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 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 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 filed an expert report of Dr. Sumanth Addanki (the Addanki Report).

4. This report purports to propose a novel method of determining the "therapeutic class" for SOLIRIS® by proposing a new method of selecting comparators for medicines intended to treat rare diseases (so-called orphan drugs). This new method has the potential to affect the interests of BIOTECanada's members generally, as it is a departure from the known definition of the term in industry, a departure from the PMPRB's Guidelines, a

breach of procedural fairness and a breach of the principles of statutory interpretation as discussed further below.

5. The Board Staff and Dr. Addanki appear to apply the new definition of "therapeutic class" only to orphan drugs. This new definition and approach will thus affect BIOTECanada's members as it:

   (a) Is not the accepted definition of "therapeutic class" known to industry;

   (b) Breaches the principles of statutory construction as it appears to provide for the term "therapeutic class" to have one meaning if the drug is not orphan and another if it is. Furthermore, there appears to be some ambiguity as to what meaning is to be ascribed if an orphan drug has comparators; and

   (c) Breaches the principles of procedural fairness as one definition of "therapeutic class" was used to determine the maximum non-excessive initial price of SOLIRIS®, and the new definition was used in a later determination of whether the ongoing, unchanged, price was excessive. No notice was given prior to this change, nor were public consultations held.

Issue

6. This written argument addresses solely the issue of the Board Staff's use of the Addanki report to provide a new definition of therapeutic class.

The *Patent Act*

7. Section 85 of the *Patent Act* sets out the factors that shall be taken into consideration by the Board in determining whether a medicine is sold at an excessive price.

> 85 (1) In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:
>
> (a) the prices at which the medicine has been sold in the relevant market;
>
> (b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
>
> (c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
>
> (d) changes in the Consumer Price Index; and
>
> (e) such other factors as may be specified in any regulations made for the purposes of this subsection.[1]

8. The term "therapeutic class" is found in sections 8(b) and (c). Thus, the Board must interpret this term when determining whether a medicine is sold at an excessive price.

9. The *Patent Act* does not define "therapeutic class". BIOTECanada submits that this is because the term needs no definition. It is commonly understood by industry, Health Canada and Innovation, Science and Economic Development Canada to have a singular meaning.

10. The "therapeutic class" of a drug relates to the class of medicines intended to treat the same medical condition. The class is defined by the therapy which the medicine is used to treat. It is a scientific term.

11. The Addanki Report essentially ignores the scientific underpinnings of the term. Indeed it ignores the key word "therapeutic" which is a fundamental part of the term. Instead, it purports to ascribe an entirely new, non-scientific and arbitrary meaning, which it then uses as a basis to find so-called comparator drugs for SOLIRIS®.

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[1] *Patent Act*, R.S.C. 1985, c. P-4 ("*Patent Act*"), s. 85, Tab 2.

The Addanki Definition of "Therapeutic Class"

12. Dr. Addanki argues that in a case where a patented medicine has no comparators that share its chemistry, mechanism of action, or approved indication (the scientific, and common understanding of "therapeutic class"), an economic interpretation of "therapeutic class" is appropriate.[2] On its face, this approach is wrong because "therapeutic class" already has a clear meaning understood by all the relevant parties.

13. Dr. Addanki proposes to begin his purported economic interpretation of the "therapeutic class" for SOLIRIS® with a list of orphan drugs from the United States.[3] He then arbitrarily limits that list through a number of factors, designed to show similarity to SOLIRIS®.

14. He starts with a limitation to drugs that treat populations of a similar size to SOLIRIS®.[4] He then excludes all drugs taken for a short period of time, because SOLIRIS® must be taken for life.[5] Further limitations are to drugs that show a significant advantage over other existing treatments; [6] and to drugs that treat terminal state diseases; and to drugs for which other treatments are available.[7]

15. At the end of these eliminations, only seven drugs remain.[8] In a non-scientific analysis, this may seem like a reasonable number to use for comparison purposes. However, one should not be aiming for a particular number of comparators, one should be aiming for the correct comparators, no matter what the number.

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[2] Addanki Report, paragraph 19.
[3] Addanki Report, paragraph 37.
[4] Addanki Report, paragraph 38.
[5] Addanki Report, paragraph 40.
[6] Addanki Report, paragraph 41.
[7] Addanki Report, paragraph 42.
[8] Addanki Report, paragraph 42.

16. Any one of these arbitrary limitations could have been substituted for another, different, arbitrary characteristic of SOLIRIS® to produce an equally small, but equally arbitrary list.

17. Addanki's definition of "therapeutic class" is not based in science. It is not what is known and understood by the pharmaceutical and biotechnological community. It starts with the principle that "therapeutic class" can have different definitions depending upon the medicine being considered. It arbitrarily selects a starting point for this circumstance. It then arbitrarily adds limitations.

18. This approach is not appropriate under any circumstances.

Commonly Understood Definition of "Therapeutic Class"

19. Section 85 of the *Patent Act* requires the Board to consider the price of other medicines in the same therapeutic class in both the relevant market (85(b)) and in countries other than Canada (85(c)).

20. As discussed above, "therapeutic class" is not defined by the *Patent Act*, however, it is a term understood by all health professionals, and the pharmaceutical and biotechnological community to relate to the class of medicine as defined by the therapy for which that medicine is used.

21. "Therapeutic class" and "therapeutic classifications" are terms of art used consistently (until the Addanki report) by the PMPRB, the Ministry of Health, Innovation, Science and Economic Development Canada, and the provincial formularies in relation to medicines.

22. Until the filing of the Addanki Report, to our knowledge, the PMPRB has not ever tried to use a different definition of "therapeutic class" than the scientific term of art known to the industry and relevant professionals

PMPRB Guidelines Use A Scientific Definition of "Therapeutic Class"

23. In evaluating a patented medicine, the PMPRB's 2010 Guidelines, as updated in 2012 (Guidelines) indicate that the PMPRB is to conduct a scientific review, an evidence based process, to determine the level of therapeutic improvement of a new patented drug.[9] The Guidelines were published after consultation with stakeholders. Section C.3.1 of the PMPRB's (Guidelines) provides that a Human Drug Advisory Panel (HDAP) provides expertise and advice to Board Staff during that scientific review and recommends the level of therapeutic improvement of the new patented drug product, and identifies drug products for comparison purposes.[10]

24. This identification of drug products for comparison purposes is the identification of other drug products in the therapeutic class, as confirmed by section C.8 which sets out criteria for the selection of drug products to be used for comparison purposes:

> C.8.1 HDAP uses the World Health Organization (WHO) Collaborating Centre for Drug Statistics Methodology's Anatomical Therapeutic Chemical (ATC) Classification System in the selection of drug products to be used for comparison purposes.
>
> C.8.2 The chemical substances to be used for comparison purposes will typically be those identified under the ATC classification system at the sub-class level above the single chemical substance. This will normally be the fourth sub-class level. HDAP may also choose from the next higher sub-class or another sub-class. In some instances, it may be appropriate to select from the fifth or single chemical substance level.
>
> C.8.3 HDAP may omit from the comparison a chemical substance of the same ATC therapeutic class as the new patented drug product under review if, in HDAP's opinion, it is unsuitable for comparison. For example, drug products with a primary indication/use other than the primary indication/use of the new patented drug product under review may be omitted from the comparison.[11] [emphasis added]

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[9] PMPRB Compendium – Policies, Guidelines Procedures Compendium, 2010 updated in 2012 ("Compendium"), Part. C, page 10, Tab 16.
[10] Compendium, Part C, s. C.3.1, Tab 16
[11] Compendium, Part. C, ss. C.8.1-C.8.3, Tab 16.

25. This scientifically defined "therapeutic class" is the common understanding of the term. Moreover, this is an admission by the PMPRB as to the proper meaning of the term "therapeutic class".

PMPRB Has Applied the Scientific Definition of "Therapeutic Class" in Previous Decisions

26. In previous decisions, the PMPRB has applied the commonly understood, scientific definition of "therapeutic class" when determining comparable medicines:

> When a patented medicine is introduced to the market in Canada, the maximum non-excessive price ("MNE") of the medicine is determined by the staff of the Board based on either the price of comparable medicines, i.e. medicines in the same therapeutic class, or on the international prices of the medicine – median or the highest – as sold in the seven countries specified in the Regulations. ... **As suggested by the Board's Guidelines, the comparable medicines used by Board Staff to establish the introductory MNE of a Category 1 medicine and to conduct price tests under subsection 85(1) of the Act are determined pursuant to a scientific review designed to identify medicines that are clinically equivalent in addressing the approved condition for which they are used, and having comparable dosage form and strength.** These criteria establish the therapeutic class of the medicine for the purposes of paragraphs 85(1)(b) and (c) of the Act.[12] [emphasis added]
>
> A necessary starting point in the Panel's analysis is a description of what constitutes a "therapeutic class" as that expression is used in paragraphs 85(1)(b) and (c) of the Act. **The Guidelines use the concept of therapeutic equivalence (termed "clinical equivalence") to define a therapeutic class. ... The Panel concludes that clinical equivalence is the appropriate concept to use when defining a therapeutic class for the purposes of implementing paragraphs 85(1)(b) and (c) of the Act. It reflects the wording of the Act, in that a therapeutic "class" connotes a group of medicines that share a common feature or features.**[13] [emphasis added]
>
> He described the TCC Test as a methodology to determine which drugs are therapeutic comparators at the time the test is performed.

[12] ratiopharm Inc. and the medicine "ratio-Salbutamol HFA", PMPRB-08-D3-ratio-Salbutamol HFA dated May 27, 2011, paragraphs 66-68, Tab 5.

[13] sanofi-aventis Canada Inc. and the medicine "Penlac Nail Lacquer", PMPRB-07-D2-PENLAC, dated January 31, 2011, paragraphs 17-18, Tab 6.

> **The HDAP is not concerned with the pricing of drugs. Rather, it assesses which drugs have similar therapeutic purposes and characteristics such that they can be considered to be in the same therapeutic class.**[14] [emphasis added]

27. The PMPRB's consistent use of "therapeutic class" in relation to drugs that have similar therapeutic purposes and characteristics accords with industry's understanding of the term.

28. Furthermore, in the Copaxone case, the PMPRB specifically stated that the HDAP, which determines "therapeutic class" is not concerned with pricing. This is directly at odds with the Board Staff's reliance on the Addanki affidavit.

Health Canada Also Uses A Scientific Definition of "Therapeutic Class"

29. Health Canada, as Canada's drug regulator, also commonly refers to "therapeutic class" in relation to its approved drugs. The most clear example is Health Canada's website listing "Notice of Compliance (NOC) Database Terminology".[15] The explanation for "therapeutic class" states:

> A drug's Therapeutic Classification (Class) is assigned on the NOC according to its main therapeutic use.

30. This accords with BIOTECanada and its members' understanding that "therapeutic class" is linked to the therapy the medicine is approved to treat.

31. "Therapeutic Classification" is also defined in the explanation for "Drug Product Database (DPD) Online". This explanation indicates that The American Hospital Formulary Service (AHFS) and the Anatomical Therapeutical Chemical (ATC) Classification Systems are used to determine "Therapeutic Classification."

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[14] Teva Neuroscience G.P.-S.E.N.C. and the medicine "Copaxone", PMPRB-2010-D3-Copaxone, dated February 23, 2012, paragraph 29, Tab 8.

[15] Health Canada, "Notice of Compliance (NOC) Database Terminology", <http://www.hc-sc.gc.ca/dhp-mps/prodpharma/notices-avis/noc-acc/term_noc_acc-eng.php>, Tab 15.

32. This is the same ATC classification system used by the PMPRB's own HDAP. Thus, in the past, the PMPRB and the HDAP have been consistent in their definition of the term.

33. When one reads Health Canada's other Guidance Documents, it is clear that whenever the term "Therapeutic Class" is used, it has the consistent scientific meaning relating to the therapy for which the medicine is used.[16]

34. The arbitrary economic definition of "therapeutic class" proposed by Dr. Addanki and the Board Staff cannot be substituted into these documents. This is further evidence that the Addanki report analysis should be disregarded.

35. Health Canada does not consider what medicines are similar from an economic perspective when assessing drug safety and efficacy. It considers those medicines that are similar from a therapeutic perspective. Thus, it refers to the therapeutic class of drugs.

Provincial Formularies Also Use A Scientific Definition of "Therapeutic Class"

36. Similarly, when one looks at provincial formularies, one can search for medicines by "Therapeutic Classification", while in others, the "therapeutic classification" is part of the drug listing.[17] These classifications relate to the

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[16] See for example:

- Health Canada, "Guidance Document - Labelling of Pharmaceutical Drugs for Human Use" <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/label_guide_ld-eng.pdf>, Tab 12.
- Health Canada, "Guidance for Industry: Health Canada Addendum to ICH Guidance Document E11: Clinical Investigation of Medicinal Products in the Pediatric Population" <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/clini/e11_addendum-eng.pdf>, Tab 13.
- Health Canada, "Guidance Document - Fees for the Review of Drug Submissions and Applications", <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/fees-frais/fee_frais_guide-eng.pdf>, Tab 11.
- Health Canada, "Guidance for Industry: Management of Drug Submissions", <http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/mgmt-gest/mands_gespd-eng.pdf>, Tab 14.

[17] British Columbia Formulary: https://pcbl.hlth.gov.bc.ca/pharmacare/benefitslookup/faces/Search.xhtml; Alberta Formulary: https://idbl.ab.bluecross.ca/idbl/load.do; Saskatechewan Formulary: http://formulary.drugplan.health.gov.sk.ca/; Manitoba Formulary: http://web22.gov.mb.ca/eFormulary/advancedSearch.aspx; Ontario Formulary: https://www.formulary.health.gov.on.ca/formulary/; Quebec Formulary:

therapy for which the drug is used and are based on known scientific classification systems. Indeed for British Columbia, one can search using ATC Therapeutic Classification, the same system used by the PMPRB's HDAP.

37. The provincial formularies, like the PMRPB, deal with drug pricing. However, they use the conventional, scientific definition of "therapeutic class", and not the arbitrary, economic analysis performed by Addanki.

Innovation, Science and Economic Development Canada's Other Departments Also Use a Scientific Definition of "Therapeutic Class"

38. The Competition Bureau, which administers the *Competition Act*, which like the *Patent Act* falls under the purview of Innovation, Science and Economic Development Canada, has published a Generic Drug Sector Study. In section 4, it lists pharmacy sales by therapeutic class.[18] Similarly, the "therapeutic class" relates to the therapies for which the medicines are used (cardiovasculars; antihyperlipidemic agents; psychotherapeutics; …). A further list is found in relation to hospital purchases.[19] It also classifies the medicines by therapy.

39. Similar types of lists, by therapy, are found in Innovation, Science and Economic Development Canada's Discussion Paper on Canada's Pharmaceutical Industry and Prospects. [20]

40. Thus, Innovation, Science and Economic Development Canada's understanding of the term "therapeutic class" outside of the PMRPB, accords with Health Canada's.

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https://www.prod.ramq.gouv.qc.ca/DPI/PO/Commun/PDF/Liste_Med/Liste_Med/liste_med_2016_05_04_en.pdf;; New Brunswick Formulary: http://www2.gnb.ca/content/dam/gnb/Departments/h-s/pdf/en/NBDrugPlan/NewBrunswickDrugPlansFormulary.pdf; Nova Scotia Formulary: http://novascotia.ca/dhw/pharmacare/documents/formulary.pdf; Prince Edward Island Formulary: http://www.gov.pe.ca/photos/original/hpei_formulary.pdf?_ga=1.242257735.43001454.1463413271;

[18] Competition Bureau Canada, "Canadian Generic Drug Sector Study", October 2007 ("Study"), Table 5, <http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/02495.html>, Tab 10.

[19] Study, Table 10, <http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/02495.html>, Tab 10.

[20] Study, Table 3, <http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/hn01768.html>, Tab 10.

Summary on "Therapeutic Class"

41. Health Canada, Innovation, Science and Economic Development Canada and the provincial formularies all use a scientific definition of "therapeutic class" relating to the therapeutic use of the medicine. This is logical given that medicines are intended for therapy.

42. None of these governmental departments use an *ad hoc* collection of arbitrary medicines based on a non-scientific economic analysis that has no relation to the therapy for which the medicine is approved. This common term of art is not open to interpretation. It is understood by those who use it. To attempt to import a different definition for this term without any corresponding legislative amendment would effectively circumvent the due process, including consultation with the public, that is part of proper legislative change.

43. The PMPRB has also previously and consistently relied upon the scientific definition of "therapeutic class". In one case, it also specifically rejected the idea that the HDAP would consider pricing when determining therapeutic class.

44. Furthermore, Dr. Addanki's definition could not be substituted in any of the situations described above. First, the definition is limited to orphan drugs. The PMPRB's approach to drug pricing must be consistent, and cannot be if it takes one approach for orphan drugs and a different approach for all other medicines. This issue is discussed further below.

45. Furthermore, the US list of orphan drugs is not recognized in any official capacity by the *Patent Act*, Innovation, Science and Economic Development Canada, or Health Canada. Furthermore, it is but one of the countries the PMPRB is supposed to consider when comparing outside of Canada. Thus, it is not an appropriate starting point.

46. Finally, the arbitrary limitations proposed by Addanki are not generally applicable to other medicines which are part of the purview of the PMPRB. Some medicines are taken for both long and short periods of time, by different

patient populations. Similarly, some drugs are taken for both terminal state diseases and non-terminal state diseases. If one were to apply these arbitrary limitations to other every other drug regulated by the PMPRB, there would have to be almost no variation between the prices of any medicine. The comparator classes would be so big as to be unwieldly. Furthermore, they would cover every type of drug product from acne treatments to cancer therapies to erectile dysfunction treatments to high blood pressure therapies. Surely these vastly different therapeutic classes of drugs should have different price considerations. And, in fact, they do, under the PMPRB's current analysis.

47. Dr. Addanki's arbitrary, non-scientific approach should be disregarded on this basis alone.

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

48. Addanki and the PMPRB are proposing to develop a new definition of "therapeutic class" that applies solely to drugs, like SOLIRIS® that are used to treat rare diseases. This approach fundamentally disregards the basic principles of statutory interpretation.

49. As discussed above, section 85 of the *Patent Act* sets out the factors that shall be taken into consideration by the Board in determining whether a medicine is sold at an excessive price.

> 85 (1) In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:
>
> (a) the prices at which the medicine has been sold in the relevant market;
>
> (b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
>
> (c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;
>
> (d) changes in the Consumer Price Index; and

(e) such other factors as may be specified in any regulations made for the purposes of this subsection.[21]

50. The Board does not have any discretion to disregard any of these factors.

51. "Therapeutic class" arises in both s. 85(1)(b) and (c). The principles of statutory interpretation dictate that unless the contrary is clearly indicated by the context, it must have the same meaning in both sections.[22] There is no different context in these provisions.

52. Furthermore, this term must have the same meaning whenever it is applied.

53. The PMPRB does not have the jurisdiction to amend the *Patent Act* to use one definition of "therapeutic class" when considering whether orphan drugs are being sold at an excessive price, and another definition when considering whether all other drugs are being sold at an excessive price.

54. Similarly, the PMPRB cannot use one definition when considering breakthrough drugs which have no therapeutic class, and a different definition when considering other drugs, which do have a therapeutic class.

55. The PMPRB's Guidelines do provide guidance on how to address all of these issues in a scientifically based analysis. Furthermore, they provide for the same principles to be applied in all cases. Thus, there is certainty in the current Guidelines. Furthermore, these Guidelines were developed after consultation with stakeholders.

56. The PMPRB should not be permitted to change its approach in this arbitrary manner that increases uncertainty to the patentee at every turn. Furthermore, any such changes should also be subject to consultation with stakeholders, which would include BIOTECanada's members.

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[21] *Patent Act*, s. 85, Tab 2.
[22] *Thomson v. Canada (Deputy Minister of Agriculture)*, [1992] 1 S.C.R. 385 at p. 400, Tab 9.

Procedural Fairness and Legitimate Expectations

57. The PMPRB has breached the principles of procedural fairness and legitimate expectations by changing its approach to the determination of "therapeutic class" as between the initial determination of whether the price for SOLIRIS® is excessive and the later determinations as to whether the continuing price is excessive.

58. The Supreme Court has set out the considerations that are relevant to the common law duty of procedural fairness.[23] The Federal Court has held that the duty of fairness applies to the PMPRB's decisions.[24] The Supreme Court has held that:

> Where a government official makes representations within the scope of his or her authority to an individual about an administrative process that the government will follow, and the representations said to give rise to the legitimate expectations are clear, unambiguous and unqualified, the government may be held to its word, provided the representations are procedural in nature and do not conflict with the decision maker's statutory duty. Proof of reliance is not a requisite. It will be a breach of the duty of fairness for the decision maker to fail in a substantial way to live up to its undertaking.[25]

59. In this case, BIOTECanada submits that the PMPRB made a representation to Alexion that no comparators for SOLIRIS® were identified. The PMPRB used the HDAP's recommendations based on the scientific definition for "therapeutic class". The PMPRB's excessive pricing analysis should have continued on that basis.

60. Alexion had a legitimate expectation that further pricing analysis would also continue on the basis of the HDAP applying the scientific definition for "therapeutic class" when deciding if any comparators had entered the market.

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[23] *Baker v. Canada (Minister of Citizenship and Immigration)*, [1999] 2 S.C.R. 817 at paragraphs 23-27, Tab 3.
[24] *Sanofi-Aventis Canada Inc. v. Canada (Attorney General)*, 2009 FC 965 at paragraph 41, Tab 7.
[25] *Canada (Attorney General) v. Mavi*, 2011 SCC 30, [2011] 2 S.C.R. 504 at paragraph 68 [citations omitted], Tab 4.

61. However, instead, with the Addanki report, the PMPRB is changing the definition of "therapeutic class." This is a breach of procedural fairness. BIOTECanada's members have an interest in pursuing this issue, and if the PMPRB is applying this breach to Alexion, it may well do the same to another of BIOTECanada's members in the future.

62. There is a further breach of procedural fairness in the PMPRB changing the Guidance Document without a public consultation. 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.[26]

63. 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 going to be effected. BIOTECanada's members relied on the scientific definition of "therapeutic class" in the Guidelines.

Conclusions

64. In this case, the PMPRB, through the Board Staff filing of the Addanki report, has indicated that it is changing the definition of "therapeutic class" it applies in its Guidelines. Furthermore, it is changing that definition in an arbitrary and non-scientific, arbitrary manner, that seems open to change depending upon the medicine being considered.

65. BIOTECanada submits that this new definition of "therapeutic class" should be disregarded. Furthermore, having different definitions of the same term within the same statute, as it applies to different medicines is a breach of the principles of statutory interpretation, and should not be permitted. Finally, the PMPRB should not be permitted to change its definition of "therapeutic class"

[26] Compendium, Part C, Tab 16.

as between its initial assessment, and ongoing assessment of the price of a medicine; nor should it be permitted to do so without public consultations with its stakeholders.

Dated: June 15, 2016

Original signature redacted

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