if he was ordering me to end the meeting immediately.

(b) Meeting with board members on 30 November 2022

On the same day, we held a board meeting at 5:30 p.m.

During this meeting, the executive secretary, who was however not present at the meeting with Mr. Lucas, led members to believe that I had committed them to "suspend" the consultation period during the Teams meeting with Mr. Lucas.

The executive secretary was thus reporting statements – inaccurate – that Mr. Clark would also later make in his email dated 1 December 2022, which I refer to below (**Annex F3**).

As for me, during the board meeting on 30 November 2022, I stated that, during the Teams meeting with Mr. Lucas, I confirmed to him that the minister did not wish to "suspend" but only to give time for stakeholders to be consulted.

At this meeting on 30 November 2022, board members discussed the minister's request and the request from Innovative Medicines Canada (IMM) to take more time to meet with stakeholders (**Annexes A1, A2, A3 and B**). The following options were discussed: meet with IMM within the consultation period, extend it, not meet with them. My recollection is that we were all of the opinion that suspending the consultations was not an option, contrary to the testimony from Mr. Clark and Mr. Herder, who stated that I wanted to suspend the consultation.

During this meeting on 30 November 2022, board members wished to do nothing and to let the consultation period run out on 5 December 2022.

For my part, doing nothing and letting the consultation period run out essentially amounted to making the decision not to extend the consultation period to adequately hear from stakeholders (**Annex F1**).

(c) Discussions after the board meeting held on 30 November 2022

After the Teams meeting with Mr. Lucas and the board meeting on 30 November 2022, Mr. Clark sent me an email on 1 December 2022 **(Annex F3)** in which he alleged that I wanted to be [translation] "in the good books" of the deputy minister and the minister (and that he wished he could do the same).

In the email **(Annex F3)**, Mr. Clark implied that I made a commitment and I had committed board members during our Teams meeting with Mr. Lucas (and Mr. Kippen and Mr. Clark) on 30 November 2022 to "suspend" the consultation period.

In the same email (**Annex F3**), Mr. Clark implied that I was not transparent with the other members about this matter.

I must admit that to this day, I do not quite understand where I lacked transparency on this file.

Moreover, a scrutiny of the annexes will show you my constant determination to consult with board members at all times prior to making any decision regarding the guidelines, despite alternative proposals from the executive director. Specifically:

- In the first version of the letter he wanted me to sign (I do not have the draft letter, but it is referred to it in the text messages) (**Annex D1**), Mr. Clark, the executive director had indicated that it was likely that the guidelines would not be passed on 1 January 2023. Although I was not opposed to such an eventuality, I considered that the decision rested solely with members of the board. I therefore deleted this passage because we had not had an opportunity to discuss it (**Annex D1**).

- Mr. Clark, the executive director, suggested that I indicate in my letter to the minister dated 30 November 2022 that I had agreed to suspend consultations, without sharing this with members. I refused to do so and made it clear to him that the decision rested with members of the board (it was neither mine nor that of the minister). We therefore needed to discuss it first. (**Annex D2**).

3. Lawfulness of the guidelines

After hearing the testimony of witnesses, it is important for me to clarify some misunderstanding.

In my letter to explain my resignation, I indicated that, during my selection interview, I had highlighted my doubts about the constitutionality of the proposed regulatory reform. I teach pharmaceutical law and, in this course, I cover the subject of division of powers.

This reform was developed before I joined the board. When I agreed to join the board, it was not my place to express my views about the constitutionality of this reform, which was well underway, especially since it fell under the responsibility of the Government of Canada and not that of members of the board.

With respect to the legal validity of the guidelines, in my testimony, I indicated that the guidelines could have a weakness, and for that reason, it was appropriate to allow more time for consultations. I

was referring in particular to the discretionary power conferred upon personnel from the investigation team under these guidelines.

In the first draft of the guidelines, when board personnel members presented them to us at a meeting in Ottawa on 31 May 2022, I asked whether granting this discretionary power holds water from a legal standpoint. To my recollection, the answer provided at the time was reassuring.

However, upon receipt of letters from IMC and the minister, I had fresh doubts about the legal validity of our guidelines. In fact, I discussed it with members at the meeting held on 30 November 2022. In my personal opinion, a legal weakness in our guidelines would expose us to fresh judicial recourse, at the taxpayer's expense. Another loss before the courts would also cause more significant delays to our activities than extending the consultation period by a few days.

4. Adequacy of the consultation period and appropriateness of extending consultations given that industry remained unyielding

In his testimony, Mr. Clark indicated:

> *Although the initial reaction from stakeholders was muted, it did not take long for anti-PMPRB rhetoric from industry to ramp-up along recent lines. On November 10, IMC issued a news release calling on Health Canada to direct the PMPRB to suspend its consultations, failing which, "Canadian patients will be deprived of potentially life-saving new medicines." On November 22, IMC issued another news release claiming that the PMPRB was, "misleading Canadians," because the findings in our latest annual report about domestic R&D did not agree with the report IMC commissioned from Statistics Canada. This is the same annual report that the PMPRB has published every year for the past 35 years and which is bound by a legislative definition of R&D set by parliament and the Minister of Health*.

Throughout his testimony, Mr. Clark mentioned that "we" had sufficiently consulted industry.

(a) Adequacy of the consultation period

In his testimony, Mr. Herder, who echoed (because Mr. Herder did not undertake the consultations) Mr. Clark's statement (which is also contained in his letter of resignation) confirmed that the consultation period was "adequate."

Later in his testimony, he added that board members were supposed to meet mid-December, after the close of the consultation period on 5 December 2022, to know the details of the consultations carried out to determine, after the fact, if they were adequate,

(b) Board members' duty to consult regardless of stakeholders' position

On 27 April 2022, Mr. Davis asked me if I thought it was appropriate to take more time to hear from the pharmaceutical industry, while I had, among others, indicated in my letter to explain my resignation on 3 March 2023 that we were faced with a dialogue of the deaf.

I replied in the affirmative.

Pursuant to section 96 (5) of the *Patent Act*, before the board issues 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."

Legal duty to consult and to be impartial

As board members, it is not for us to determine that consulting with one or some stakeholders is unnecessary due to their lack of flexibility or their attitude.

Our duty under the Act is to consult with stakeholders impartially, and, above all, not to appear to have consultations in the full knowledge of implementing guidelines as proposed, regardless of the submissions, without considering these submissions.

In listening to testimony from Mr. Clark and Mr. Herder, we will understand that according to them, it was not necessary to take time to adequately consult (meet with, listen to and try to understand) some stakeholders explicitly identified in section 96 (5) of the *Patent Act,* who board members are required to consult. To them, the pharmaceutical industry is hostile, consumer groups are biased because they are funded by the pharmaceutical industry, and the minister is beholden to the pharmaceutical industry.

As the acting chairperson and board member, I could not endorse this sort of approach.

Responsibility of board members and not that of the executive director

As I noted earlier, pursuant to the *Patent Act,* the duty to consult with regard to the guidelines lies with board members and not with the executive director. Admittedly, according to the *Chairperson's Guidelines,* the executive director is authorized to conduct these consultations.

However, upon receipt of the Minister's letter and upon review of the IMC's detailed response, (**Annex A3**), I realized that as a board, we had to assume this authority directly and to be involved in the consultation process.

As the duty to consult is the responsibility of board members, it was incumbent upon us to be well versed with the demands and challenges the guidelines posed for stakeholders.

Accordingly, board members taking time to meet with stakeholders, either before the consultation period closed on 5 December 2022 or by extending the consultation by a few days, was, in my view, the only option that met our obligations under the Act.

Other stakeholders and requests for extensions unknown to members

It was not until after my resignation, when submissions were published online, that I learned about the submissions received in consultations.

In particular and to my surprise, submissions were received before 5 December and these submissions, which do not come from IMC, were asking for the consultation period to be extended, and in particular, pointed to granting discretionary power to board personnel in our guidelines as being problematic.

By the time I resigned, I had not been informed about these submissions and these concerns with respect to our guidelines. To my knowledge, other members were not informed about these submissions prior to publication, or at least, were not informed about them prior to my resignation.

We can ask ourselves the following questions: If members had been privy to these requests, would they have made the same decision? Did the minister intervene in accordance with sections 96 and 102 of the *Patent Act*, seeing that the board remained silent about these requests, which did not come exclusively from industry?

5. Reasons for my resignation

During his testimony, Mr. Clark noted that I had resigned because I wanted to "suspend" the consultation and that other members of the board did not support me:

> ***Mr. Luc Thériault***: *No no, I'm asking you, the question. If everything was going well, Mr. Clark, why did your chair resign?*
>
> ***Mr. Douglas Clark****: Mr. Thériault, everything wasn't going well. I think Ms. Bourassa Forcier resigned because the other members of the board didn't agree with her willingness to give in to the minister's request. But I think it's more…*
>
> ***Mr. Luc Thériault****: What you're telling us is that she wanted to make sure that all stakeholders were heard. You had enough time in the current process to hear everyone's views, and all members were against it. Did you have a meeting on that, Mr. Clark?*
>
> ***Mr. Douglas Clark****: We had many meetings. She wanted to suspend the consultation, not extend it.*

This is false. You will see that from a review of the attached communication, starting from 18 November 2022.

As I noted above, I never had any intention to "suspend" the consultations. This term, which I admittedly used, just as the minister did, was taken out of context by both Mr. Clark and Mr. Herder, both in their testimonies and in communications that followed our Teams meeting with Mr. Lucas, Mr. Kippen and Mr. Clark on 30 November 2022.

In his testimony, Mr. Clark said that I wanted to "give in" to the minister's request.

On its own, the minister's request was not very important to me, and neither was that of the IMC. What was important was (1) for us to comply with my obligations within the meaning of the *Patent Act* and hold adequate consultations; (2) to choose dialogue and not confrontation; and (3) to promote the viability of the guidelines and limit risks of judicial recourse.

Briefly stated, the reasons for my resignation are as follows:

Pursuant to section 96 (5) of the *Patent Act*, it is the responsibility of board members to conduct consultations regarding guidelines, including with the pharmaceutical industry and consumer groups. It is incumbent upon us to be impartial.

Two requests were addressed to me directly to take more time to meet with stakeholders and better assess the impact of the guidelines.

Upon receipt of these requests, I understood that the proposed guidelines could have some weaknesses legally and that, without taking time to meet with stakeholders, fresh judicial recourse at the taxpayer's expense was likely.

I proposed board members meet with IMC within the consultation period or to extend the consultation period. We had multiple exchanges on this subject between 30 November 2022 and 5 December 2022.

Ultimately, in particular following a board meeting in my absence, members upheld their decision "do nothing," to let the consultation period run out on 5 December, to stay silent in the face of the minister's request, and to propose a meeting with IMC in 2023 **(Annexes F4, F5, G1 and G2).**

For my part, to "do nothing" was tantamount to making the decision not to have more consultation with stakeholders. **(Annexes F1, F2 and H).**

Also, in my view, staying "silent" in the face of the minister's request, which was made in keeping with respect for his rights under sections 96 and 102 of the *Patent Act*, amounted to adopting confrontation, and I was extremely uncomfortable with this stance. It was incumbent upon us, at least, to give him an answer in the negative. I therefore wanted to brief the minister about our decision out of respect and to maintain good relationships. I was prohibited from doing this. I could not support this way of doing things. (**Annexes F1, F2, F5 and H**).

Lastly, to me, meeting with a stakeholder (IMM) after the consultation period seemed to be in direct contravention with the principles of fundamental justice and procedural fairness. We would thus have been unfair to other stakeholders. I was uncomfortable supporting this decision (**Annexes F1 and F5**).

In light of the foregoing, I could not remain with the board. I notified the Privy Council on 5 December 2022.

IV. CONCLUSION

As stated during my testimony, I do not believe that there was any interference from the minister in the board.

I strongly recommend that members of parliament consider my proposals if their intent is to ensure effective governance of the board and access to patented medicines for Canadians.

Annexe A1

INNOVATIVE MEDICINES CANADA | MÉDICAMENTS NOVATEURS CANADA

President's Office | Bureau de la présidente

November 18, 2022

Dr. Mélanie Bourassa Forcier
Interim Chair
Patented Medicine Prices Review Board (PMPRB)
Box L40, Standard Life Centre
1400-333 Laurier Avenue West
Ottawa, ON K1P 1C1

Via email: melanie.bourassa.forcier@usherbrooke.ca

Dear Dr. Bourassa Forcier:

On behalf of Innovative Medicines Canada (IMC), I am writing to you with respect to the revised draft Guidelines (Guidelines) released by the Patented Medicine Prices Review Board (PMPRB) for consultation on October 6, 2022. Specifically, IMC's leadership requests a meeting with you and with the other members of the PMPRB's Board of Directors to discuss our membership's significant concerns with the Guidelines.

Given that the PMPRB's consultation period with respect to the Guidelines ends on December 5, 2022, and that the Board intends to have a final set of Guidelines in place by the end of 2022, we would request that the meeting take place at your earliest convenience.

Thank you for your consideration of this request. Should you have any questions or if I can be of any further assistance, please do not hesitate to contact me.

Sincerely,

Pamela C. Fralick
President

cc: Sherri Wilson, Director, Board Secretariat, PMPRB, sherri.wilson@pmprb-cepmb.gc.ca

Patented Medicine Prices Review Board Canada
Conseil d'examen du prix des médicaments brevetés Canada

Box L40, Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
K1P 1C1

By email

November 21, 2022

Pamela Fralick
President
IMC
55 Metcalfe Street, Suite 1220
Ottawa, Ontario
K1P 6L5

RE: Consultation Meeting on Proposed Guidelines 2022

Dear Ms. Fralick:

Thank you for your email. Could you please resend your request to my PMPRB email address and include the following:

- The elements of the proposed guidelines that are problematic for your members.
- Your detailed constructive proposal that would ensure access to non-excessively priced patented medicines for all Canadians.

  Specifically, how do you propose the Board's guidelines respect the factors listed in the *Patent Act*, while avoiding those elements that, according to the IMC in its recent court challenge (T-1419-20), would make them *ultra vires* the *Act*.

  - "(a) the Guidelines establish formulas that set what the Board considers to be the non-excessive price for each patented medicine;

…

  - (c) the Guidelines will be applied by Board Staff in all but "exceptional circumstances"; where the price of a patented medicine exceeds the

…/2

price set by the formulas in the Guidelines, Board Staff notify the patentee that its price is “outside the thresholds set out in the Guidelines” and immediately begins to calculate the patentee’s “excess revenues”, which becomes a liability for the patentee;

- (d) Board Staff will commence an investigation where the price of a patented medicine exceeds the maximum non-excessive price determined by the Guidelines by 5% or more, or results in annual revenues that are $50,000 higher than allowed by the Guidelines.”

Once we have the information outlined above, we will be able to have a constructive meeting. We value dialogue with all our stakeholders and look forward to receiving your feedback.

Thank you very much in advance.

Yours very truly,

E-SIGNED by Mélanie Forcier
on 2022-11-21 14:40:31 EST

Mélanie Bourassa Forcier
Acting Chairperson

cc. The Honourable Jean-Yves Duclos, Minister of Health
Stephen Lucas, Deputy Minister of Health
Sherri Wilson, Director, Board Secretariat

Annexe A3

INNOVATIVE MEDICINES CANADA | MÉDICAMENTS NOVATEURS CANADA

President's Office | Bureau de la présidente

November 28, 2022

Dr. Mélanie Bourassa Forcier
Acting Chairperson
Patented Medicines Prices Review Board
Box L40, Standard Life Centre
1400–333 Laurier Avenue West
Ottawa, Ontario, K1P 1C1

Via email: melanie.forcier@pmprb-cepmb.gc.ca

Dear Dr. Bourassa Forcier:

Thank you for your letter dated November 21, 2022, I appreciate your openness to have a constructive dialogue on the Patented Medicines Prices Review Board's (PMPRB) revised draft Guidelines. This is something we have respectfully sought previously, in 2018 and again in 2019, and I sincerely believe that such an engagement would be productive for all.

In your response to our request for a meeting, you invited Innovative Medicines Canada (IMC) to list the elements of the proposed Guidelines that are problematic to our members and provide a detailed proposal concerning changes to the Guidelines.

IMC will be pleased to provide a submission to the PMPRB on its revised draft Guidelines proposal by the current consultation deadline. However, as a first step towards the establishment of a constructive dialogue, we would propose a meeting between the Chair of IMC and yourself, accompanied by a few members of leadership of our respective organizations. This meeting would be an opportunity for us to better understand the intent of the proposed draft guidelines changes, and for you to have a better understanding of our interpretation of these changes.

In the hope that the following will set the table for a productive meeting and pave the way to a better appreciation of the issues from both of our perspectives, IMC would like to discuss several issues within the proposed Guidelines, including:

- The proposed use of the lower of the Median International Price (MIP) and the domestic Therapeutic Class Comparison (dTCC) as an investigation trigger;
- The anticipated use of a multifactorial series of other potential investigation triggers at the discretion of Board staff;
- The need for an impact assessment prior to Guidelines implementation; and
- The need for more time to consult on all these issues. IMC remains concerned with the PMPRB's proposal to finalize the 2022 Guidelines by the end of the year.

In IMC's view, to abide by its legal and constitutional obligations, the PMPRB must focus on excessive prices – prices that exceed the PMPRB11 and other section 85 benchmarks, as expressed in recent cases, rather than the proposed measures that seem more designed to regulate pharmaceutical prices downward. Additionally, while the proposed Guidelines suggest there are no longer any price ceilings, the only criteria provided appear unrelated to the Board's mandate to regulate for patent abuse in the form of excessive prices.

To further nurture a spirit of collaboration and dialogue, IMC would propose that the PMPRB consider holding quarterly meetings with IMC to discuss policy matters, as happens with other departments and agencies of government. Such meetings have proven to help promote a better understanding of issues and foster the development of mutually acceptable solutions. The modernization of the definition of R&D expenses is a good example of the type of policy issue that could be examined during such meetings.

A postponement of the new Guidelines implementation would be a strong signal of the PMPRB's intent to establish a more constructive dialogue, not only with IMC, but with all stakeholders concerned.

Thank you for your consideration of this request and I look forward to your reply. Should you have any questions or if I can be of any further assistance, please do not hesitate to contact me.

Sincerely,

Pamela C. Fralick
President

cc: The Honourable Jean-Yves Duclos, Minister of Health, hcminister.ministresc@canada.ca
Stephen Lucas, Deputy Minister of Health, stephen.lucas@hc-sc.gc.ca
Sherri Wilson, Director, Board Secretariat, PMPRB, sherri.wilson@pmprb-cepmb.gc.ca

Annexe B

Conseil d'examen du prix des médicaments brevetés
canada

Patented Medicine Prices Review Board Canada

PO Box L40
Standard Life Centre
333 Laurier Avenue West
Suite 1400
Ottawa, Ontario
K1P 1C1

November 30, 2022

The Honourable Jean-Yves Duclos
Minister of Health
Ottawa, ON

Dear Minister:

SUBJECT: Consultation on the PMPRB's draft guidelines

Thank you for your letter of November 28, 2022. I must confess to having been surprised by your doubts about the new draft guidelines. To be frank, until I received your letter, I thought that Health Canada officials (who consult with you) were comfortable and in agreement with the approach taken in the draft guidelines. This situation shows the need for more dialogue to avoid any confusion and to prevent the government from sending mixed message to the public.

The draft guidelines do move away somewhat from the status quo given that, following the regulatory changes of July 2022, Canada must now compare the prices of patented medicines sold in our market to the prices in 11 comparator countries, where prices are lower than the seven comparator prices previously used as the basis for analysis. The Board, as the expert in this area, is of the view that the status quo tends to produce negative impacts on the industry because the current approach leads to the widespread implementation of strict and inflexible price controls. In particular, we believe the status quo would result in the pharmaceutical industry being in total non-compliance. This outcome would in our view be contrary to recent caselaw concerning the role of the PMPRB and the scope of its mandate. An approach based on the status quo would therefore be especially vulnerable to legal challenges. The proposed approach would instead provide for a rational and contextual analysis of proposed prices in Canada.

.../2

As you know, section 96 of the *Patent Act* authorizes the Board to issue non-binding guidelines on matters within its jurisdiction. This is a function that is central to the expertise and autonomy of the Board as an independent quasi-judicial body. Section 96 of the Act further requires the Board, as part of the federal health portfolio, to consult with you, along with the provincial ministers of health, before issuing such guidelines. While we have not yet had the opportunity to meet with you or your staff, the PMPRB has from the start communicated the existence of these consultations to your department and all provincial health departments and held follow-up meetings with provincial health department officials and with the Pan-Canadian Pharmaceutical Alliance (pCPA). We have also hosted webinars for the pharmaceutical industry and held lengthy meetings with Innovative Medicines Canada (IMC) and multiple IMC member corporations.

At present, the deadline for making written submissions on the draft guidelines is December 5. However, since the Board controls its own consultation process under the Act, your questions, like those of the industry, obviously weigh significantly on its decisions. Accordingly, to better understand your request and inform members soon enough that they can consider it, I propose that we meet. I would take the opportunity to discuss the invitation I extended to IMC to meet with us, which the industry responded to favourably. Finally, I would like to discuss the PMPRB's role in Canadian drug policy, which, as you know, is designed to achieve two objectives: promoting innovation and ensuring access to medicines. Indeed, I agreed to join this organization when I did because that was how I perceived our role.

Thank you again for your letter, and I hope that this letter will enable us to start a dialogue that will prove worthwhile for Canada.

Yours sincerely,

E-SIGNED by Melanie Bourassa Forcier
on 2022-11-30 17:48:06 GMT

Mélanie Bourassa Forcier
Acting Chairperson, PMPRB
Full Professor, Faculty of Law, Université de Sherbrooke
Director, Health Law and Policy and Life Sciences Law programs
Fellow, CIRANO

cc: Sherri Wilson, Director, Board Secretariat
Stephen Lucas, Deputy Minister, Health

Annexe C1

2022-11-18

La mise en œuvre des Lignes directrices proposées par le Conseil d'examen du prix des médicaments brevetés portera préjudice aux patients canadiens.

médicamentsnovateurs.ca

What did the Minister say?

That's what I'm trying to find out. Nothing yet, but I'll call the chief of staff today.

Okay. Keep me posted.

Then we'll look at strategy.

Do we have a chairperson?

2022-11-18

Okay. Keep me posted.

Then we'll look at strategy.

Do we have a chairperson?

You'll be the first to know.

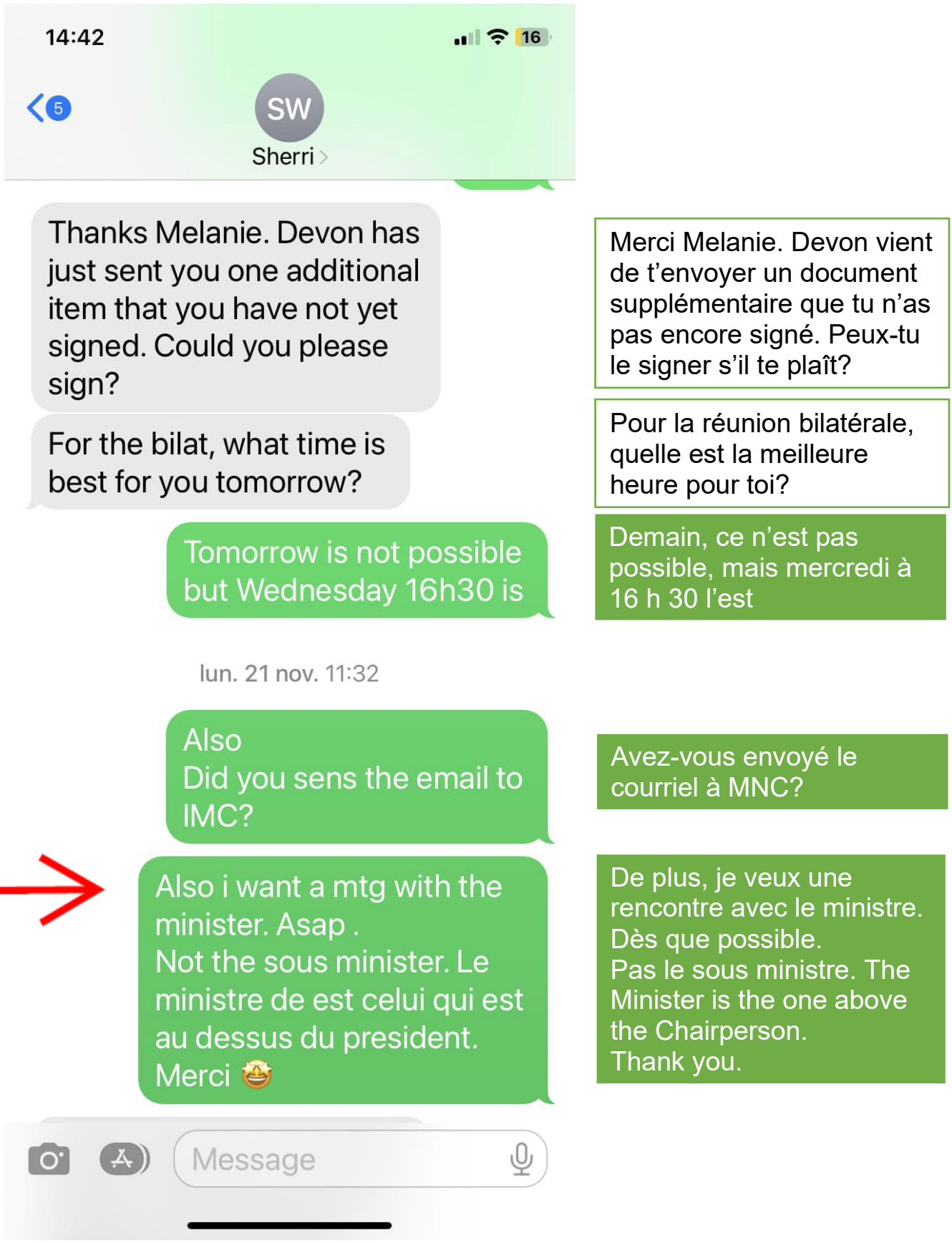
Okay. You can reach me starting at 4:30 p.m. I'll be on the road.

Who am I under? Deputy Minister?

Minister.

Please arrange a meeting with him

I think it's time we talked.


14:42
16
5
SW
Sherri
Thanks Melanie. Devon has just sent you one additional item that you have not yet signed. Could you please sign?
Merci Melanie. Devon vient de t'envoyer un document supplémentaire que tu n'as pas encore signé. Peux-tu le signer s'il te plaît?
For the bilat, what time is best for you tomorrow?
Pour la réunion bilatérale, quelle est la meilleure heure pour toi?
Tomorrow is not possible but Wednesday 16h30 is
Demain, ce n'est pas possible, mais mercredi à 16 h 30 l'est
lun. 21 nov. 11:32
Also
Did you sens the email to IMC?
Avez-vous envoyé le courriel à MNC?
Also i want a mtg with the minister. Asap .
Not the sous minister. Le ministre de est celui qui est au dessus du president.
Merci
De plus, je veux une rencontre avec le ministre. Dès que possible.
Pas le sous ministre. The Minister is the one above the Chairperson.
Thank you.
Message

Ok, merci

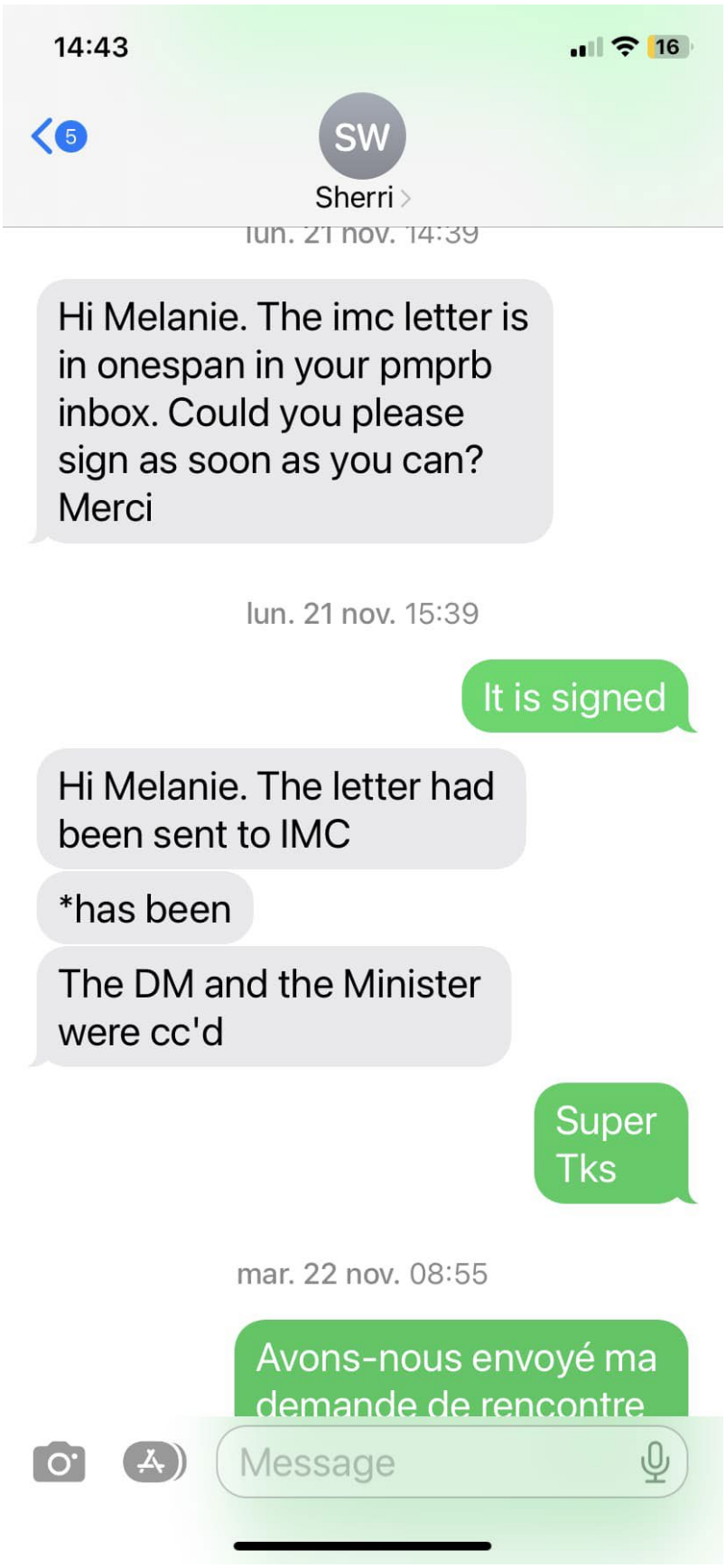
Je vais voir ce qui peut être fait pour l'entretien avec le ministre

Merci.

Subject: Relationship with the PMPRB and strategic and overall.

Thank you.

You can just send him my request. It doesn't make sense that I can't have a discussion with him.



Bonjour Melanie. La lettre de MNC est dans OneSpan dans ta boîte de réception du CEPMB. Peux-tu la signer dès que possible?

Merci.

Elle est signée.

Bonjour Melanie. La lettre a été envoyée à MNC.

Le CM et le ministre ont reçu une copie conforme

Merci beaucoup

Did we send my request to meet

Did we send my request to meet with the Minister?

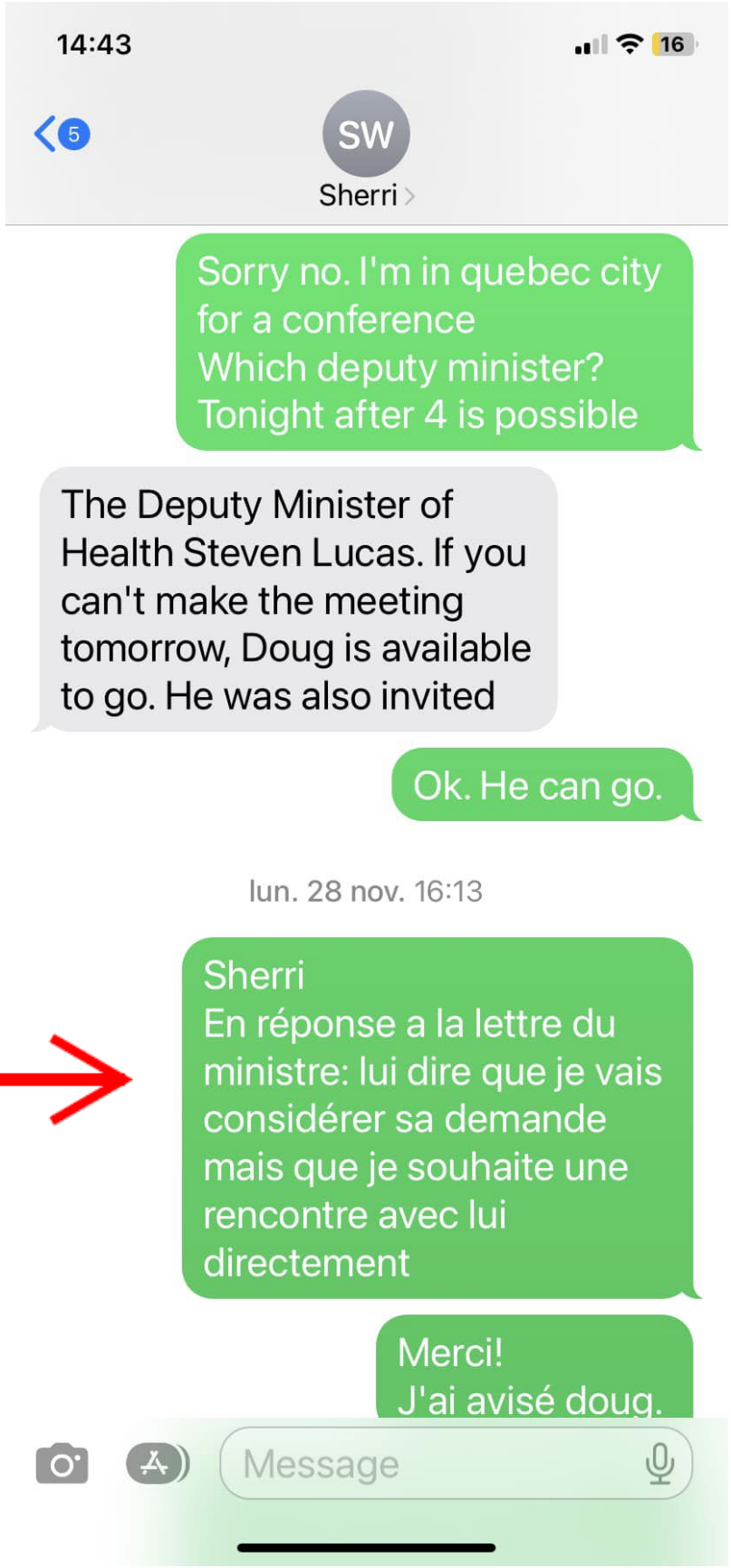
Bonjour Mélanie. Pourrais-tu répondre à Ashley au sujet de ton voyage pour la réunion du Conseil? Nous avons besoin de finaliser tes arrangements pour faire avancer le tout.

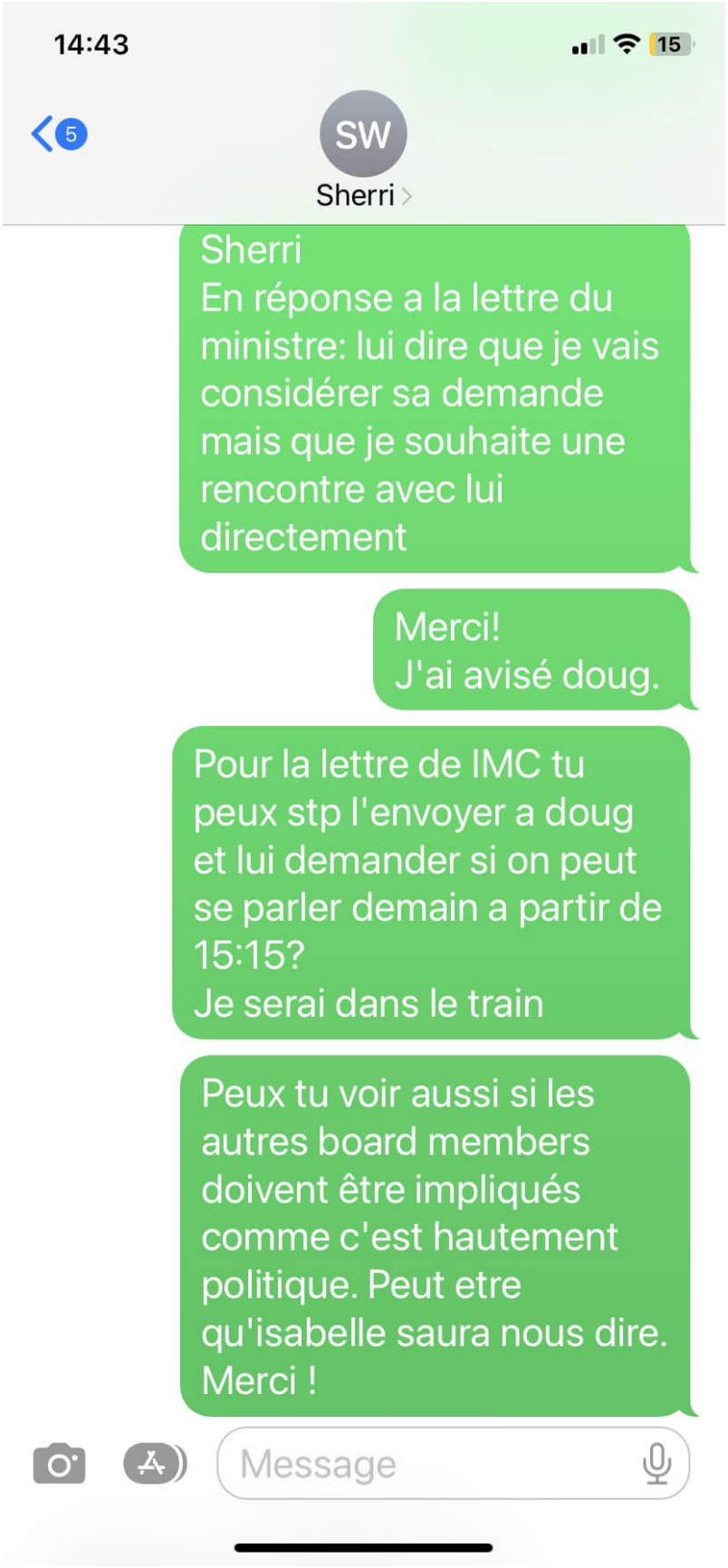
Je ne suis pas chez moi.

On peut faire ça dans environ 1 h?

Oui, s'il te plaît. Merci.

Bonjour Melanie. Êtes-vous disponible pour une réunion avec le


14:43
16
5
SW
Sherri
Sorry no. I'm in quebec city for a conference
Which deputy minister?
Tonight after 4 is possible
Désolé, non. Je suis à Québec pour une conférence. Quel sous-ministre? Ce soir, après 16 heures, c'est possible.
The Deputy Minister of Health Steven Lucas. If you can't make the meeting tomorrow, Doug is available to go. He was also invited
Le sous-ministre de la Santé, Steven Lucas. Si vous ne pouvez pas assister à la réunion demain, Doug peut y aller. Il a également été invité.
Ok. He can go.
D'accord. Il peut y aller.
lun. 28 nov. 16:13
Sherri
En réponse a la lettre du ministre: lui dire que je vais considérer sa demande mais que je souhaite une rencontre avec lui directement
Sherri.
In response to the Minister's letter: tell him I will consider his request but that I want to meet with him directly.
Merci!
J'ai avisé doug.
Thanks.
I've informed Doug.
Message



Sherri.

In response to the Minister's letter: tell him I will consider his request but that I want to meet with him directly.

Thanks.

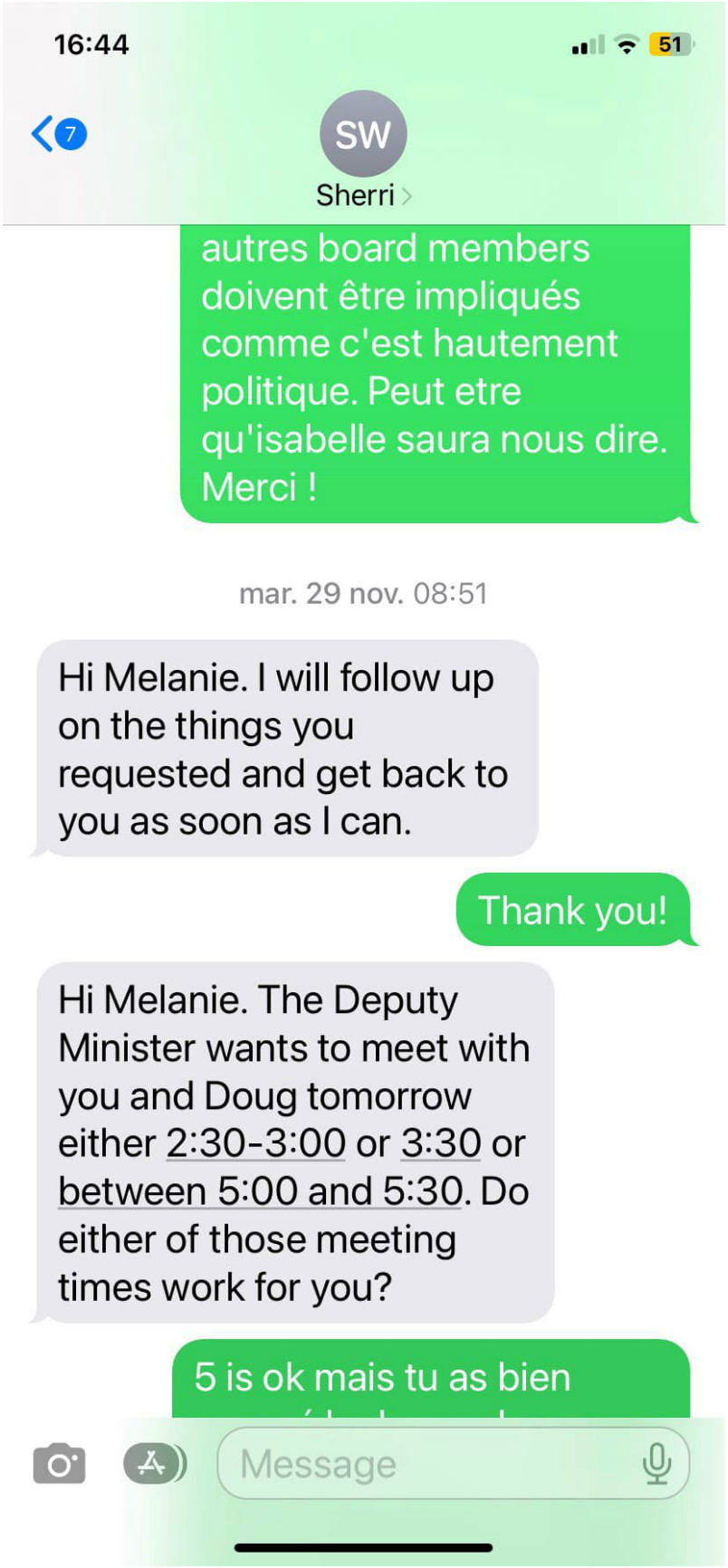
I've informed Doug.

For the IMC letter, could you send it to Doug and ask him if we can discuss it tomorrow sometime after 3:15?

I will be on the train.

Could you also determine whether the other board members need to be involved since it's highly political. Perhaps Isabelle could tell us.

Thank you!


16:44
51
7
SW
Sherri
autres board members doivent être impliqués comme c'est hautement politique. Peut etre qu'isabelle saura nous dire. Merci !
the other board members need to be involved since it's highly political. Perhaps Isabelle could tell us.
Thank you!
mar. 29 nov. 08:51
Hi Melanie. I will follow up on the things you requested and get back to you as soon as I can.
Bonjour Melanie. Je vais faire un suivi au sujet de ce que tu as demandé et te recontacter dès que possible.
Thank you!
Merci!
Hi Melanie. The Deputy Minister wants to meet with you and Doug tomorrow either 2:30-3:00 or 3:30 or between 5:00 and 5:30. Do either of those meeting times work for you?
Bonjour Melanie. Le sous-ministre veut vous rencontrer, vous et Doug, demain, soit de 14 h 30 à 15 h, 15 h 30, soit de 17 h à 17 h 30. Est-ce que l'une ou l'autre de ces heures de réunion vous convient?
5 is ok mais tu as bien
5 est ok but did you
Message

dès que possible.

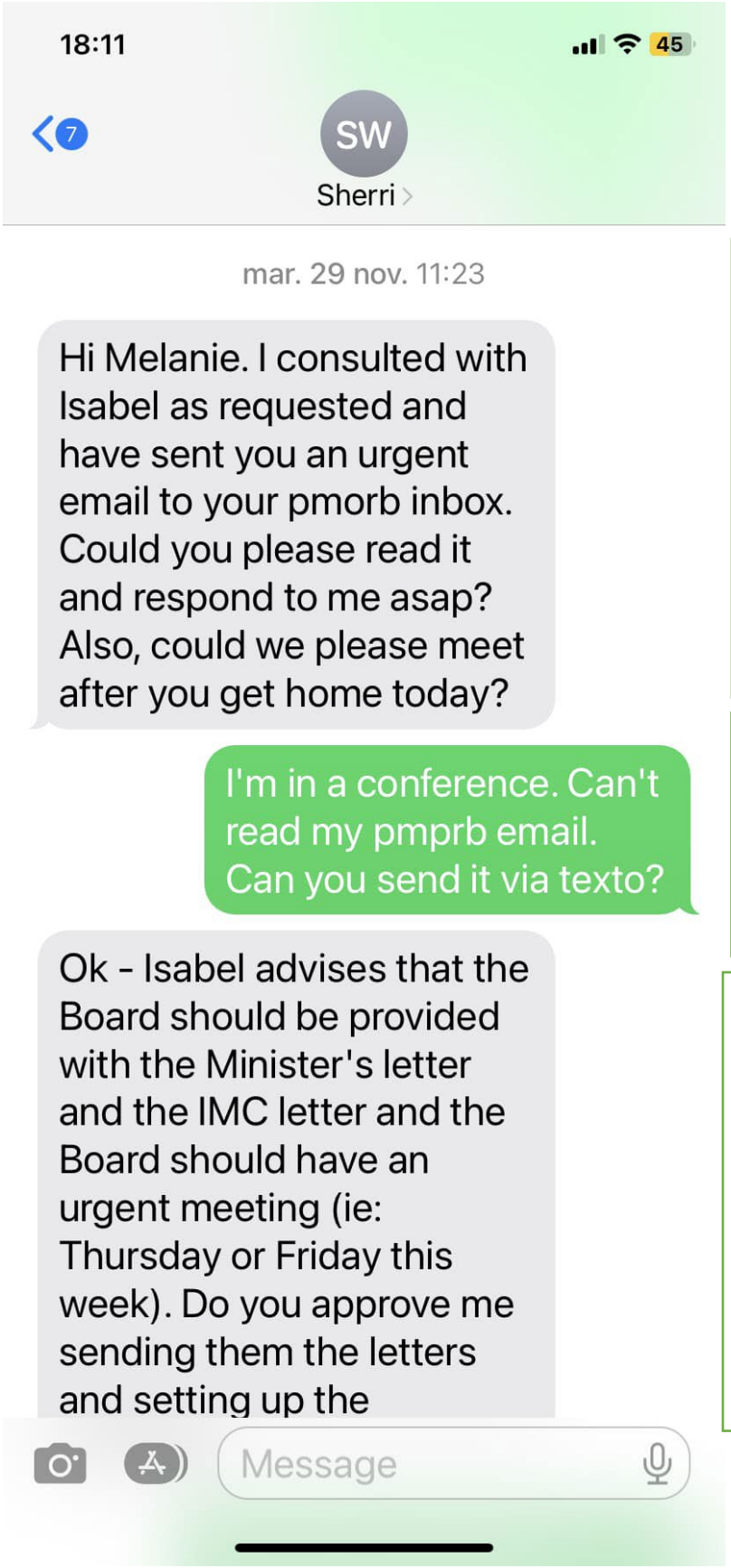
Merci!

Bonjour Melanie. Le sous-ministre veut vous rencontrer, vous et Doug, demain, soit de 14 h 30 à 15 h, 15 h 30, soit de 17 h à 17 h 30. Est-ce que l'une ou l'autre de ces heures de réunion vous convient?

5 est ok but did you send the request to the Minister? I want to talk to the Minister about his letter, not with Lucas.

And without Doug.

Doug is aware of this.



Bonjour Melanie. J'ai consulté Isabel sur demande et je vous ai envoyé un courriel urgent à votre boîte de réception du cepmb. Pourriez-vous la lire et me répondre le plus tôt possible? De plus, pourriez-vous vous réunir après votre retour à la maison aujourd'hui?

Je participe à une conférence. Je ne peux pas lire mon courriel à l'adresse du cepmb. Pouvez-vous l'envoyer par texto?

OK- Isabel indique que le Conseil devrait recevoir la lettre du ministre et la lettre de MNC et le Conseil devrait tenir une réunion de toute urgence (c.-à-d. : jeudi ou vendredi de cette semaine). Êtes-vous d'accord pour que je leur envoie les lettres et que j'organise la

et la lettre de MNC et le Conseil devrait tenir une réunion de toute urgence (c.-à-d. : jeudi ou vendredi de cette semaine). Êtes-vous d'accord pour que je leur envoie les lettres et que j'organise la réunion?

Thursday at 4 p.m. is the only time I am available.

Yes, ok for the letters.

Did you send my meeting request to the Minister? Please let me know.

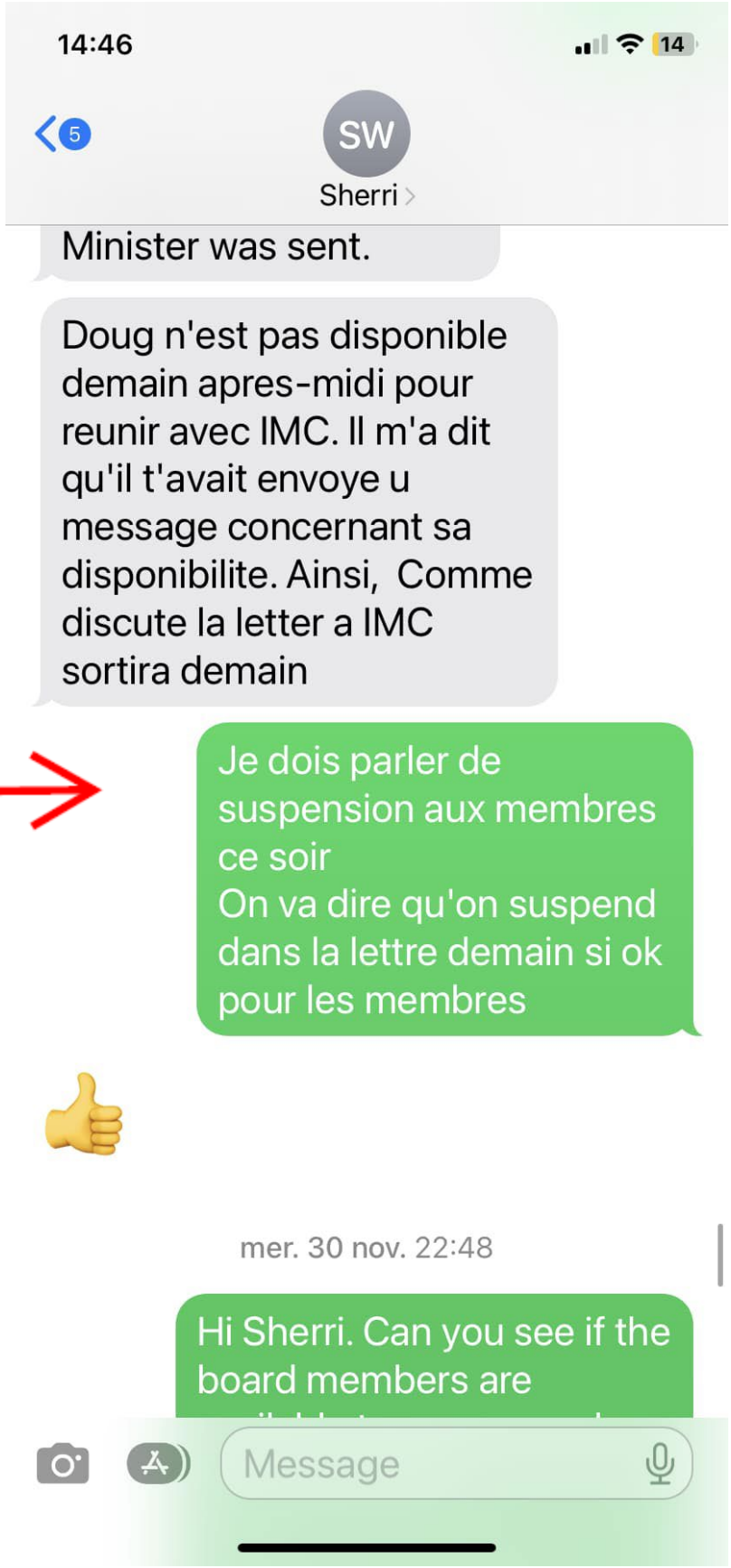
Please let me know, please.

Je ne l'ai pas fait parce que je ne suis pas certaine de la façon de procéder, étant donné que, habituellement, les demandes d'entretien avec le ministre passent

Je ne l'ai pas fait parce que je ne suis pas certaine de la façon de procéder, étant donné que, habituellement, les demandes d'entretien avec le ministre passent par les processus bureaucratiques Bureau du sous-ministre parce que nous sommes tenus de suivre la chaîne de commandement en tant que fonctionnaires.

Oui, c'est la chaîne de commandement.

The person I have to report to is not my equivalent, but the Minister. I am a deputy minister.



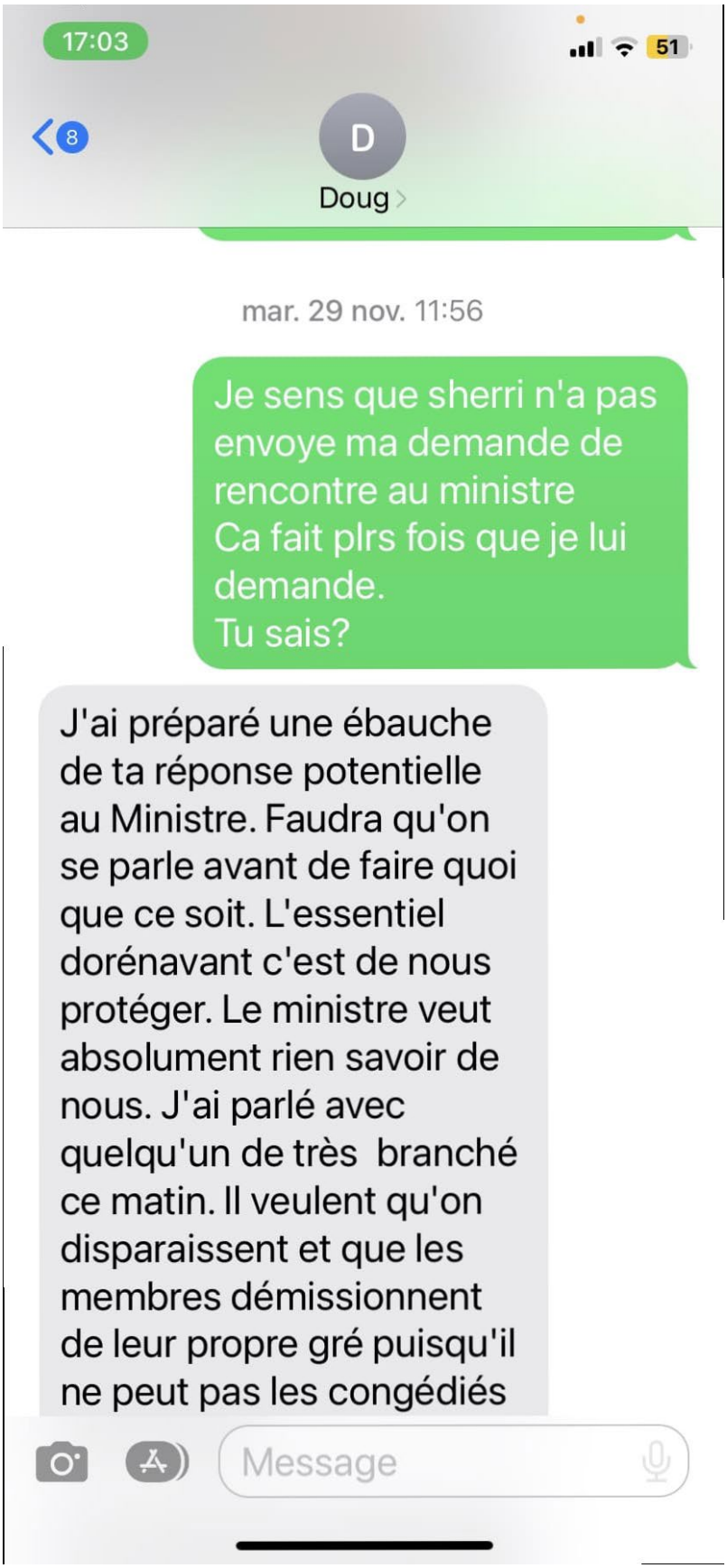
ministre a été envoyée

Doug is not available tomorrow afternoon to meet with IMC. He said he sent you a message about his availability. So, as discussed, the letter to IMC will go out tomorrow.

I have to talk about the suspension to the members this evening. We will say we are suspending in the letter tomorrow if the members agree.

Bonjour Sherri, Pouvez-vous voir si les membres du Conseil sont

Annexe C3

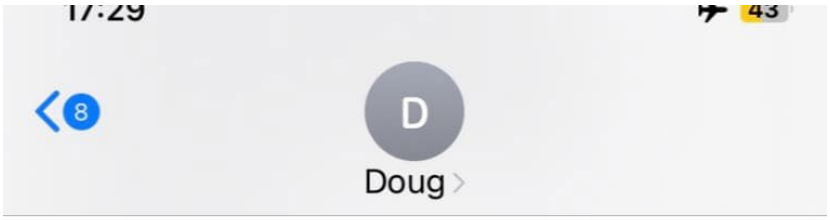


I have a feeling that Sherri didn't send my request for a meeting to the Minister.

I've asked several times now.

You know?

I've prepared a draft of your potential response to the Minister. We'll have to talk before we do anything. The most important thing right now is to protect ourselves. The Minister doesn't want anything to do with us. I spoke to a very connected person this morning. They want us to go away and the members to resign of their own accord, since they can't fire them.



Il n'y a aucune chance que le ministre te rencontre. Aucune.

There's no way the Minister will meet with you.

Not a chance.

mar. 29 nov. 13:16

On lui demande stp. On verra sa reponse.

Please ask him. Let's see what he says.

Sherri va t'envoyer l'ébauche sous peu. On devrait discuter avant de faire de quoi.

Sherri will send you the draft shortly. We should talk before we do anything.

Parlons nous a 15:15

Let's talk at 3:15 p.m.

Une rencontre avec Lucas va-t-elle avoir lieu?

Will there be a meeting with Lucas?

Je serai en réunion avec la présidente de Roche Canada.

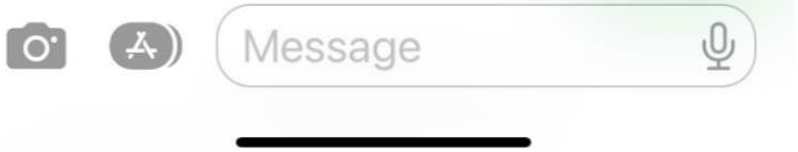
I'll be in a meeting with the President of Roche Canada.

Il semble que oui.

It seems so, yes.

Apres?

After?



Annexe C4

From: Douglas Clark <douglas.clark@pmprb-cepmb.gc.ca>
Sent: November 30,comme 2022 8:47 AM
To: Melanie Bourassa Forcier <melanie.forcier@pmprb-cepmb.gc.ca>; Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>
Subject: RE Revised letter

Melanie, I have serious concerns about your additions. I'm going to write in English because time is running out.

In order to better understand your request and inform the members in time for us to consider it, I'd like to meet with you. I'd like to take this opportunity to discuss the invitation I extended to IMC to meet with us, to which the industry responded positively. Finally, I'd like to talk to you about the role of the PMPRB in Canada's drug policy, which, as you know, has two objectives: promoting innovation and ensuring access to medicines. It was with this perception of the role that I agreed to join the organization at the time.

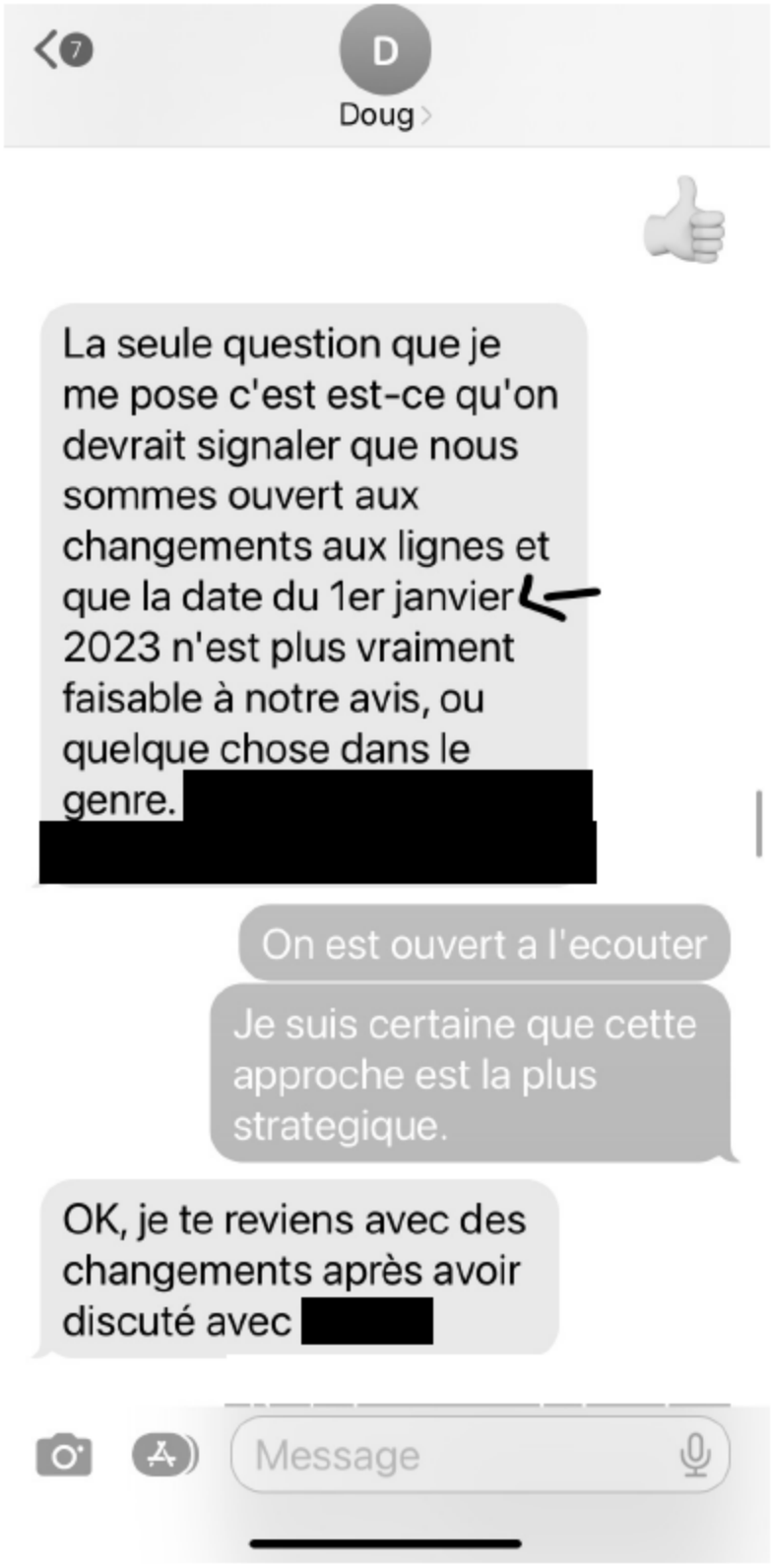
The sole purpose of the letter is to communicate to the Minister that the Board is doing the best in can in a difficult environment and that everyone needs to stay in their lanes and be mindful of their legal responsibilities and the confines of their respective mandates, or bad things can happen. We should not be seeking to engage with the Minister on his request but rather on the substance of the proposed Guidelines. In fact, we should be trying to respectfully communicate that what he is "requesting" is highly problematic. In any event, the Minister is not going to meet with you. He may try to fire you, but he has no cause to do so as you are just trying to do your job to the best of your ability.

Nothing about what is happening right now is personal. It's one hundred percent political, which is why it is especially problematic that the Minister is "asking" us to suspend our consultations. Whatever your motivations were for joining the Board are entirely irrelevant and the mere mentioning of them makes it look like you are conflating yourself with the Board and making this all about you. It is a very bad look.

Moreover, your reflections on Canadian policy are gratuitous and run contrary to not only the Board's recent decision in Procysbi but also to the approach we have taken in the draft Guidelines in eliminating the different categories of therapeutic improvement. The reality is that the Board has no policy role beyond the issuance of its Guidelines and its rules of practice and procedure. I understand that you have strongly held personal views on Canada's overarching policy on innovation and access but it is inappropriate to express them in your official capacity as acting Chair of the Board and would be received in a very bad light by the DM or the Minister.

Doug

2022-11-28

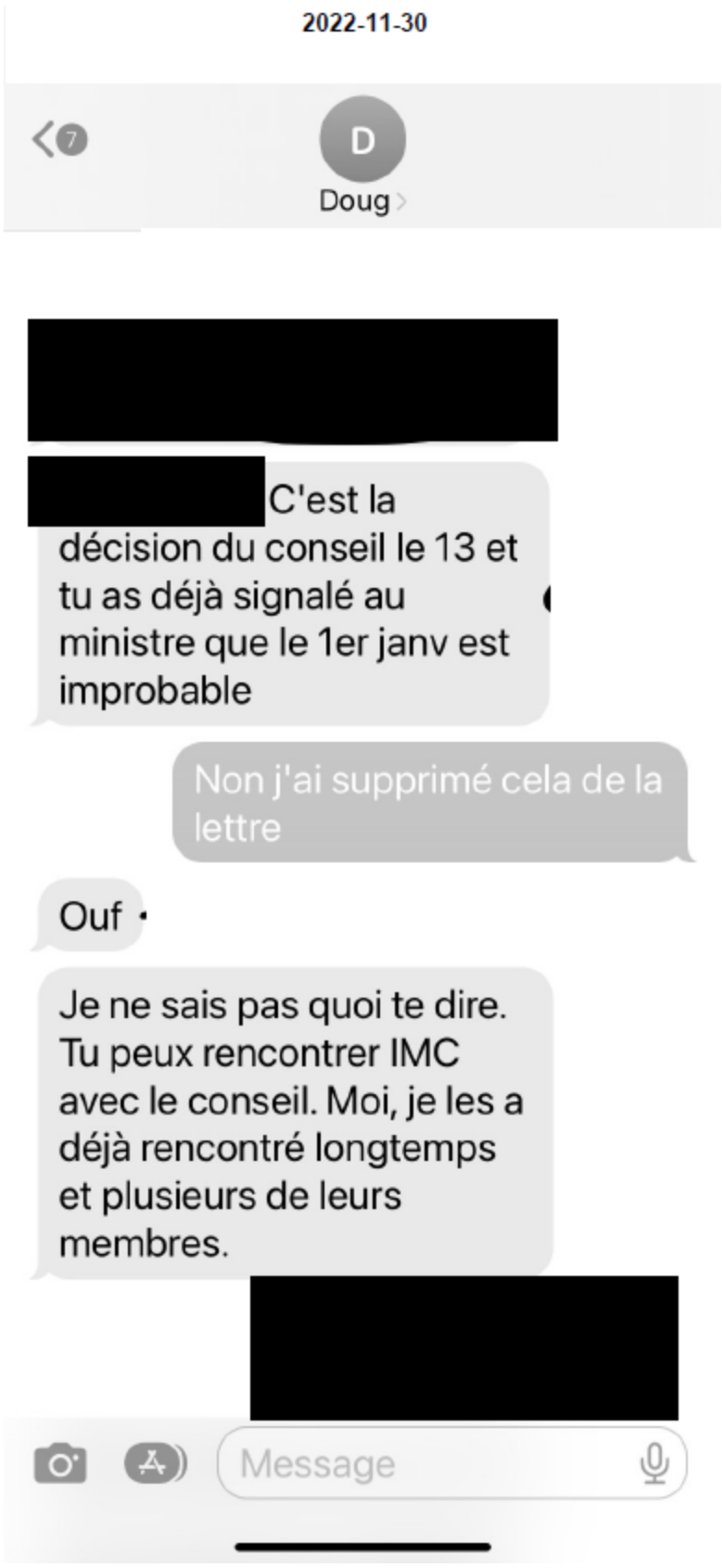


The only question I have is whether we should make it known that we're open to changes to the lines and that we believe that January 1, 2023, is no longer really feasible, or something like that.

We're open to listening.

I'm sure this is the most strategic approach.

Okay, I'll get back to you with some changes after talking with



It's the board's decision on the 13th and you've already pointed out to the Minister that January 1 is unlikely.

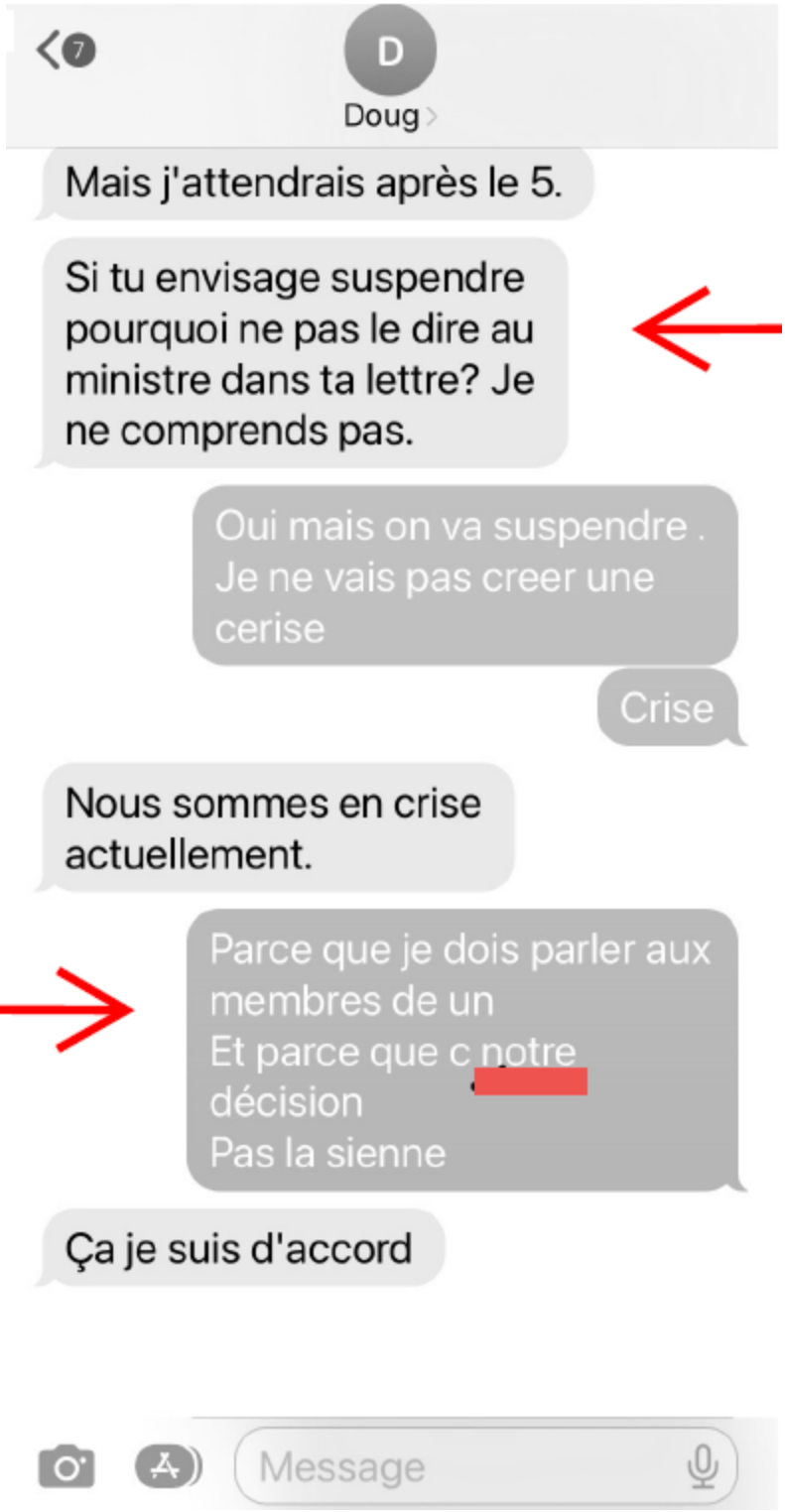
No, I left that out of the letter

Ouf.

I don't know what to tell you. You can meet IMC with the board. I've already met with them a long time ago and several of their members.

Annexe D2

2022-11-30



But I'll wait until after the 5th.

If you're thinking of suspending, why not tell the Minister in your letter? I don't understand.

Yes but we're going to suspend. I'm not going to cause a crisis.

Crisis

We're already in a crisis.

Because I have to talk to the members, first of all, and because it's our decision, not his

I agree.

Annexe E

I'm online.

No one is here.

Me too.

I think you want to stop there.

Okay, got it, thank you.

Annexe F1

From: Mélanie Bourassa Forcier <Melanie.Bourassa.Forcier@USherbrooke.ca>
Sent: December 1, 2022 9:19 AM
To: Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca>
Subject: Re:

E-mail to members

Thank you, Sherri.

We are under no obligation to report to the Minister. However, in the interests of good governance and maintaining a relationship of trust, I have told the Deputy Minister that we will inform him of our decision.

Yesterday's reference to implementation was, as I said, a mistake. I made it clear that I was talking about extending the discussion period. If we do nothing, the discussion period ends on the 5th. Right? If doing nothing means ending the discussion period on schedule, we must inform IMC and the Minister. It is a decision, one to not change anything...

Thank you. You can send the e-mail.

Mélanie

Annexe F2

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

Chers membres du Conseil

J'ai pris le temps de réfléchir à la décision que vous avez prise hier lors de notre rencontre. Cette décision est celle de ***proposer une rencontre à Médicament Novateur Canada pour le 13 décembre et de terminer la période de consultation pour les lignes directrices à la date prévue, soit le 5 décembre (si nous ne faisons rien cette période se termine par elle-même…).***

Moralement et professionnellement, il me sera impossible d'appuyer cette décision (de ne rien faire). Hier, j'ai assuré le sous-ministre M. Lucas du fait qu'il était pour moi essentiel de prendre le temps de rencontrer l'industrie et de mieux saisir les incompréhensions en lien avec les lignes directrices. Rencontrer l'industrie après la fin de la période de consultation aurait pour effet d'envoyer le message à l'effet que nos discussions du 13 ne seront pas prises en considération dans la modification des lignes directrices. Légalement, afin de nous conformer aux critères de justice administrative, nous devons donner la chance à l'ensemble des acteurs de nous rencontrer dans ce processus. Prendre en compte les commentaires de l'industrie après la période de consultation aurait pour effet de privilégier un acteur plutôt qu'un autre. Même si légalement cela est possible, cela est dangereux d'un point de vue politique.

Considérant ce qui précède, deux options s'offrent à nous :

1. *Rencontrer MNC avant la fin de la période de consultation (donc avant le 5 décembre); ou*
2. *Suspendre ou prolonger la période de consultation jusqu'à notre rencontre avec IMC.*

Ces options ne représentent aucun risque à mes yeux alors que celle que vous avez privilégiée en comporte plusieurs. Je comprends que plusieurs d'entre vous sont à bout de souffle, sentiment que je ne partage pas parce que je me suis jointe au CEMPB beaucoup tardivement mais que je comprends. Néanmoins, il est important que les sentiments n'influencent pas la rationalité de nos décisions.

Les deux options proposées ne remettent nullement en cause la période de mise en œuvre de directives. Nous déterminerons ce que nous souhaitons faire à ce sujet après notre rencontre avec IMC tout simplement.

Merci de m'indiquer votre position avant 10h afin que le Ministre soit informé avant sa rencontre avec IMC: option 1, option 2 ou si vous souhaitez aller de l'avant avec celle avancée hier (ne rien faire quant à la date finale des consultations et rencontrer IMC le 13)

.Si tel est le cas je ne pourrai appuyer cette décision comme précédemment mentionné (de toute façon il ne s'agit d'une décision du président mais bien du board) et je le soulignerai au Ministre. Je devrai aussi nécessairement réfléchir ma place au sein du Conseil du fait qu'il est pour moi essentiel, dans l'élaboration de politiques publiques, de prendre le temps d'écouter et de considérer les acteurs. Comme je l'indiquais hier, il ne s'agit pas que d'informer et de recevoir des commentaires, mais bien de collaborer dans l'identification des éléments qui nous permettent de mieux atteindre nos objectifs.

Nous pourrons discuter du tout si vous êtes disponibles ce matin.

Merci

Mélanie

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 favoring 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 MNC 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 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

Professeure titulaire

Directrice des programmes maîtrise en Droit et Politiques de la Santé

Co-responsable du programme de Droit et Sciences de la vie

Faculté de droit, Université de Sherbrooke

Fellow, CIRANO

Collaboratrice, CSBE

Présidente par intérim, CEPMB

Annexe F3

Douglas Clark

À : Melanie Bourassa Forcier **+1 autre(s)**

Jeu 2022-12-01 10:26

Cc : Sherri Wilson

Melanie, a week ago today, I briefed you on my meeting with IMC on November 23. You'll recall that I was very harsh with them about their recent highly critical public communications regarding the PMPRB and our consultation on the guidelines. I told them in no uncertain terms, in front of senior PMPRB staff and around twenty IMC members, that the PMPRB was responsible for its consultation process and that IMC should stop publicly calling for outside involvement in this process, as it was inappropriate and would not have the desired effect. When we spoke, you approved of the message I conveyed to IMC.

I know that you want to get in the good graces of the MP and the Minister (I'd like to do the same myself) and that you think you made commitments to the MP yesterday about next steps, but, if this is the case, those commitments were inappropriate and should never have been made before meeting with the Board. As Acting Chairperson, you can't expect the Board to make a decision on this issue without being totally transparent about the things you've said and done this week (including your letter to the Minister from yesterday) and I can't do anything at the staff level until that happens and there's a decision from the Board on the best way to move forward. Needless to say, if the Board decides to suspend consultations and make a public announcement to that effect, staff members will lose credibility with IMC, and any future meetings between us will be window dressing at best, as IMC will know that if it hears anything it doesn't like, the Minister will order the Board to back off. Please don't put us in this situation.

Douglas Clark
Executive Director/Directeur exécutif
Patented Medicine Prices Review Board/Conseil d'examen du prix des médicaments brevetés
Government of Canada/Gouvernement du Canada

Annexe F4

Le 2 déc. 2022 à 10:10, Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca> a écrit :

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.

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

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

Chers membres du Conseil

J'ai pris le temps de réfléchir à la décision que vous avez prise hier lors de notre rencontre. Cette décision est celle de ***proposer une rencontre à Médicament Novateur Canada pour le 13 décembre et de terminer la période de consultation pour les lignes directrices à la date prévue, soit le 5 décembre (si nous ne faisons rien cette période se termine par elle-même…).***

Moralement et professionnellement, il me sera impossible d'appuyer cette décision (de ne rien faire). Hier, j'ai assuré le sous-ministre M. Lucas du fait qu'il était pour moi essentiel de prendre le temps de rencontrer l'industrie et de mieux saisir les incompréhensions en lien avec les lignes directrices. Rencontrer l'industrie après la fin de la période de consultation aurait pour effet d'envoyer le message à l'effet que nos discussions du 13 ne seront pas prises en considération dans la modification des lignes directrices. Légalement, afin de nous conformer aux critères de justice administrative, nous devons donner la chance à l'ensemble des acteurs de nous rencontrer dans ce processus. Prendre en compte les commentaires de l'industrie après la période de consultation aurait pour effet de privilégier un acteur plutôt qu'un autre. Même si légalement cela est possible, cela est dangereux d'un point de vue politique.

Considérant ce qui précède, deux options s'offrent à nous :

1. *Rencontrer MNC avant la fin de la période de consultation (donc avant le 5 décembre); ou*
2. *Suspendre ou prolonger la période de consultation jusqu'à notre rencontre avec IMC.*

Ces options ne représentent aucun risque à mes yeux alors que celle que vous avez privilégiée en comporte plusieurs. Je comprends que plusieurs d'entre vous sont à bout de souffle, sentiment que je ne partage pas parce que je me suis jointe au CEMPB beaucoup tardivement mais que je comprends. Néanmoins, il est important que les sentiments n'influencent pas la rationalité de nos décisions.

Les deux options proposées ne remettent nullement en cause la période de mise en œuvre de directives. Nous déterminerons ce que nous souhaitons faire à ce sujet après notre rencontre avec IMC tout simplement.

Merci de m'indiquer votre position avant 10h afin que le Ministre soit informé avant sa rencontre avec IMC: option 1, option 2 ou si vous souhaitez aller de l'avant avec celle avancée hier (ne rien faire quant à la date finale des consultations et rencontrer IMC le 13)

.Si tel est le cas je ne pourrai appuyer cette décision comme précédemment mentionné (de toute façon il ne s'agit d'une décision du président mais bien du board) et je le soulignerai au Ministre. Je devrai aussi nécessairement réfléchir ma place au sein du Conseil du fait qu'il est pour moi essentiel, dans l'élaboration de politiques publiques, de prendre le temps d'écouter et de considérer les acteurs. Comme je l'indiquais hier, il ne s'agit pas que d'informer et de recevoir des commentaires, mais bien de collaborer dans l'identification des éléments qui nous permettent de mieux atteindre nos objectifs.

Nous pourrons discuter du tout si vous êtes disponibles ce matin.

Merci

Mélanie

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 favoring one stakeholder over another. Even if this is ok on a legal standpoint, I considering that this is problematic on a political standpoint.

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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

Professeure titulaire

Directrice des programmes maîtrise en Droit et Politiques de la Santé

Co-responsable du programme de Droit et Sciences de la vie

Faculté de droit, Université de Sherbrooke

Fellow, CIRANO

Collaboratrice, CSBE

Présidente par intérim, CEPMB

Annexe F5

MF

Mélanie Bourassa Forcier <Melanie.Bourassa.Forcier@USherbrooke.ca>

Ven 2022-12-02 10:17

To: Sherri Wilson

Cc: Melanie Bourassa Forcier, C Kobernick <carolynkobernick@gmail.com +2 others

Hello,

I've noted the members' position, which I do not share and cannot endorse.

Therefore, I will not sign any letter dictated to me.

Thank you,

On Dec. 2, 2022 at 10:10 AM, Sherri Wilson <Sherri.Wilson@pmprb-cepmb.gc.ca> wrote:

Annexe G1

MH

Matthew Herder <Matthew.Herder@Dal.Ca>

À : Melanie Bourassa Forcier; Ingrid Sketris <Ingrid.Sketris@Dal.Ca> **+1 autre(s)**

Dim 2022-12-04 14:17

Cc : Sherri Wilson; Douglas Clark

Dear Melanie,

Carolyn, Ingrid and I chatted earlier today. We're happy to meet tomorrow although we're only available in the afternoon. Also, if we do meet, staff must be present.

We should add that, after further discussion, our position remains the same: we think the current consultations should run their course and the Board should meet on the 13th to discuss next steps at that time. Additional consultations with all stakeholders can always be had if necessary.

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

Annexe G2

CK

Carolyn Kobernick <carolynkobernick@gmail.com>

À : Melanie Bourassa Forcier

Lun 2022-12-05 15:31

Cc : Matthew Herder <Matthew.Herder@dal.ca>; Ingrid Sketris <Ingrid.Sketris@dal.ca>; Sherri Wilson

Dear Melanie. Ingrid and I have spoken. Our position remains the same i.e. that consultations end today.

That being said we are prepared to discuss this issue further at our meeting on Dec 13th in Ottawa. As you know the Board can decide to reope consultations to all stakeholders.

Carolyn
647 987-8555

Annexe H

Re: Soumission de Santé Canada relativement aux consultations sur les lignes directrices du CEPMB

MF

Melanie Bourassa Forcier

À : Matthew Herder <Matthew.Herder@Dal.Ca>; Ingrid Sketris <Ingrid.Sketris@Dal.Ca> **+1 autre(s)**

Lun 2022-12-05 11:58

ENGLISH BELLOW
Bonjour Matthew

Merci pour ta réponse. Depuis les derniers jours je fais face à des attaques personnelles et on remet en question mon jugement, mon indépendance et mon impartialité parce qu'il me semble important de répondre positivement aux demandes du ministre de la santé et de IMC, c'est-à-dire, de prendre plus de temps pour rencontrer les acteurs, ceci afin de bien remplir notre obligation de consultation.

Faire autrement, poursuivre en étant muets face à ces demandes lance, selon moi, un message de confrontation avec lequel je ne suis pas confortable. Faire autrement, aller à l'encontre de la demande du ministre qui est maintenant accessible au public, me rend extrêmement inconfortable.

Nous pourrions en effet ne rien faire et reprendre des consultations plus tard. Tout est dans le message. Ne rien faire, ne rien dire, lance ce message avec lequel je ne suis pas confortable. Le dialogue a toujours été extrêmement important pour moi. Je vois bien que plusieurs considèrent que ce dialogue est impossible avec l'industrie. Par contre, je crois que notre mandat, à titre de membres du CEPMB, est néanmoins d'être ouverts à ce dialogue et de ne pas assumer que nous avons rempli nos obligations. Encore une fois, cela ne nous engage à rien quant au moment d'implantation de nos lignes directrices ni quant au contenu des guidelines.

Maintenant, j'avoue que j'hésite à tenir la rencontre si votre décision est prise. Je pense que nous sommes à un point où le personnel et moi-même avons besoin de prendre du recul.

Si vous êtes prêts à rediscuter de votre décision prise hier matin entre vous (toi, Carolyn et Ingrid), je crois qu'il s'agit alors de délibérations qui se doivent d'être confidentielles. Tout au plus Sherri pourra être présente.

Je suis sincèrement affectée par l'ampleur de la crise, tout ceci parce que j'ai manifesté ma divergence d'interprétation de notre obligation de consultation.

Re: Soumission de Santé Canada relativement aux consultations sur les lignes directrices du CEPMB

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 launch another consultation period after we meet on Dec 13 . It'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. 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 and the decision of the other board members 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 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