PATENTED MEDICINE PRICES REVIEW BOARD

IN THE MATTER OF the *Patent Act*,
R.S.C., 1985, c. P-4, as amended

AND IN THE MATTER OF
Alexion Pharmaceuticals Inc. (the "Respondent")
and the medicine "Soliris"

BIOTECANADA MOTION FOR LEAVE TO INTERVENE

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TAB 1

IN THE MATTER OF the Patent Act,
R.S.C., 1985, c. P-4, as amended

AND IN THE MATTER OF
Alexion Pharmaceuticals Inc. ("Respondent")
and the medicine "Soliris®"

BIOTECANADA MOTION FOR LEAVE TO INTERVENE

TAKE NOTICE THAT BIOTECanada submits this motion before the Patented Medicine Prices Review Board (PMPRB).

THE MOTION IS FOR an order granting BIOTECanada further intervener status in this matter in order to permit BIOTECanada to file written submissions with the PMPRB in the form attached as **Exhibit A** to this motion, and speak for 30 minutes in closing argument, regarding its position and that of its members on this hearing.

THE GROUNDS FOR THE MOTION ARE:

Facts Upon Which this Motion is Based

1. BIOTECanada, on behalf of its member companies, has an interest in another of the issues in dispute in this proceeding.

2. BIOTECanada was previously granted leave to intervene on the issue of the Board Staff's presentation of a new definition of "therapeutic class" in this proceeding (the "Leave Order").

3. BIOTECanada represents the interests of over 200 member companies located across the country, many of whom produce and/or market medicines which are used to treat serious illnesses and the manner in which the prices of those medicines are determined may be affected by the outcome of this proceeding.

4. BIOTECanada, on behalf of its member companies, is in a position to provide information that is relevant to these proceedings.

5. BIOTECanada has learned from monitoring the Board's website that after the previous Leave Order, the Board issued Reasons for Decision in relation to a motion by the patentee, Alexion, to strike an Amended Statement of Allegations (the "Amended Statement") filed by Board Staff.

6. This Amended Statement is not available publically. However, portions of it have been cited in publically available documents, and it appears that the Board Staff is purporting to create new tests, not found in the Guidelines, for determining whether a medicine's price is excessive and how to calculate the excess revenues that should be forfeited.

7. These new tests, if adopted in this case, have the potential to affect the interests of BIOTECanada's members generally, as they are yet another departure from the PMPRB's Guidelines, and could be used again in the future in respect of other patented medicines.

8. So far as we can determine from the public record, the Amended Statement seeks an order, *inter alia*, requiring:

   (a) Alexion to reduce its price for SOLIRIS® in Canada to the "lowest international price" (LIP) among comparator countries;

   (b) Alexion to forfeit "excessive revenues" based on either this LIP comparator (LIPC) or the Median International Price Comparison (MIPC); and

   (c) Alexion's forfeitures to be retroactive to the outset of its sales of SOLIRIS®.

9. The Board Staff had not previously raised these potential remedies, they were only raised by the Ministers of Health as represented by the Minister of Health from British Columbia. Now that the Board Staff is adopting these issues, they represent a fundamental change from the Guidelines published by the PMPRB, that purport to set out how the Board Staff should be determining whether an excessive price exists.

10. Accordingly, this is a novel issue not previously disclosed in the information posted to the Board's website and one which, as stated above, is of direct concern to BIOTECanada and its members.

The Test for Intervention

11. Rule 20(5) of the *Patented Medicines Prices Review Board Rules of Practice and Procedure*, (the *Rules*) sets out that:

> the Board may grant or deny the intervention and impose any conditions or restrictions on the intervention that it determines to be appropriate after considering relevant factors, including
>
> (a) whether the person has an interest in the proceeding that is sufficient to warrant the intervention;
>
> (b) whether the intervention will prejudice any party to the proceeding; and
>
> (c) whether the intervention will interfere with the fair and expeditious conduct of the proceeding.[1]

12. The PMPRB has held that:

> As a general matter, and consistent with past practice at the Board, the Board would expect that other persons with an interest in the Board's hearings, in the sense contemplated by Rule 19, would be in one of the following three categories:
>
> 1. Persons who, in one manner or another, will bear some or all of the cost burden of the medicine in question, or the cost burden of other medicines where the prices of such medicines could be affected by the outcome of the proceeding;
>
> 2. Patentees, the maximum non-excessive prices of whose medicines will be affected by the specific outcome of the proceeding, or by the establishment of a point of principle pertaining the non-excessive pricing of medicines or the Board's jurisdiction; or
>
> 3. Organizations representing persons in the two previous categories.[2]

13. BIOTECanada is an organization representing patentees whose maximum non-excessive medicine prices will be affected by the specific outcome of this proceeding. Furthermore, the organization's members will be affected by a point of principle pertaining to the pricing and the Board's jurisdiction –

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[1] *Patented Medicines Prices Review Board Rules of Practice and Procedure*, SOR/2012-247, Rule 20(5), Tab 5.

[2] Sanofi Pasteur Limited and the medicines "Quadracel and Pentacel", PMPRB-07-D1 – QUADRACEL and PENTACEL, dated July 26, 2007, Tab 6.

specifically in relation to the new remedies sought by the Board Staff in response to the investigation.

14. BIOTECanada submits that it meets these criteria, as set out below.

BIOTECanada's Interest in this Proceeding

15. BIOTECanada represents the interests of over 200 member companies located across the country, many of whom produce and/or market medicines which are used to treat serious illnesses.[3]

16. One of BIOTECanada's strategic objectives is to seek to establish a globally competitive regulatory policy framework to support all aspects of Canadian biotechnology.[4] The PMPRB is part of the regulatory policy framework that affects Canadian biotechnology.

17. An important part of this framework is its consistent application and predictability. BIOTECanada is concerned with the Board Staff's new remedies for excessive pricing for the following broad reasons:

    (a) It sets a new calculation to determine whether pricing is excessive. This is problematic as this is not the test used by the Board staff as part of the analysis to determine the Maximum Average Potential Price (the "MAPP") of the patented medicine.

    (b) The MAPP is what is used by the patentee to set its pricing for the medicine in Canada. The patentee then reports its prices to the PMRPB. Thus, if a price is deemed excessive on the basis of a test other than the test at which that price was set, there is a disconnect between the Guidelines and the remedies sought by the Board Staff.

    (c) As a result, this new purported remedy could be used to require forfeiture of revenues that were obtained as a result of sales made at a price determined in accordance with the Guidelines.

[3] Affidavit of Andrew Casey sworn December 20, 2016 ("Casey Affidavit"), paragraph 7, Tab 3.
[4] Casey Affidavit, paragraph 9, Tab 3.

(d) This extraordinary remedy is sought to be retroactive to the first sale made.

(e) This system, as described, would create a lot of uncertainty for BIOTECanada's members, as they could never be sure what test will be used when the Board analyzes the prices of their medicines.

(f) Furthermore, the retroactive nature of this new purported remedy is unfair to BIOTECanada's members who have relied on the Guidelines in order to set the prices of their medicines up until now.

(g) In seeking this purported new remedy, the Board Staff is seeking to amend the Guidelines without consultation. This is contrary to the *Patent Act*, and as such, is outside the Board's jurisdiction. In addition, seeking this remedy breaches the principles of fundamental fairness. In representing that the MIPC could be used to determine the MAPP, the Board is estopped from using the LIPC to determine whether a medicine's price is excessive.

18. The purpose of a globally competitive regulatory policy framework is to create certainty, not uncertainty. This certainty is what makes such a framework globally competitive. To date, the PMPRB's Regulations and their application have generally been certain. The PMPRB encourages voluntary compliance with the Guidelines. And, the Guidelines are used. Thus, the approaches between different drugs have been generally consistent. However, the approach suggested in the Amended Statement jeopardizes that certainty, and is of great concern to BIOTECanada's members.

19. BIOTECanada submits that its intervention is necessary, as it can provide the perspective of the biotechnology industry as a whole in relation to these new purported retroactive remedies that use the LIPC to determine forfeitures. It appears as though the PMPRB may be trying to effect a policy shift, or regulatory change without any sort of statutory authority, or even a

consultation period.[5] In BIOTECanada's submission, if this change is being effected through the SOLIRIS® proceeding, which is improper in any event, BIOTECanada's intervention may be the only representation the broader industry has on this issue.

Issues BIOTECanada Intends to Address

20. BIOTECanada intends to address solely the issue of the Board Staff's use of the new tests in the Amended Statement to determine whether a medicine's price is excessive, and seek forfeiture of excess revenues based on these new tests.

Pricing in the Guidelines vs Excessive Pricing as Determined by the New Remedies Sought by the Board Staff

21. BIOTECanada seeks leave to intervene in this matter, as the Board Staff has put forward the Amended Statement and its purported new remedies as part of what it is seeking from Alexion in this pricing dispute. If the PMPRB intends to use these new remedies on a going forward basis, BIOTECanada's members will be greatly affected.

22. BIOTECanada has drafted written argument in support of its position in relation to these purported new remedies. That argument is attached as **Exhibit A** to this Notice of Motion. It sets out BIOTECanada's concerns under these main categories:

(a) The current test for the introductory price or MAPP uses the MIPC test. If the LIPC test is used to determine whether a price is excessive, and as a basis for forfeitures, the determination of the MAPP in accordance with the Guidelines is rendered moot.

(b) The Guidelines are meant to be used by patentees for Voluntary Compliance, and thus need to provide certainty and predictability.

[5] Casey Affidavit, paragraphs 19-24, Tab 3.

(c) In order for the Guidelines to be amended, the *Patent Act* requires a public consultation. Thus, any amendment without a public consultation is both contrary to the principles of procedural fairness and legitimate expectations and outside the jurisdiction of the Board.

(d) The Board is estopped from using the LIPC test to determine whether excessive pricing exists and to determine the quantum of forfeiture after setting the MAPP using the MIPC test. Furthermore, the Board is estopped from amending the Guidelines in this manner after representing to patentees that the Guidelines are to be used for voluntary compliance.

(e) The principles of statutory interpretation and the prohibition against retroactivity as they apply to the effective Guidelines' amendments that result from the purported remedies sought by the Amended Statement;

23. BIOTECanada also seeks to speak for 30 minutes in closing argument on these issues.

There is No Prejudice in BIOTECanada's Intervention in this Proceeding

24. BIOTECanada represents a large number of the manufacturers whose drugs are regulated by the PMPRB. BIOTECanada is seeking no additional remedies. Nor is BIOTECanada seeking to raise any new issues. Thus, its voice cannot cause prejudice to any party.

25. To the contrary, it is the lack of a voice from BIOTECanada that will be prejudicial. The PMPRB appears to be trying to effect a change to the Guidelines and the determination of the MAPP through changes to remedies sought as a result of an excessive price determination. However, this change is being effected in the middle of the price analysis of SOLIRIS®; and without any consultation.

26. The PMRPB's website indicates that the Guidelines were developed in consultation with stakeholders, including Ministers of Health, consumer groups and the pharmaceutical industry.[6] A current consultation is ongoing, but it is in the "Discussion Paper" phase. Furthermore, as explained on the PMPRB website, the LIPC test is not sought to be used for "first in class" drugs such as SOLIRIS®.[7]

27. If no consultation is planned on this additional change to the pricing scheme sought to be effected in this case, then this intervention may be the only opportunity the pharmaceutical industry has to have a voice in this fundamental change.

BIOTECanada's Intervention Will Not Affect the Fair and Expeditious Conduct of the Hearing

28. BIOTECanada is seeking to file the attached written representations, and is only proposing to participate at the hearing by speaking for 30 minutes in closing argument. BIOTECanada is not seeking to present witnesses.

29. The parties will be familiar with BIOTECanada's representations from their responses to this motion. Furthermore, BIOTECanada's 30 minute submission should not prejudice any of the parties. Indeed, it may help in that the Board will be able to ask questions of BIOTECanada should it seek any clarification of BIOTECanada's submissions.

30. Thus, BIOTECanada's intervention will not delay the hearing in any way.

Conclusions

31. BIOTECanada's interest in this proceeding is apparent. The PMPRB has indicated, through the filing of the Amended Statement that it wants to change

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[6] Government of Canada, "Regulatory Process", <http://www.pmprb-cepmb.gc.ca/en/regulating-prices/regulatory-process>, Tab 7.

[7] Patented Medicine Prices Review Board, "Rethinking the Guidelines", <http://www.pmprb-cepmb.gc.ca/en/news-and-events/consultations/current-major-consultations/rethinking-the-guidelines>, Tab 8.

the methods of determining excessive price, and thus the methods for determining MAPP that it currently applies in its Guidelines.

32. These changes have a broader effect than just in the case of SOLIRIS®. These changes, and the manner in which the PMPRB is trying to make them, will affect all of BIOTECanada's members who research and develop patented medicines.

33. This will lead to a great deal of uncertainty for BIOTECanada's members in relation to how the PMPRB will consider their medicines in the future. If the prices at which they currently sell patented medicines, in accordance with the Guidelines, can render them subject to forfeiture of what had previously been deemed proper revenues, the resulting uncertainty could be catastrophic. The PMPRB's system, which is built on voluntary compliance, would have no effective meaning, rendering every patented medicine possibly subject to these new forfeitures.

34. BIOTECanada submits that these changes should not be permitted for the reasons described in the Written Argument at **Exhibit A**. In addition, BIOTECanada submits that since the PMPRB is seeking to effect these fundamental changes through the filing of an Amended Statement, and not through proper channels (statutory, regulatory or guideline channels with appropriate consultations), it should be permitted to provide its submissions to the Board, as these may be the only "consultations" its members will receive on these issues.

35. BIOTECanada's intervention in this proceeding will not cause prejudice to any party. To the contrary, it will provide the views of a large portion of the PMPRB's users in relation to a policy change that the PMPRB is trying to effect without consultation. It would be prejudicial to the industry to change the policy without BIOTECanada's intervention.

36. BIOTECanada's intervention will not cause any delay in the proceeding. As we are only seeking to speak for 30 minutes in closing argument, in addition to filing the attached written representations, our participation will not prejudice any of the parties. Indeed, our presence in closing argument will permit the Board to ask questions and seek clarification of the issues raised by BIOTECanada in its written argument.

37. Thus, we respectfully submit that BIOTECanada's motion to intervene in this proceeding be granted, and that the Board accept the Written Representations at **Exhibit A** to this motion on the merits of the proceeding.

Dated at Ottawa, Ontario this 20th day of December, 2016

ON BEHALF OF:
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TAB 2

Exhibit A to
BIOTECANADA MOTION FOR LEAVE TO INTERVENE

IN THE MATTER OF the Patent Act,
R.S.C., 1985, c. P-4, as amended

AND IN THE MATTER OF
Alexion Pharmaceuticals Inc. ("Respondent")
and the medicine "Soliris®"

BIOTECANADA WRITTEN REPRESENTATIONS ON THE MERITS

Facts

1. BIOTECanada, on behalf of its member companies, has an interest in at least one of the subject matters of this proceeding. BIOTECanada, on behalf of its member companies, is in a position to provide information that is relevant to these proceedings.

2. BIOTECanada's members include a wide variety of biotechnology organizations, most of which are in the business of researching and developing patentable technologies relating to medicines. Thus, their medicines would come under the jurisdiction of the Patented Medicine Prices Review Board (PMRPB) when they reach the market. Many of BIOTECanada's members produce and/or market medicines which are used to treat serious illnesses. Furthermore, many of BIOTECanada's members research, develop and sell drugs to treat rare diseases (orphan drugs).

3. In this proceeding, the Board Staff have amended their Statement of Allegations (the "Amended Statement").

4. The Amended Statement is not available publicly. However, portions of it have been cited in publically available documents. BIOTECanada is concerned about several of those amended provisions, as they purport to create new tests, not found in the Guidelines, for determining whether a medicine's price is excessive and how to calculate the excess revenues that should be forfeited.

5. These new tests have the potential to affect the interests of BIOTECanada's members generally, as they are a significant departure from the PMPRB's Guidelines. Furthermore, they are a breach of procedural fairness and a breach of the principles of statutory interpretation as discussed further below. In addition, they are outside the PMPRB's jurisdiction.

6. In particular, the Amended Statement seeks an order, *inter alia,* requiring:

   (a) Alexion to reduce its price for SOLIRIS® in Canada to the "lowest international price" (LIP) among comparator countries;

   (b) Alexion to forfeit "excessive revenues" based on either this LIP comparator (LIPC) or the Median International Price Comparison (MIPC); and

   (c) Alexion's forfeitures to be retroactive to the outset of its sales of SOLIRIS®.

Issue

7. This written argument addresses solely the issue of the Board Staff's use of the new tests in the Amended Statement to determine whether a medicine's price is excessive, and to then seek forfeiture of excessive revenues based on these new tests.

The Introductory Price is Determined using the MIPC Test

8. The Guidelines set out several different criteria for determining the test applicable to the introductory price of a new patented medicine (the Maximum Average Potential Price or MAPP), depending upon the level of therapeutic improvement assigned to the drug. However, each of these criteria involves an analysis of the MIPC test.[1]

[1] Patented Medicines Price Review Board, "Compendium of Policies, Guidelines and Procedures" (July/August, 2016) ("Guidelines"), Schedule 8.

9. When a party starts selling a patented medicine in Canada, it must submit to the PMPRB its pricing information on a regular basis. The Board Staff then determines the "National Average Transaction Price" (NATP) for the medicine based on this pricing information.

10. Schedule 11 of the Compendium sets out the criteria to be used to decide whether to commence an investigation:

> **Criteria for Commencing an Investigation**
>
> Board Staff will commence an investigation into the price of a patented drug product when any of the following criteria are met:
>
> 1. The National Average Transaction Price or any Market-Specific Average Transaction Price of a new drug product exceeds the Maximum Average Potential Price during the introductory period by more than 5%.
>
> 2. Excess revenues for a new or existing drug product are $50,000 or more.
>
> 3. PMPRB receives a complaint.[2]

11. Criteria 1 and 2 are based on the relevant tests used to calculate the MAPP. However, Criteria 3 is outside of this test. Thus, in theory, anyone could make a complaint about pricing. Once that complaint is made, the Board Staff will commence an investigation.

12. Any individual or group affected by the price of a patented medicine can submit a complaint.[3]

13. The PMPRB's entire methodology in setting the MAPP would be undermined if the remedy was to lower the price and require forfeitures based on the LIPC, or MIPC, when used as a test for years following the introduction. There would be no reason to even start with the MIPC. Every Party (including BIOTECanada's members) selling a patented medicine would open

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[2] Guidelines, Schedule 11.

[3] Patented Medicine Prices Review Board, "How to Make a Complaint", <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1014>.

themselves up to punitive forfeiture measures if it accepted the Guidelines as a determination of the MAPP for its medicines.

14. Considering that companies have always been told to start with the MIPC, it is unconscionable for the Board to unilaterally change the system in this fashion.

15. Indeed, such rendering of the Guidelines as moot, is an end-run around the statutory requirement to hold public consultations before amending the Guidelines.[4] This statutory requirement is discussed further below. However, in effect, by purporting to apply the LIPC (or alternatively the MIPC) methodology to remedies, and make those remedies retroactive, the Board Staff has amended the terms in the Guidelines that set out how to calculate MAPP, and thus, NATP.

16. Furthermore, if accepted in this case, it would open every medicine being sold in Canada to the same process. Every Party (including BIOTECanada's members) selling a patented medicine in Canada could be subject to retroactive, punitive measures requiring them to forfeit previously proper revenues as excess due to the new application of the LIPC methodology to excessive price determinations.

17. This is improper and should not be countenanced. Furthermore, it is outside the Board's jurisdiction.

The Guidelines are Meant to be Used by Patentees for Voluntary Compliance

18. The Guidelines themselves state that one of their primary objectives is to ensure patentees are aware of the guidelines, policies and procedures used by the Board to review prices of patented medicines. In addition, the Guidelines are meant to uphold the principles of fairness, transparency, openness, and predictability.

> One of the primary objectives of the Compendium of Policies, Guidelines and Procedures (Compendium) is **to ensure that patentees**

[4] *Patent Act*, R.S.C., 1985, c. P-4 [hereinafter *Patent Act*], s. 96 [emphasis added].

> **are aware of the policies, guidelines and procedures under which Board Staff reviews the prices of patented drug products sold in Canada, and the procedures normally undertaken in the scientific and price review processes and when a price appears to be excessive.**
>
> From time to time, the PMPRB finds it necessary to update the Guidelines under which it operates to ensure that they remain relevant and appropriate, **as well as uphold the principles of fairness, transparency, openness, and predictability**. When considering Guidelines amendments, the PMPRB consults with its stakeholders through its Notice and Comment process.[5]

19. These objectives cannot be met if the Board Staff is permitted to retroactively amend the Guidelines through the remedies process in its investigations.

20. Furthermore, the PMPRB publishes Annual Reports every year. These Reports contain statements indicating that the Board's Guidelines are to be used by patentees to ensure that their pricing is not excessive. The 2009 Report states:

> Although patentees are not required to obtain approval of the price beforehand, they are required under the Act to ensure that prices of patented drug products sold in Canada are not excessive. **The Board's Guidelines detail how to determine whether a price is excessive.**[6]

21. The 2015 Report contains a similar statement:

> The Regulatory Affairs and Outreach Branch reviews the prices of patented drug products sold in Canada to ensure that they are not excessive; **encourages patentees to comply voluntarily with the Board's Guidelines**; implements related compliance policies; and investigates complaints into the prices of patented medicines. This branch also informs and educates patentees on the Board's Guidelines and filing requirements.[7]

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[5] Guidelines, p. 6 [emphasis added].

[6] Patented Medicine Prices Review Board, "Annual Report 2009" ("2009 Report"), <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=898> [emphasis added].

[7] Patented Medicine Prices Review Board, "Annual Report 2015" ("2015 Report"), <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1273#a5>.

22. Thus, the Board's public positon on its website, in its Guidelines, and in its Annual Reports, is that the Guidelines set out how a patentee can determine whether its price will be considered excessive. Furthermore, patentees are encouraged to voluntarily comply with the Board's Guidelines.

23. This public position is at odds with both the effective retroactive amendment to the Guidelines and the use of a different test to determine which revenues should be paid back if the Board deems a Party's price to be excessive.

24. In the Board Staff's Supplementary Reply to the Supplementary Response to Board Staff's Amended Statement of Allegations, the Board Staff states:

> To the extent that Alexion relied upon "publications, practices and representations" of the Board, it did so at its own peril.[8]

25. This statement is of great concern to BIOTECanada's members, given the principles of procedural fairness, legitimate expectations and detrimental reliance discussed herein. Furthermore, it is contrary to the Board's own statements that patentees are encouraged to voluntarily comply with the Guidelines.

Procedural Fairness and Legitimate Expectations

26. The PMPRB has breached the principles of procedural fairness and legitimate expectations by filing the Amended Statement seeking remedies that require Alexion to reduce its price for SOLIRIS® in Canada to the LIP (or MIP) among comparator countries; to forfeit excessive remedies based on this LIP (or MIP); and to make those forfeitures retroactive to the introduction of SOLIRIS® in Canada.

27. These new remedies are not found in the Guidelines, nor in the *Patent Act*.

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[8] Patented Medicine Prices Review Board, "Supplementary reply of Board Staff to the Amended Statement of Allegations: August 11, 2016", <http://www.pmprb- cepmb.gc.ca/CMFiles/Hearings %20and%20Decisions/Decisions%20and%20Orders/supplementary_reply.pdf>, paragraph 19.

28. The *Patent Act* requires the Board to consult before it issues Guidelines. Thus, there is a breach of procedural fairness in the PMPRB purporting to change the Guidelines, through the implementation of these remedies, without a public consultation.

29. In this regard, the *Patent Act* states:

> 96 (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 patentee.
>
> (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.[9]

30. The Board has no jurisdiction to act in a manner contrary to the *Patent Act*, which it is clearly attempting to do in this case by contravening s. 96(5).

31. The Guidance Document states:

> The Board, following considerable deliberation and consultation with all stakeholders, pursuant to subsection 96(5) of the Act, published the PMPRB'S Guidelines pursuant to subsection 96(4) of the Act.[10]

32. Even the PMPRB acknowledges that changes to the Guidelines require consultations.[11] As discussed below, the PMPRB has opened a consultation with respect to the Guidelines.

33. The Board thus established a procedure for setting Guidelines. Stakeholders, including BIOTECanada's members had a legitimate expectation that further consultations would occur if any substantive changes to the Guidelines were

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[9] *Patent Act*, s. 96 [emphasis added].
[10] Guidelines, Part C.
[11] Patented Medicine Prices Review Board, "PMPRB Guidelines Modernization – Discussion Paper – June 2016" ("June 2016 Discussion Paper"), <http://www.pmprb-cepmb.gc.ca/en/news-and-events/consultations/current-major-consultations/rethinking-the-guidelines/discussion-paper>.

going to be effected. BIOTECanada's members relied on the methods for calculating MAPP and NATP in the Guidelines.

34. There is a further breach of procedural fairness and legitimate expectations in the Board Staff changing their approach to determining whether a price is excessive as between the initial determination of the MAPP and the remedies sought in the Amended Statement.

35. BIOTECanada submits that the PMPRB made a representation to Alexion when determining the MAPP for SOLIRIS®. That representation was based on the Guidelines and the use of the MIPC test. The PMPRB should continue its excessive pricing analysis and order remedies based on that representation.

36. Alexion relied on that representation, and had a legitimate expectation that further pricing analysis would continue on the basis of the MIPC test, as set out in the Guidelines. However, in suggesting the LIPC test be applied in this situation, the Board Staff are breaching the principles of procedural fairness.

37. If the Board Staff is breaching these principles as against Alexion, it may do so as against other BIOTECanada's members. Thus, BIOTECanada has an interest in pursuing this issue.

38. In addition to the general legal principles of procedural fairness, the Board's own enabling legislation requires the Board to act in accordance with the principles of fairness:

> 97 (1) All proceedings before the Board shall be dealt with as informally and expeditiously as the circumstances and **considerations of fairness permit.**[12]

39. Should the Board retroactively amend the Guidelines in the manner suggested by the Board Staff, the Board will be outside of its jurisdiction, and moreover, such amendment is against the principles of fairness, as described above.

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[12] *Patent Act*, s. 97(1).

The Board is Estopped from using the LIPC Test

40. The principles of estoppel and detrimental reliance apply to prevent the Board from using the LIPC test (or MIPC test, following introduction) to determine whether excessive pricing exists, and to determine the quantum of forfeiture.

41. The Supreme Court of Canada set out the essential factors for determining whether an estoppel exists:

> (1) A representation or conduct amounting to a representation intended to induce a course of conduct on the part of the person to whom the representation is made.
>
> (2) An act or omission resulting from the representation, whether actual or by conduct, by the person to whom the representation is made.
>
> (3) Detriment to such person as a consequence of the act or omission.[13]

42. In this case, the Board set the MAPP for Alexion to sell SOLIRIS® (and for BIOTECanada's members to sell each of their patented medicines) by using the MIPC test. This determination of the MAPP for a particular patented medicine is a representation intended to induce a course of conduct on the part of the patentee. The Board, in setting the MAPP is representing to the patentee, the price at which its medicine will not be considered excessive.

43. The patentee sets its initial selling price of its medicine based on the representation of the MAPP by the Board. This act satisfies the second criterion from the Supreme Court.

44. Finally, if the Board changes conduct such that the LIPC (or MIPC) test is used to determine excessive pricing, rather than the test used to determine the MAPP, the patentee who has relied on the Board's initial representation regarding the MAPP will be harmed.

---

[13] *Canadian Superior Oil v. Hambly*, [1970] S.C.R. 932 at 939-40

45. Thus, if permitted to change course, the patentee will have relied on the Board's representations to their detriment. This reliance applies to all of BIOTECanada's members.

46. Similarly, as described above, the Board represented to patentees every year in their Annual Report that the Guidelines are to be used by patentees to ensure that their pricing is not excessive, and encouraging patentees to comply voluntarily with the Guidelines. Patentees rely on those representations when determining their pricing.

47. Thus, if the Board changes conduct such that a different test, not found in the Guidelines, and outside of what is stated in the Guidelines, is suddenly used by the Board to determine whether pricing is excessive, the patentees who have relied on the Board's initial representations that the Guidelines are to be used, will be harmed.

48. Again, if permitted to change course, the patentee will have relied on the Board's representations to their detriment.

49. As a result, the Board is estopped from changing course in the manner described by the Board Staff in the Amended Statement. The LIPC test cannot be used to determine excessive pricing or forfeitures when the MIPC test was used to determine the price of the drug at the outset.

The Board Has No Jurisdiction to Order Remedies Based on a Test not found in the Guidelines

50. The Board was established by and its conduct is governed by the *Patent Act*.[14] The Board has no jurisdiction to act in any manner not set out in the *Patent Act* and in particular s. 96(5) as discussed above.

51. Thus, the Board is required to act in accordance with considerations of fairness, and is required to consult with stakeholders before amending the Guidelines. Any contrary actions would be outside the Board's jurisdiction.

[14] *Patent Act*, s. 91.

52. Thus, the Board has no jurisdiction to determine excessive pricing based on the LIPC test, and has no jurisdiction to grant the remedy sought by Board staff case, namely requiring forfeiture based on an application of the LIPC test.

The Principles of Statutory Interpretation Apply to the *Patent Act*

53. It is a fundamental principle of statutory interpretation that in order for legislation to have a retroactive effect, that intent must be expressly communicated. The Federal Court of Appeal has recognized that people choose their actions based on what is known at the time, and to change the rules later to catch those who planned under the former law is unfair.

> The concern of courts about unauthorized regulations that cause retrospective or retroactive effects or interfere with vested rights is founded upon aspects of the rule of law. "**Citizens choose how to act in the belief that the state will impose the legal consequences determined by the legal text discoverable at that time and not on other texts which were not in existence at the time of the relevant action**"... . **It is unfair to change the rules later and catch those who planned their affairs under the former law.**[15]

54. A similar principle must apply to the Guidelines published by Boards and Tribunals. Otherwise, the results would be similarly unfair.

55. Thus, even if the Guidelines had been amended, there could be no retroactivity without explicit intention in those amendments.

56. The PMPRB has opened a consultation with respect to the Guidelines, and the determination of pricing is one of the issues in the consultation.[16] However, that consultation is in the "discussion paper" phase. New Guidelines have not yet been published, even in draft form. The PMPRB has accepted submissions on its "PMPRB Guidelines Modernization – Discussion Paper –

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[15] *Merck Frosst Canada & Co. v. Apotex Inc.*, 2011 FCA 329 at para. 53 [emphasis added; citations omitted].
[16] June 2016 Discussion Paper.

June 2016".[17] The date for publication of proposed changes has not even been announced.[18] Furthermore, the actual proposed changes will be subject to comment.[19]

57. The Discussion Paper refers to possible retroactivity in applying new pricing guidelines as one of its 12 questions for discussion in its consultations pursuant to section 96(5) of the *Patent Act*. Thus, the question is still open. Even if these new remedies can be found in the Discussion Paper, and even if the Discussion Paper can be read as having the same effect as the Guidelines, both of which are denied, there is certainly no explicit statement that these changes would be retroactive.

58. Furthermore, the references in the Discussion Paper are to lowering the price comparison for patented drugs that already have a therapeutic class.[20] In this case, SOLIRIS® was a 'first in class' drug. Thus, the new pricing implications generally set out in the Discussion Paper would not apply to SOLIRIS®.

59. The retroactive application of these purported amendments to the Guidelines, by the Board Staff, in seeking these remedies is contrary to the laws of statutory construction, and should not be permitted.

Conclusions

60. In BIOTECanada's submission, the Board Staff with its Amended Statement, have sought to amend the Guidelines. By using a different standard when determining revenues that should be paid back if a price is deemed excessive, other than that used when the initial MAPP is determined, the Board Staff have brought uncertainty into the process and created a situation where after years of selling at a particular price, a complaint may trigger an Investigation

[17] Patented Medicine Prices Review Board, "Rethinking the Guidelines", <http://www.pmprb-cepmb.gc.ca/en/news-and-events/consultations/current-major-consultations/rethinking-the-guidelines>.
[18] *Ibid.*
[19] *Ibid.*
[20] June 2016 Discussion Paper.

which leads to forfeiture of what had previously been deemed proper revenues.

61. This is a breach of both the principles of statutory interpretation, which prohibit retroactive application of the law unless explicitly provided in that law, and the principles of fundamental fairness and legitimate expectation in relation to the Guidelines that were relied upon by patentees. Furthermore, estoppel should apply to prevent the Board from changing course in this manner. In addition, such remedies are outside the Board's jurisdiction.

62. Thus, these new, retroactive, remedies sought by the Board Staff should not be granted.

Dated: December 20, 2016

Original signature redacted

Borden Ladner Gervais LLP
World Exchange Plaza
100 Queen Street, Suite 1300
Ottawa, Ontario

Jamie Mills/Beverley Moore
Tel: 613.369.4782/4784
Fax: 613.230.8842

Lawyers for BIOTECanada

Authorities

Tab	Description

Statues, Rules and Regulations

1. *Patent Act,* R.S.C. 1985, c. P-4.

Authorities

2. *Canadian Superior Oil v. Hambly*, [1970] S.C.R. 932.
3. *Merck Frosst Canada & Co. v. Apotex Inc.*, 2011 FCA 329.

Guidance and Other Government Documents

4. Patented Medicine Prices Review Board, "Annual Report 2009", <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=898>.
5. Patented Medicine Prices Review Board, "Annual Report 2015", <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1273#a5>.
6. Patented Medicines Price Review Board, "Compendium of Policies, Guidelines and Procedures" (July, 2016).
7. Patented Medicine Prices Review Board, "How to Make a Complaint", <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1014>.
8. Patented Medicine Prices Review Board, "PMPRB Guidelines Modernization – Discussion Paper – June 2016", <http://www.pmprb-cepmb.gc.ca/en/news-and-events/consultations/current-major-consultations/rethinking-the-guidelines/discussion-paper>.
9. Patented Medicine Prices Review Board, "Rethinking the Guidelines", <http://www.pmprb-cepmb.gc.ca/en/news-and-events/consultations/current-major-consultations/rethinking-the-guidelines>.
10. Patented Medicine Prices Review Board, "Supplementary reply of Board Staff to the Patented Medicine Prices Review Board, "Supplementary reply of Board Staff to the Amended Statement of Allegations: August 11, 2016", <http://www.pmprb- cepmb.gc.ca/CMFiles/Hearings%20and %20Decisions/Decisions%20 and%20Orders/supplementary_reply.pdf>.

TAB 3

IN THE MATTER OF the Patent Act,
R.S.C., 1985, c. P-4, as amended

AND IN THE MATTER OF
Alexion Pharmaceuticals Inc. ("Respondent")
and the medicine "Soliris"

BIOTECANADA MOTION FOR LEAVE TO INTERVENE

AFFIDAVIT OF ANDREW CASEY

I, Andrew Casey, of the City of Ottawa, in the Province of Ontario,

MAKE OATH AND SAY AS FOLLOWS:

1. I am the President and Chief Executive Officer of BIOTECanada and have been since 2012. As such, I have knowledge of the matters set out in this affidavit.

2. I am the same Andrew Casey who swore an affidavit in this matter on May 16, 2016. My background remains as described in my previous affidavit.

OVERVIEW

3. This affidavit is made in support of a second motion by BIOTECanada for leave to provide further written representations in this proceeding and speak for 30 minutes in closing argument.

4. On May 30, 2016, BIOTECanada was granted leave to intervene in this proceeding. BIOTECanada's written representations were filed on June 15, 2016.

5. However, since that time, the Board Staff has filed a further Amended Statement of Allegations (the "Amended Statement") that raises a significant new issue relevant to BIOTECanada. In particular, BIOTECanada has a interest in the new relief sought by the Board Staff, namely:

   (a) Alexion to reduce its price for SOLIRIS® in Canada to the "lowest international price" (LIP) among comparator countries;

(b) Alexion to forfeit "excessive revenues" based on either this LIP comparator (LIPC) or the Median International Price Comparison (MIPC); and

(c) Alexion's forfeitures to be retroactive to the outset of its sales of SOLIRIS®.

6. That argument will be attached as Exhibit A to the Notice of Motion seeking leave.

BIOTECanada and its Members

BIOTECanada

7. BIOTECanada is a nation-wide, not-for profit, non-government association with over 200 member companies. It was founded in 1987 and its mandate is to promote the sustainable development of the biotechnology industry in Canada. In fulfilling this mandate, it advocates for its members, a community of researchers and innovators, on public policy issues, including pricing of their innovative, patented medicines in Canada.

8. The Canadian bioeconomy is worth 7% of Canada's GDP, or approximately 86.5 million dollars. It also represents, directly and indirectly, 1 million Canadian jobs.

9. On behalf of the member companies, BIOTECanada pursues the objective of leading the advancement of a globally competitive Canadian biotechnology ecosystem by seeking to:

(d) Increase Canadian biotechnology innovation, research and commercialization;

(e) Establish a globally competitive regulatory policy framework to support all aspects of Canadian biotechnology;

(f) Establish Canada and Canadian biotechnology as a destination for investment capital.

10. BIOTECanada frequently works with all levels of government, international bodies, and interest groups on initiatives that may affect the protection of the biotechnology industry in Canada. BIOTECanada's activities in this regard have included the following recent matters:

    (g) making representations on biotechnology-related patent issues, including advocating legislative and regulatory change, before various provincial and federal government organizations and committees, such as the House of Commons Standing Committees on Agriculture and Agri-Food, on Health, and on Finance;

    (h) on-going consultations with the Federal Ministers of Innovation, Science and Economic Development, Health, Agriculture, Global Affairs Canada, and Natural Resources, Deputy Ministers and other officials, and the submission of position papers on a wide spectrum of biotechnology protection reform issues including making written submissions to Innovation, Science and Economic Development Canada and Health Canada regarding proposed regulations amending the *Food and Drug Regulations* and regulations amending the *Patented Medicines (Notice of Compliance) Regulations* (*the NOC Regulations*); and

    (i) serving as an information resource and as a commentator on biotechnology issues to national and international media outlets such as CBC Radio and TV, Global Television, CTV, The Globe & Mail, The Hill Times, New Scientist Magazine, and Canadian Business Magazine.

11. In meeting its objective of establishing a globally competitive regulatory policy framework to support all aspects of Canadian biotechnology, BIOTECanada regularly interacts with PMPRB, CADTH and the pCPA. With respect to CADTH specifically, BIOTECanada is a member of CADTH's Industry Liaison Forum (ILF).

12. BIOTECanada is the convener and a member of the National Biotechnology Accord (the "Accord"), a coalition of regional and provincial biotechnology associations, whose members combined account for approximately 85% of the Canadian biotechnology community.

13. The Accord aligns regional and national organizations leading the development of the Canadian bio-economy. Representing all facets of technology, these organizations forge a national entity working to secure the long term sustainability for Canadian biotechnology-based companies and organizations.

14. The Accord meets regularly to establish a national agenda geared to promoting the best of Canadian biotechnology to Canada and the world. Partnered projects include National Biotechnology Week, national and international conferences and advocacy supporting public policy initiatives in the biotechnology sector.

BIOTECanada's Members

15. The members of BIOTECanada include a wide variety of biotechnology organizations and work in all sectors of biotechnology, such as healthcare, agriculture, aquaculture, food, bioinformatics, research and industrial biotechnology. The majority of member companies are early stage, pre-commercial SME's. BIOTECanada's membership spans the country and includes both pre-commercial companies, such as Aquinox Pharmaceuticals, Xenon Pharmaceuticals, Zymeworks, Imstar, Transition Therapeutics, Agrisoma, and CO2 Solutions. The association also includes multinational companies such as Novartis, Pfizer, Celgene, Amgen, Sanofi-Genzyme, and BioAmber.

16. In addition to innovators and manufacturers, another important membership class includes organizations from the finance sector such as Versant Capital, Teralys Capital, CTI Life Sciences Fund – companies that directly invest in the small and medium enterprises (SMEs). Also included as members of

BIOTECanada are academic and research institutions and other organizations engaged in activities relating to supporting the development and commercialization of biotechnology innovation. A list of BIOTECanada's current members is attached as **Exhibit "1"** to this affidavit.

17. Many of BIOTECanada's members produce and/or market medicines which are used to treat serious illnesses. Furthermore, many of BIOTECanada's members research, develop and sell drugs to treat rare diseases (orphan drugs).

18. In addition, many of BIOTECanada's members hold patents that relate to medicines, and would be reportable to the PMPRB if and when their product(s) eventually reach the market. Patent protection and patent-related matters are therefore considered to be essential to their business and to the industry as a whole.

BIOTECanada's Interest in this Proceeding

19. The PMPRB, through this Amended Statement is again changing its approach to determining whether a medicine has an excessive price.

20. These new tests, if adopted in this case, have the potential to affect the interests of BIOTECanada's members generally, as they are yet another departure from the PMPRB's Guidelines, and could be used again in the future in respect of other patented medicines.

21. These changes to remedies could require forfeiture of revenues obtained by sales made in compliance with the Guidelines. This obviates the function of the Guidelines and creates uncertainty in the application of the PMPRB's pricing regime. BIOTECanada's members will have trouble complying with the PMPRB's pricing requirements if it does not know what those requirements are, due to their changing as between market entry and an investigation.

22. Furthermore, this change was made without any public consultations.

23. The remedies sought by the Board Staff in this proceeding will have a direct and significant impact on BIOTECanada's members as commercially focused members rely on patents to protect their investments in research related to medicines. Thus, they generally fall within the jurisdiction of the PMPRB and will be subject to these changes.

24. Accordingly, this Board Staff's decision will seek these new remedies that depart from the PMPRB's Guidelines will significantly impact the members of BIOTECanada. Furthermore, these new remedies, if left to stand, will have significant impact on the industry going forward yet will have been introduced without any opportunity for public/industry input/comment.

SWORN BEFORE ME at the City of Ottawa, on the 20th day of December, 2016

Original signature redacted

Commissioner for taking affidavits

Tracey Marie Doyle, a Commissioner, etc., Province of Ontario, while a Student-at-Law. Expires August 3, 2019.

Original signature redacted

ANDREW CASEY

TAB 4

THIS IS EXHIBIT "1" TO THE

AFFIDAVIT OF ANDREW CASEY

SWORN December 20, 2016

Original signature redacted

A Commissioner, etc.

Tracey Marie Doyle, a Commissioner, etc.,
Province of Ontario, while a Student-at-Law.
Expires August 3, 2019.

3Sixty Public Affairs Inc.

AbbVie Canada

Accel-Rx Health Sciences

Acuitas Therapeutics

Aegerion Pharmaceuticals

Ag-West Bio Inc.

Agricultural Institute Of Canada

Agrisoma Biosciences Inc.

Akshaya Bio Inc.

Alethia Biotherapeutics

Alexion Pharma Canada

Amgen Canada Inc.

AmorChem

Antibe Therapeutics Inc.

Appili Therapeutics

AquaBounty Canada, Inc.

Aquinox Pharmaceuticals Inc.

AstraZeneca Canada Inc.

Atuka Inc.

Augurex Life Sciences Corp.

Aurinia Pharmaceuticals Inc.

AusBiotech Ltd.

Avir Pharma Inc.

AVROBIO Inc.

Bayshore Specialty Rx Ltd

BELLUS Health Inc.

Bio-K Plus International Inc.

BioAlberta BioAmber Canada Inc.

Biodextris

Bioenterprise Corporation

Biogen Canada Inc.

Bioindustrial Innovation Canada

BioMarin Pharmaceutical Inc

BioNB

BioNova

Biopharm Management Inc.

BIOQuébec

BioTalent Canada

Biotechnology Industry Organization

BioVectra Inc.

Blake Cassels & Graydon LLP

Blanchard Law Office

Bloom Burton & Co.

BMS Canada Risk Services

Borden Ladner Gervais LLP

Canada's Venture Capital and Private Equity Association

Canadian Seed Trade Association

Caprion Biosciences Inc.

Cardiome Pharma Corp.

CDRD

Ceapro Inc.

Celator Pharmaceuticals Corp.

Celgene

Celverum Inc.

Centre for Probe Development & Commercialization

Centre For The Commercialization of Antibodies And Biologics

Chelation Partners

Chestnut Pharmaceuticals

CO2 Solutions Inc.

Contextual Genomics Inc.

CQDM

Critical Outcome Technologies Inc.

CTI Life Sciences Fund

Cyclenium Pharma Inc.

Cynapsus Therapeutics Inc.

Dalton Pharma Services

DelMar Pharmaceuticals

Drug Development and Innovation Centre

Eisai Limited

Eleven Biotherapeutics

Eli Lilly Canada Inc.

Encycle Therapeutics

enGene Inc.

ESSA Pharma Canada

ExCellThera

Farris Vaughan Wills & Murphy LLP

Fasken Martineau Dumoulin LLP

Fonds de Solidarité FTQ

Formation Biologics Inc.

Genentech GenePOC Inc.

Genome Canada

Global Public Affairs

GMD Pharma Solutions

Gowling WLG (Canada) LLP

Grifols

Highland Therapeutics

Hoffmann-La Roche Limited

Immune Biosolutions

Immunovaccine Inc.

Impres Pharma Inc.

ImStar Therapeutics Inc.

Innovation PEI

Innovative Targeting Solutions Inc.

InnovoXL Inc.

InSymbiosis Management Inc.

Intercept Pharma Canada

International Centre For Infectious Diseases

Intrinsik Health Sciences Inc.

Ipsen Biopharmaceuticals Canada Inc.

IRICoR

iTP Biomedica Corp

Janssen Inc.

JLABS – Johnson & Johnson

KalGene Pharmaceuticals Inc.

Kane Biotech Inc.

KMT Hepatech Inc.

Korea Biotechnology Industry Organization

KPMG

Laurent Pharmaceuticals Inc.

Life Sciences Association of Manitoba

Life Sciences Ontario

LifeSciences British Columbia

Linnaeus Plant Sciences Inc.

Mallinckrodt Pharmaceuticals

MaRS Discovery District

McDougall Scientific Ltd.

McKesson Canada

MEDEC

MedGenesis Therapeutix Inc.

Medicago Inc.

Medicenna Therapeutics Inc.

Medicure Inc.

Medunik Canada

Merck Canada Inc.

Milestone Pharmaceuticals

MSI Methylation Sciences Inc.

Nanovista Inc.

National Research Council Canada

Neomed Institute

Neurodyn Life Sciences Inc.

New Zealand Biotech

Nfld & Labrador Association Of Tech Industries

Northern Biologics Inc.

Norton Rose Fulbright Canada LLP

Novartis Pharmaceuticals Canada Inc.

Novicol International Holding

Novo Nordisk Canada Inc.

Okanagan Specialty Fruits Inc.

Oncolytics Biotech Inc.

Ontario Bioscience Innovation Organization

Pan-Provincial Vaccine Enterprise Inc.

Pangaea Group

Patient Access Solutions Inc.

PBR Laboratories Inc.

Pfizer Canada Inc.

Phoenix Molecular Designs

PlantForm Corporation

POS Bio-Sciences

Precision NanoSystems Inc.

Prevtec Microbia Inc.

PricewaterhouseCoopers LLP

Prince Edward Island BioAlliance

Pro Bono Bio Inc.

ProMIS Neurosciences

ProNAi Therapeutics Canada ULC

PROOF Centre Of Excellence

Qu Biologics

Quality & Compliance Services Inc.

Raptor Pharmaceuticals

Renaissance Bioscience Corp.

Replikins Ltd

Research Canada

Resverlogix

Roubaix Strategies Inc.

Royal Bank Of Canada

Sanofi Canada

Sanofi Canada – Sanofi Diabetes & Cardiovascular

Sanofi Canada – Sanofi Genzyme

Sanofi Canada – Sanofi Pasteur

ScarX Therapeutics

Sequence Bio

Sernova Corporation

Shire Pharma Canada ULC

Shoppers Drug Mart Specialty Health Network

SignalChem Lifesciences Corporation

SinoVeda Canada Inc.

Smart & Biggar/Fetherstonhaugh & Co.

Sobi Inc.

Soricimed Biopharma Inc.

Sound Insurance Services Inc.

SPharm Inc.

Takeda Canada Inc.

TEC Edmonton

Temple Therapeutics

Teralys Capital inc.

Teva Canada Innovation

Therapure Biopharma Inc.

Thrasos Inc.

Transition Therapeutics Inc.

Trillium Therapeutics Inc.

UCB Canada Inc.

University of Guelph

University Of Waterloo

Valeant Canada LP

Valeo Pharma Inc.

Valneva Canada Inc.

Vasomune Therapeutics

VBI Vaccines Inc.

Versant Ventures Canada Ltd.

Vertex Pharmaceuticals Inc.

viDA Therapeutics Inc.

VIDO-InterVac

VWR International

Wex Pharmaceuticals Inc

Wilson Sonsini Goodrich & Rosati

Xagenic Inc.

Xenon Pharmaceuticals Inc.

Zenith Epigenetics Inc.

Zymeworks Inc

TAB 5

CANADA

CONSOLIDATION

CODIFICATION

Patented Medicine Prices Review Board Rules of Practice and Procedure

Règles de pratique et de procédure du Conseil d'examen du prix des médicaments brevetés

SOR/2012-247

DORS/2012-247

Current to November 21, 2016

À jour au 21 novembre 2016

Published by the Minister of Justice at the following address:
http://laws-lois.justice.gc.ca

Publié par le ministre de la Justice à l'adresse suivante :
http://lois-laws.justice.gc.ca

OFFICIAL STATUS OF CONSOLIDATIONS

Subsections 31(1) and (3) of the *Legislation Revision and Consolidation Act*, in force on June 1, 2009, provide as follows:

Published consolidation is evidence
31 (1) Every copy of a consolidated statute or consolidated regulation published by the Minister under this Act in either print or electronic form is evidence of that statute or regulation and of its contents and every copy purporting to be published by the Minister is deemed to be so published, unless the contrary is shown.

...

Inconsistencies in regulations
(3) In the event of an inconsistency between a consolidated regulation published by the Minister under this Act and the original regulation or a subsequent amendment as registered by the Clerk of the Privy Council under the *Statutory Instruments Act*, the original regulation or amendment prevails to the extent of the inconsistency.

NOTE

This consolidation is current to November 21, 2016. Any amendments that were not in force as of November 21, 2016 are set out at the end of this document under the heading "Amendments Not in Force".

CARACTÈRE OFFICIEL DES CODIFICATIONS

Les paragraphes 31(1) et (3) de la *Loi sur la révision et la codification des textes législatifs*, en vigueur le 1er juin 2009, prévoient ce qui suit :

Codifications comme élément de preuve
31 (1) Tout exemplaire d'une loi codifiée ou d'un règlement codifié, publié par le ministre en vertu de la présente loi sur support papier ou sur support électronique, fait foi de cette loi ou de ce règlement et de son contenu. Tout exemplaire donné comme publié par le ministre est réputé avoir été ainsi publié, sauf preuve contraire.

[...]

Incompatibilité — règlements
(3) Les dispositions du règlement d'origine avec ses modifications subséquentes enregistrées par le greffier du Conseil privé en vertu de la *Loi sur les textes réglementaires* l'emportent sur les dispositions incompatibles du règlement codifié publié par le ministre en vertu de la présente loi.

NOTE

Cette codification est à jour au 21 novembre 2016. Toutes modifications qui n'étaient pas en vigueur au 21 novembre 2016 sont énoncées à la fin de ce document sous le titre « Modifications non en vigueur ».

(b) the grounds on which the proposed order is opposed and the material facts on which the respondent is relying;

(c) the name and address of the person on whom service of any document in relation to the proceeding may be effected.

b) les motifs d'opposition au projet d'ordonnance et les faits pertinents sur lesquels se fonde l'intimé;

c) les nom et adresse de la personne à qui les documents relatifs à l'instance peuvent être signifiés.

No response filed

(3) If a respondent has not filed a response within the period set out in subsection (1), the Board may, where the Board is satisfied that a copy of the notice of hearing was served on the respondent and where the Board has received any evidence that it required the respondent to provide, make any finding and issue any order that the Board considers appropriate under section 83 of the Act.

Absence de défense

(3) Dans le cas où l'intimé ne dépose pas de défense dans le délai prévu au paragraphe (1), le Conseil peut, s'il est convaincu qu'une copie de l'avis d'audience a été signifiée à l'intimé et s'il a reçu les éléments de preuve qu'il a exigés, formuler la conclusion et rendre l'ordonnance qu'il juge indiquées en application de l'article 83 de la Loi.

Reply

Filing of reply

19 (1) If Board Staff wishes to reply to the response it must, within 20 days after being served with the response, file with the Board and serve on all other parties a reply that is dated and signed by Board Staff.

Content of reply

(2) A reply must be set out in consecutively numbered paragraphs and must set out an admission or denial of each ground or material fact that was set out in the response.

No reply filed

(3) If Board Staff does not file a reply, it is deemed to have denied each ground and each material fact alleged in the response.

Réponse

Dépôt

19 (1) Si le personnel du Conseil souhaite répondre à la défense, il dépose auprès du Conseil et signifie aux autres parties une réponse datée et signée par lui, au plus tard vingt jours après avoir reçu signification de la défense.

Contenu

(2) La réponse est divisée en paragraphes numérotés consécutivement et contient la reconnaissance ou la dénégation de chacun des motifs ou des faits pertinents exposés dans la défense.

Absence de réponse

(3) Si le personnel du Conseil ne dépose pas de réponse, il est réputé avoir nié chacun des motifs et des faits pertinents exposés dans la défense.

Intervention

Motion for leave to intervene

20 (1) Any person who claims an interest in the subject-matter of a proceeding may, within any period and under any conditions that the Board may specify, bring a motion to the Board for leave to intervene in the proceeding.

Content of motion for leave to intervene

(2) A motion for leave to intervene must set out

(a) the name and address of the proposed intervener and of any counsel representing the intervener;

(b) a concise statement of the nature of the proposed intervener's interest in the hearing and the reasons the intervention is necessary;

Intervention

Requête — autorisation d'intervenir

20 (1) Toute personne qui prétend avoir un intérêt dans une question soulevée dans l'instance peut, par requête, dans le délai et selon les conditions fixés par le Conseil, demander à celui-ci l'autorisation d'intervenir.

Contenu de la requête

(2) La requête pour obtenir l'autorisation d'intervenir contient les éléments suivants :

a) le nom et l'adresse de l'intervenant éventuel et de tout conseiller juridique le représentant;

(c) a concise statement of the facts upon which the motion is based; and

(d) the issues that the proposed intervener intends to address.

b) un exposé concis de la nature de son intérêt dans l'affaire et des raisons pour lesquelles l'intervention est nécessaire;

c) un exposé concis des faits sur lesquels la requête est fondée;

d) les questions que l'intervenant se propose de soulever.

Filing of motion

(3) A motion for leave to intervene must be filed with the Board and served on the parties in accordance with Rule 10.

Dépôt de la requête

(3) La requête pour obtenir l'autorisation d'intervenir est déposée auprès du Conseil et signifiée aux parties conformément à la règle 10.

Filing of representations

(4) The parties who are served with a motion for leave to intervene may make submissions with respect to the motion by filing their submissions with the Board and serving a copy of the submissions on the person seeking leave to intervene.

Dépôt des observations

(4) Les parties auxquelles la requête pour obtenir l'autorisation d'intervenir est signifiée peuvent déposer auprès du Conseil leurs observations et en signifier copie à la personne qui demande l'autorisation d'intervenir.

Factors considered by the Board

(5) Subject to section 87 of the Act, if a person has moved to intervene in a proceeding, the Board may grant or deny the intervention and impose any conditions or restrictions on the intervention that it determines to be appropriate after considering relevant factors, including

(a) whether the person has an interest in the proceeding that is sufficient to warrant the intervention;

(b) whether the intervention will prejudice any party to the proceeding; and

(c) whether the intervention will interfere with the fair and expeditious conduct of the proceeding.

Facteurs à considérer par le Conseil

(5) Sous réserve de l'article 87 de la Loi, lorsqu'une personne a demandé par requête l'autorisation d'intervenir dans une instance, le Conseil peut autoriser ou refuser l'intervention et imposer des conditions ou restrictions à l'intervention qu'il juge indiquées après l'examen des facteurs pertinents, notamment :

a) la question de savoir si la personne a un intérêt dans l'instance qui est suffisant pour justifier l'intervention;

b) la question de savoir si l'intervention causera un préjudice à une partie à l'instance;

c) la question de savoir si l'intervention portera atteinte au déroulement équitable et expéditif de l'instance.

Appearance by Minister

Filing of notice of appearance

21 (1) A concerned minister who intends to appear and make representations with respect to a matter that is before the Board must, within 20 days after being served with the notice of hearing, file with the Board and serve on all parties a notice of appearance that is dated and signed by the concerned minister.

Comparution d'un ministre intéressé

Dépôt d'un avis de comparution

21 (1) Tout ministre intéressé qui a l'intention de comparaître et de présenter ses observations sur une question dont est saisi le Conseil dépose auprès de celui-ci et signifie à toutes les parties un avis de comparution daté et signé par lui, au plus tard vingt jours après avoir reçu signification de l'avis d'audience.

TAB 6

Decision: PMPRB-07-D1-QUADRACEL and PENTACEL
Application for leave to intervene by GlaxoSmithKline Inc.

IN THE MATTER OF the *Patent Act* R.S.C. 1985, c. P-4, as amended

AND IN THE MATTER OF sanofi pasteur Limited (the "Respondent") and the medicines "Quadracel and Pentacel"

Introduction

1. This proceeding concerns the pricing by sanofi-pasteur Limited ("sanofi pasteur") of the medicines Quadracel and Pentacel, vaccines used for the immunization of infants against diphtheria, tetanus, whooping cough, polio and *haemophilus influenzae type b* disease (the "medicines").

2. The Statement of Allegations produced by Board Staff in this proceeding alleges that sanofi pasteur sold, and engaged in a policy of selling, the Medicines at excessive prices during the period 2002-2006.

3. GlaxoSmithKline Inc. ("GSK") has sought intervener status in this proceeding. GSK brought a motion for such status, sanofi pasteur filed submissions opposing the motion, and GSK filed responding submissions.

Positions of the parties

4. GSK notes that it and sanofi pasteur are the only two suppliers of quadravalent and pentavalent vaccines in Canada. GSK argues that, as the only other supplier of these vaccines than sanofi pasteur, it has a significant interest in pricing "irregularities" in sales by sanofi pasteur of the Medicines.

5. GSK also takes the position that, with its experience and expertise in what is alleged to be a unique market for these vaccines, it could provide the Board with relevant information concerning that market, the manner in which that market is and was served by sanofi pasteur and GSK, and the remedy that would be appropriate, given that market, if the Board were to find that sanofi pasteur had sold the Medicines at excessive prices.

6. In its reply submissions, GSK also urged the Board to conclude that the Board's mandate to protect consumers from excessive prices of patented medicines includes ensuring that its decisions promote, and do not dissuade, competition in the marketplace. GSK suggested that there could be a link between the allegedly excessive prices charged by sanofi pasteur in the 2002-2006 period and the price that sanofi pasteur bid for the contract to sell vaccines to Canada from 2007 forward, and that this link could involve anti-competitive conduct by sanofi pasteur.

7. sanofi pasteur has submitted that GSK has not identified any legitimate interest in the proceeding, or any contribution that GSK could make to the hearing that would be useful to the Board. sanofi pasteur argues that GSK is seeking intervener status because GSK is a competitor of sanofi pasteur with respect to the Medicines and is trying to use this proceeding as a way to achieve a competitive advantage over, or impose a competitive disadvantage on, sanofi pasteur.

General Analysis

8. Rule 19 of the (proposed) *Patented Medicine Prices Review Board Rules* provides that the Board may grant leave to intervene to a party that "has an interest in the subject-matter" of the proceeding.

An excessive price hearing before a panel of the Board involves a dispute between Board Staff and a patentee about whether the patentee is, or has been, selling the medicine in question at an excessive price. Jurisdictional issues sometimes also arise in an excessive price hearing.

9. In the course of an excessive price hearing, the Board determines the maximum non-excessive price of the medicine and whether the patentee is or has been selling the medicine in any market above that price. If a finding of excessive pricing is made, the Board has the authority to order the patentee to take such measures as will offset the excessive revenues that have been earned, such as a payment to the Crown or a reduction in the price of the medicine.

10. In an excessive price hearing, Board Staff prosecutes the case by establishing that the price of the medicine exceeds or exceeded the Board's Excessive Price Guidelines, that the Guidelines properly implement the relevant provisions of the *Patent Act,* and, where jurisdiction is in issue, that the Board has jurisdiction. The patentee has an obvious interest in the case and a statutory right to make representations rebutting the allegations of Board Staff.

11. It can be noted that the *Patent Act* provides, in subsection 86(2), that the Minister of Health and the provincial health ministers have a right to notice of, and to intervene in, excessive price hearings.

12. As a general matter, and consistent with past practice at the Board, the Board would expect that other persons with an interest in the Board's hearings, in the sense contemplated by Rule 19, would be in one of the following three categories:

1. Persons who, in one manner or another, will bear some or all of the cost burden of the medicine in question, or the cost burden of other medicines where the prices of such medicines could be affected by the outcome of the proceeding;
2. Patentees, the maximum non-excessive prices of whose medicines will be affected by the specific outcome of the proceeding, or by the establishment of a point of principle pertaining the non-excessive pricing of medicines or the Board's jurisdiction; or
3. Organizations representing persons in the two previous categories.

13. In addition, where a proposed intervener does not have a material and direct interest in the outcome of the proceeding in question, the Board would also require that an applicant for intervener status demonstrate the ability to contribute, to the proceeding, some element of evidence that was expected by the Board to be unique, or otherwise to be usefully supplementary to the evidence and argument expected to be adduced by Board Staff, the patentee of the medicine in question, or another person that is granted intervener status.

14. It must be noted that Board Staff will generally represent the interests of persons who bear the cost burden of medicines under review, and patentees, by advocating their own interests, will typically represent interests that are not unique to them or to the particular medicine under review. Perhaps as importantly, the Board is aware of the impact of each of its decisions on persons other than those appearing before it in any given proceeding, and takes the interests of those persons into account whether or not they are independently represented in a proceeding.

16. None of these factors removes the right of appropriate persons to be interveners in the Board's proceedings, or detracts from the important role that interveners can play in the Board's proceedings. However, those factors, and the Board's statutory obligation pursuant to subsection 97(1) of the *Patent Act* to conduct its proceedings as expeditiously as the circumstances and considerations of fairness permit, and the Board's need to control its process, do bear on the discretion that the Board will exercise when deciding, in a particular case, whether a person is an appropriate intervener in a proceeding.

The jurisprudence

17. sanofi pasteur placed reliance on a number of cases in which the Federal Courts made relatively restrictive pronouncements on the circumstances in which persons should be permitted to intervene, typically in judicial review applications.

GSK argued that this jurisprudence pertained to litigation that constituted "private disputes" or "disputes between private parties", and was inapplicable to the proceedings of the Board. The panel does not agree that applications for judicial review of tribunal decisions or ministerial conduct in the Federal Courts constitute private disputes, and takes some guidance from the discussions of intervener status in this jurisprudence.

18. However, the Board also notes the cases cited by GSK to the effect that the scope for intervention in a tribunal hearing can be broader than in a court proceeding. The Board would note that this is true of the Board's proceedings given the polycentric nature of the interests that are likely to be given consideration in an excessive price hearing.

GSK's application to intervene

19. It is the view of the panel that GSK has not established any grounds on which it has an interest in the outcome of the proceeding that warrants GSK's status as an intervener. The panel has also concluded that GSK could not assist the Board with the matters in issue in this proceeding by the contribution of evidence or insight that is not expected to be provided by the parties to the proceeding.

20. Also, the panel does not believe that the Board has a mandate to consider whether the price of a medicine under its jurisdiction has been or will be, for competitive purposes, set by the patentee at a level that is somehow unfairly high or low relative to the price of a medicine competing in the same market, or to otherwise inquire into the fairness of the competitive strategy of one patentee relative to another. The *Patent Act* and the Board's Excessive Pricing Guidelines deal with the prices of medicines for the exclusive purpose of ensuring that those prices are not excessive. The Board's statutory mandate does not include setting maximum prices of medicines, or taking remedial measures against patentees, to foster competition, nor to inquire into whether the prices of medicines are, or have been, somehow unfair as a matter of competition policy.

21. The panel was able to reach its decision on GSK's application without reliance on the submissions of sanofi pasteur concerning the motives of GSK in seeking intervener status in this proceeding. The mere fact that GSK is a competitor of sanofi pasteur, and that GSK would pursue its own interests if it were granted intervener status, does not disentitle GSK from being an intervener in this proceeding. Indeed, the intervention of Janssen-Ortho in the ongoing proceeding before the Board concerning Shire BioChem's medicine Adderall XR is an example of a direct competitor demonstrating an interest in a proceeding that warranted intervener status. The maximum non-excessive prices of the two companies' competing medicines were arguably logically linked. However, in the case of GSK, the Board sees no similar or analogous interest in the instant proceeding.

Conclusion

22. For the foregoing reasons, the application of GSK to intervene in this proceeding is dismissed.

Board Members: Dr. Brien G. Benoit
Anne Warner La Forest
Anthony Boardman

Board Counsel: Gordon Cameron

Original signed by

Sylvie Dupont
Secretary of the Board

July 26, 2007

TAB 7

Regulatory Process

The PMPRB (Patented Medicine Prices Review Board) monitors the prices charged by patentees for patented drugs on an ongoing basis. Under the *Patent Act*, patentees are required to file price and sales information about their patented drug products at introduction and twice a year thereafter for each strength of each dosage form of each patented drug product sold in Canada. However, patentees are welcome to consult with the PMPRB (Patented Medicine Prices Review Board) on the application of the Guidelines at any time. The Board may, on request, pre-approve a price under certain conditions by issuing an Advance Ruling Certificate (view.asp?ccid=480). Patentees are not required to obtain approval of the price before a drug is sold.

If you are a patentee, please visit Are You a Patentee? (view.asp?ccid=525) for more information about your reporting obligations.

Scientific Review

The first step in the PMPRB (Patented Medicine Prices Review Board)'s regulatory process is a scientific review, which assesses the level of therapeutic improvement of a new patented drug product. A committee of experts known as the Human Drug Advisory Panel (view.asp?ccid=478) also recommends appropriate drug products to be used for comparison. The level of therapeutic improvement of a patented drug is used to determine a ceiling price, known as the Maximum Average Potential Price, at introduction.

- More information on the scientific review (view.asp?ccid=474) process
- More information on the HDAP (Human Drug Advisory Panel) meeting schedule and filing requirements (view.asp?ccid=479)

Price Review

Board Staff reviews pricing information for all patented drug products sold in Canada on an ongoing basis to ensure that the prices charged by patentees comply with the Guidelines (view.asp?ccid=355) established by the Board. The Guidelines, which are based on the price

determination factors in Section 85 of the Act, were developed by the Board in consultation with stakeholders, including the provincial and territorial Ministers of Health, consumer groups, and the pharmaceutical industry.

- More information on the price review (view.asp?ccid=475) process

New Patented Medicines Reported to the PMPRB (Patented Medicine Prices Review Board)

The PMPRB (Patented Medicine Prices Review Board) publishes information on the price review of all new patented drug products in a searchable table format. This format was introduced in January 2012 as part of the ongoing implementation of the 2010 Guidelines. The table is updated as the review of each new patented drug product is completed.

Each new patented drug product from 2010 onward that has a status classified as “Within the Guidelines” or “Does Not Trigger an Investigation” has a link from the brand name to an individual Price Review Record. Price Review Records include information such as the level of therapeutic improvement; the price test used to establish the maximum average potential price (MAPP); comparable drug products and countries used for price comparisons; and the MAPP (maximum average potential price).

Price Review Records are currently available for almost all new drug products reported in 2010 and will be gradually populated for 2011. Summary Reports (view.asp?ccid=573) are available for new drug products reported prior to 2010.

- Listing of New Patented Medicines Reported to the PMPRB (Patented Medicine Prices Review Board) (pmpMedicines.asp?x=611)

Investigations

If Board Staff finds that a price appears to exceed the Guidelines, and the circumstances meet the criteria for commencing an investigation, Board Staff will open an investigation to determine whether the price of the patented drug product in fact exceeds the Guidelines.

An investigation could result in:

- closure of the file if the price is found to be within the Guidelines
- a Voluntary Compliance Undertaking by the patentee to reduce the price and offset excess revenues through a payment and/or a reduction in the price of another patented drug
- a public hearing to determine whether the price is excessive.

Voluntary Compliance Undertakings

A Voluntary Compliance Undertaking (VCU) is a written commitment by a patentee to comply with the Board's Guidelines, including adjusting the price of the patented drug in question to a non-excessive level and offsetting any excess revenues that may have been received as the result of having sold the patented drug at an excessive price in Canada. Patentees are given the opportunity to submit a VCU (Voluntary Compliance Undertaking) when Board Staff concludes, following an investigation, that the price of a patented drug product sold in Canada appears to have exceeded the Guidelines. A VCU (Voluntary Compliance Undertaking) can also be submitted following the issuance of a Notice of Hearing, but must then be approved by the Hearing Panel. VCU (Voluntary Compliance Undertaking)s represent a compromise between the PMPRB (Patented Medicine Prices Review Board) and the patentee as a result of negotiations between the parties in view of the specific facts and underlying context of a particular case. As such, VCU (Voluntary Compliance Undertaking)s are not intended to have precedential value.

- More information on Voluntary Compliance Undertakings (view.asp?ccid=465)

Hearings

If the price of a patented medicine appears to be excessive, the Board can hold a public hearing. If it finds that the price is excessive, it may issue an order to reduce the price and to offset revenues received as a result of the excessive price.

Board decisions are subject to judicial review in the Federal Court of Canada.

- More information on Hearings and Decisions (view.asp?ccid=482)

Date modified:

2016-01-29

TAB 8

Rethinking the Guidelines

Phase 1 public comments now available!

Phase 1 of *Rethinking the Guidelines* closed on October 31, 2016. Please scroll down to view the submissions we received.

Canada, like many countries, is facing escalating health care costs as payers struggle to reconcile finite drug budgets with patient access to promising new health technologies. Improving affordability and access to prescription drugs is a key Government of Canada commitment and a joint federal, provincial, and territorial priority.

As a first step to framework modernization, the Patented Medicine Prices Review Board (PMPRB) is undertaking major consultations regarding possible reform of its *Compendium of Policies, Guidelines and Procedures* (http://www.pmprb-cepmb.gc.ca/view.asp?ccid=492), commonly referred to as "the Guidelines."

During Phase 1 of this consultation initiative, the PMPRB (Patented Medicine Prices Review Board) asked for your input on how we can rethink the Guidelines in order to improve our performance in ensuring that pharmaceutical patent holders do not charge excessive prices. We are now analyzing the feedback we received. The (Patented Medicine Prices Review Board)PMPRB (Patented Medicine Prices Review Board) Guidelines Modernization Discussion Paper (view.asp?ccid=1260) and discussion questions (view.asp?ccid=1260&lang=en#a17) are still available online for those who wish to consult them.

Phase 2 of the consultation process is expected to consist of a public policy hearing before the Board, where stakeholders who commented on the Discussion Paper will have the opportunity to speak to their written submissions. Timelines for Phase 2 will be announced at a later date.

By *Rethinking the Guidelines*, the PMPRB (Patented Medicine Prices Review Board) seeks to contribute to a sustainable pharmaceutical system where payers have the information they need to make smart reimbursement choices and Canadians can afford the medicines they need to live healthy and productive lives.

The Consultation process

Phase	Steps	Proposed Timelines	Status

Phase 1: Consult with stakeholders on issues	Publish Discussion Paper (view.asp?ccid=1260) Meet with various stakeholder groups across Canada Obtain written comments from stakeholders and the public on questions in the discussion paper Gather and analyze all results from Phase 1 of consultation	Summer/fall 2016	Completed (October 31, 2016)
Phase 2: Engage stakeholders and gather expert input	Public Policy Hearing – invite stakeholders to appear before the Board and make representations in support of their written submissions	To be announced	
Phase 3: Presentation of proposed changes	Publication of proposed changes to Guidelines for comment through Notice and Comment Process Strike multi-stakeholder forum(s) on specific issues and proposed changes to the Guidelines	To be announced	

Phase 1 public submissions

- AbbVie Corporation (PDF – 713 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_AbbVie_Oct_2016.pdf))
- Action Hepatitis Canada (PDF – 685 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Action_Hepatitis_Canada_Oct_2016.pdf))
- Alexion Pharma Canada Corp. (PDF – 4.64 MB (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Alexion_Oct_2016.pdf))
- American Bar Association (PDF – 314 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_American_Bar_Assoc_Oct_2016.pdf))
- Amgen Canada (PDF – 28 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Amgen_Oct_2016.pdf))
- AstraZeneca Canada Inc. (PDF – 367 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_AstraZeneca_Oct_2016.pdf))
- Bayer Inc. (PDF – 4.05 MB (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Bayer_2016.pdf))
- Best Medicines Coalition (PDF – 95 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Best_Medicines_Coaltion_Oct_2016.pdf))
- Biogen Canada Inc. (PDF – 171 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Biogen_Oct_2016.pdf))
- Biosimilars Canada (PDF – 254 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Biosimilars_Canada_Oct_2016.pdf))
- BIOTECanada (PDF – 1.18 MB kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_BIOTECanada_Oct_2016.pdf))
- Blood Ties Four Directions Center (PDF – 354 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Blood_Ties_Oct_2016.pdf))
- Chris Bonnett, MHSc, PhD (PDF – 147 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Bonnett_Oct_2016.pdf))

- Cameron Institute (PDF – 375 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Cameron_Institute_Sept_2016.pdf))
- Canadian Association of PNH Patients (PDF – 530 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_PNH_Canada_Oct_2016.pdf))
- Canadian Association of Provincial Cancer Agencies (CAPCA) (PDF – 145 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_CAPCA_Oct_2016.pdf))
- Canadian Breast Cancer Network (CBCN) (PDF – 206 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Cdn_Breast_Cancer_Network_Oct_2016.
- Canadian Cancer Society (PDF – 435 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Cdn_Cancer_Society_Oct_2016.pdf))
- Canadian Diabetes Association (PDF – 110 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Cdn_Diabetes_Association_Oct_2016.pdf
- Canadian Health Coalition (PDF – 115 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Cdn_Health_Coalition_Oct_2016.pdf))
- Canadian Generic Pharmaceutical Association (PDF – 476 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_CGPA_Oct_2016.pdf))
- Canadian Life and Health Insurance Association Inc. (CLHIA) (PDF – 659 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_CLHIA_Oct_2016.pdf))
- Canadian Organization for Rare Disorders (PDF – 100 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Cdn_Org_for_Rare_Disorders_Oct_2016.
- Canadian Pharmacists Association (PDF – 526 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Cdn_Pharmacists_Assoc_Oct_2016.pdf))
- Celgene Inc. (PDF – 1.56 MB (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Celgene_Oct_2016.pdf))
- CLL Patient Advocacy Group (PDF – 80 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_CLLPAG_Oct_2016.pdf))
- Consumer Health Products Canada (PDF – 506 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Consumer_Health_Products_Canada_Oc
- Eli Lilly Canada Inc. (PDF – 3.09 MB (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Eli_Lilly_EN_Oct_2016.pdf))
- Enerflex Ltd. (PDF – 45 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Enerflex_Oct_2016.pdf))
- Marc-André Gagnon, PhD (available in French only) (PDF – 716 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Gagnon_Oct_2016.pdf))
- Galderma Canada Inc. (PDF – 2.91 MB (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Galderma_Oct_2016.pdf))
- Great-West Life Assurance Company (PDF – 111 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Great_West_Life_Oct_2016.pdf))
- GlaxoSmithKline Inc. (PDF – 3.52 MB (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_GSK_Oct_2016.pdf))
- Health Charities Coalition of Canada (PDF – 255 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Health_Charities_Coalition_of_Canada_C
- HepCBC Hepatitis C Education and Prevention Society (PDF – 145 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Hepatitis_C_BC_Oct_2016.pdf))
- Anne Holbrook, MD, PharmD, MSc, FRCPC (PDF – 69 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Holbrook_Oct_2016.pdf))
- Institut national d'excellence en santé et en services sociaux Québec (INESSS) (available in French only) (PDF – 183 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_INESSS_Oct_2016.pdf))
- Innovative Medicines Canada (PDF – 781 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Innovative_Medicines_Canada_Oct_2016
- Janssen Inc. (PDF – 430 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Janssen_Oct_2016.pdf))

- Johnson & Johnson, Family of Companies in Canada (PDF – 168 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Johson_and_Johnson_Oct_2016.pdf))
- Leo Pharma Inc. (PDF – 516 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_LEO_Pharma_Oct_2016.pdf))
- Mario de Lemos, PharmD, MSc (Oncol) (PDF – 45 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_BC_Cancer_Agency_July_2016.pdf))
- Joel Lexchin, MD (PDF – 43 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Lexchin_July_2016.pdf))
- Life Sciences Ontario (PDF – 368 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Life_Sciences_Ontario_Oct_2016.pdf))
- Manitoba Ministry of Health, Seniors and Active Living (PDF – 100 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Provincial_Submission_Manitoba_Oct_2016.pdf))
- Manulife (PDF – 88 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Manulife_Sept_2016.pdf))
- Merck Canada Inc. (PDF – 1.05 MB (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Merck_Oct_2016.pdf))
- Multiple Sclerosis Society of Canada (PDF – 382 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_MS_Society_of_Canada_Oct_2016.pdf))
- Neighbourhood Pharmacy Association of Canada (PDF – 170 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Neighbourhood_Pharmacies_Oct_2016.p
- Novartis Pharmaceuticals Canada Inc. (PDF – 1.62 MB (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Novartis_Oct_2016.pdf))
- Network of Rare Blood Disorder Organizations (NRBDO) (PDF – 129 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_NRBDO_Oct_2016.pdf))
- Otsuka Canada Pharmaceutical Inc. (OCPI) (PDF – 302 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Otsuka_Oct_2016.pdf))
- pan-Canadian Pharmaceutical Alliance (pCPA) (PDF – 47 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_PCPA_Oct_2016.pdf))
- Patient Coalition (PDF – 327 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Patient_Coalition_Oct_2016.pdf))
- PDCI Market Access Inc. (PDCI) (PDF – 111 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_PDCI_Oct_2016.pdf))
- Nav Persaud, MD, MSc, CCFP (PDF – 239 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Persaud_Oct_2016.pdf))
- Pfizer Canada Inc. (PDF – 157 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Pfizer_Oct_2016.pdf))
- Roche Canada (PDF – 561 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Roche_Oct_2016.pdf))
- Sanofi (PDF – 103 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Sanofi_Oct_2016.pdf))
- Servier Canada Inc. (PDF – 570 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Servier_Oct_2016.pdf))
- Sun Life Assurance Company of Canada (PDF – 175 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Sun_Life_Oct_2016.pdf))
- Teva Canada Innovation (PDF – 149 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Teva_Oct_2016.pdf))
- Unifor (PDF – 3.20 MB (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_UNIFOR_Nov_2016.pdf))
- Vaccine Industry Committee (PDF – 229 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Vaccine_Industry_Cmtee_Oct_2016.pdf))
- Valeant Canada (PDF – 453 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Valeant_Oct_2016.pdf))

- Gary Walters, FCIA (PDF – 414 kb (/CMFiles/Consultations/Rethinking_the_Guidelines_2016/Submission_Walters_Nov_2016.pdf))

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