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. ("Respondent") and the medicine "Soliris"

CANADIAN LIFE AND HEALTH INSURANCE ASSOCIATION INC.

REPLY TO THE WRITTEN SUBMISSIONS OF THE RESPONDENT ALEXION

Overview

1. The CLHIA disputes the position of the Respondent Alexion on the CLHIA's motion for intervener status because: (1) the CLHIA satisfies the established criteria to be granted intervener status in this proceeding; (2) the proposed intervention will not prejudice any party; and (3) the proposed intervention will not interfere with the fair and expeditious conduct of the proceeding.

Reply

2. Contrary to Alexion's submission the decision of the Board in PMPRB-07-D1 QUADRACEL and PENTACEL ("*Quadracel*") is still the leading decision on intervener status before the Board and clearly sets out that there are two types of considered and permitted interveners in Board matters. The first are those with a material and direct interest in the outcome of the proceeding. This category includes those persons "who, in one manner or another, will bear some or all of the cost burden of the medicine in question" and "organizations representing" such persons (at para. 12). The second category are those persons without a material and direct interest in the outcome but who can offer some element of evidence that is unique "or otherwise to be usefully supplementary to the evidence and argument expected to be adduced by the Board Staff..." (at para. 13).

3. The CLHIA submits that it qualifies for intervener status in this proceeding under either category in *Quadracel*. Firstly, the CLHIA is an organization which represents persons who will "in one manner or another" bear the cost burden of the price of Soliris. As noted in the Motion for Leave document, in

2013 the CLHIA estimates that private payers reimbursed more than $29 million for Soliris claims, which was up from 2012, when private payers paid approximately $21.6 million for Soliris claims. The fact that these payments are made pursuant to insured policies, group plans or group policies does not take away from the fact that CLHIA member companies are, together with plan sponsors, individual insureds and group plan members (through co-payments or by exceeding plan maximums), paying a substantial portion of the direct costs for Soliris in Canada.

4. The CLHIA further disputes that their interest in this proceeding is outside the statutory mandate of the Board. The CLHIA takes no issue with the Board's mandate being limited to the "factory-gate" pricing of patented drugs in Canada. The CLHIA submissions are directly related to the price of Soliris in Canada and the appropriate remedy should the Board determine that Alexion's pricing for Soliris has been excessive as alleged by the Board Staff.

5. The Board's mandate is not at issue in this matter whatsoever. As such the decision cited by Alexion of *Pfizer Canada v. Canada (Attorney General)* [2009] F.C.J. No. 882 ("*Pfizer*") has no application to the issues at hand. The CLHIA is not asking the Board to consider "contractual arrangements involving patentees and entities further down the distribution chain" or any "contractual arrangements". It is sufficient for the Board for the purposes of this motion to conclude that CLHIA members will satisfy the broad test that they will "in some manner or another...bear some or all of the cost burden" of Soliris as per the first category of interveners in *Quadracel*. Additional enquiries into the precise mechanism of insurance pricing and arrangements are unnecessary for the purposes of this proceeding.

6. The CLHIA submits that *Pfizer* is a decision addressing the jurisdictional authority of the Board and has no relevance to the issues at hand. The case does not address the issue of intervention before the Board and does not consider the *Quadracel* decision.

7. It is submitted that *Quadracel* sets out the appropriate factors to be considered by the Board in the Motion before it. The CLHIA made no mention that GSK was unsuccessful in its intervener application in *Quadracel*, as noted by Alexion, as it is an irrelevant point given that there is no similarity between the position of GSK, a competitor of the patentee, in *Quadracel* and the CLHIA in this matter.

8. If the Board concludes that the CLHIA does not have a direct and material interest in the proceeding then the CLHIA submits that it also satisfies the second category of intervener under *Quadracel* in that it, at the very least, offers some element of evidence that is unique and argument that is usefully supplemental to that adduced by the Board Staff. The CLHIA represents those who in part directly bear the cost of Soliris and has put forward a proposal as a remedy, should the Board find that Alexion has been charging excessive prices for Soliris, which will directly benefit all of those persons who have borne the effect any excessive pricing, not just its members.

9. The remedy proposed by CLHIA is no more retroactive than that sought by the Board Staff and relates to the exact same period of time that is at issue in this proceeding. It does not raise any solution that is not presently contemplated in the legislation and the Board's Compendium of Policies, Guidelines and Procedures and fits directly within the remedies available to the Board under section A.6 of the Compendium. The CLHIA merely proposes that the remedy imposed, should the Board find Alexion charged excessive prices for the period in question, be applied in a way that to some extent compensates those who have borne any excessive pricing. It is submitted there would be no prejudice to Alexion if the remedy proposed by the CLHIA were applied as opposed to that requested by the Board Staff presuming the pricing adjustment was approximately equal to any amount that might be payable under the remedies sought in section 30 (d) and (e) of the Statement of Allegations of the Board Staff in this matter.

10. The CLHIA does not at this time anticipate making written submissions if it is granted intervener status which goes beyond that set out in its Motion for Leave to Intervene materials. It is not expected that the CLHIA filing of written submissions would cause any delay or additional time for the hearing. It is unknown what expert evidence Alexion is alleging it would need to introduce in response to the proposed remedy put forward by the CLHIA, which should be a straightforward calculation and not materially different than the calculation required if the Board Staff's requested Order were granted.

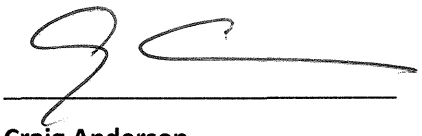
Conclusion

11. The CLHIA therefore request that it be given intervener status for the limited purpose of making a written submission to the Board in this proceeding. The CLHIA has a direct and material interest in the outcome; can offer a unique and helpful argument to supplement that put forward by the Board

Staff; and its intervention will not prejudice the parties nor interfere with the fair and expeditious conduct of the proceeding.

Dated at Toronto, Ontario this 5th day of June, 2015

ON BEHALF OF THE CANADIAN LIFE AND HEALTH ASSOCIATION INC.



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