

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.

WRITTEN SUBMISSION ON REMEDY

1. The CLHIA, on behalf of its member companies, has been granted leave to intervene for the purpose of addressing the types of remedies being sought by the PMPRB in the matter of the Respondent and the drug Soliris in the event the Panel finds there has been excessive pricing of Soliris over the period in question.

Background

2. Established in 1894, the CLHIA is a voluntary association whose member companies account for 99 per cent of Canada's life and health insurance business. Through a wide range of products and services, the life and health insurance industry helps Canadians to protect themselves and their families against the financial risks surrounding death, accident, illness and retirement. These products include individual and group life insurance, disability insurance, supplementary health insurance and individual and group annuities. In 2015, private supplementary health care benefit plans covered over 24 million Canadians and reimbursed \$10.7 billion in prescription drug costs.
3. Private benefit plans incur significant costs for Soliris in Canada annually. In 2013, the CLHIA estimates, based upon a survey of its members, that Canadian insurers reimbursed more than \$29 million for Soliris claims. This is up roughly 38% from 2012, when Canadian insurers paid just over \$21.6 million for Soliris claims.
4. The Board staff of the PMPRB are seeking issuance of an Order against Alexion, the terms of which include the following:
 - a. Alexion shall reduce the price of Soliris within 30 days from the date of the Board's Order to a price that does not exceed at least the international lowest price among the

comparator countries, or in the alternative to a price that does not exceed at least the international median price among comparative countries (in either case the “**Non-excessive Price**”);

- b. Alexion shall offset the cumulative excess revenues it has received from 2009 through 2015, calculated in accordance with alternatively proposed scenarios and options, by making a payment to Her Majesty in Right of Canada; and
 - c. Alexion shall offset the cumulative excess revenues it has received during the period of 31 December 2015 to the date on which the price reduction comes into effect (together with the cumulative excess revenue received by Alexion, referred to as the “**Total Penalty**”) by making a payment to Her Majesty in Right of Canada of an amount that is equal to the excess revenues the Board estimates that Alexion has generated from the sale of Soliris at an excessive price.
5. The CLHIA notes that the above remedies will not assist Canadian insurers, benefit plan sponsors or individual Canadians (collectively, the “**Private Payers**”) who have borne a significant portion of the burden of the alleged excessive pricing of Soliris. There is currently no mechanism in place for the Federal Government to distribute any amounts awarded as excess revenue to impacted Private Payers.
6. Given the foregoing, the CLHIA requests that the PMPRB exercise its discretion under paragraph 83(2)(a) of the *Patent Act* (Canada), and as an alternative to the remedies noted in 4(a) and (b) above that instead of making payment to Her Majesty in Right of Canada, order that Alexion further reduce the price at which Alexion sells Soliris, to such extent and for such period as results in Private Payers and other purchasers of Soliris being reimbursed in an amount equal to the Total Penalty to the extent reasonably possible, using the following methodology:
- Alexion shall reduce the price of Soliris to an amount that is less than the Non-excessive Price (the “**Further Reduced Price**”), until such time as the aggregate difference between the amounts paid by purchasers of Soliris at the Further Reduced Price and the amounts that would have been paid by such purchasers at the Non-excessive Price equals the Total Penalty plus a reasonable interest amount, to be determined by the Board staff of the PMPRB taking into account the time over which the Total Penalty is being reimbursed.

The Further Reduced Price shall be determined by the Board staff of the PMPRB, and intended to result in the recovery of the Total Penalty, plus applicable interest, within a six (6) month period;

- Alexion shall provide weekly sales volumes and such other information as may be reasonably required by Board staff to assist with the foregoing calculations; and
- Alexion shall be permitted to raise the price of Soliris to the then Non-excessive Price only once the savings to purchasers of Soliris is equal to the Total Penalty, plus applicable interest

ALL OF WHICH IS RESPECTFULLY SUBMITTED

DATED: March 31, 2017

Original signature redacted

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