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. MOTION FOR LEAVE TO INTERVENE

TAKE NOTICE THAT the Canadian Life and Health Insurance Association Inc. ("CLHIA") submits this motion before the Patented Medicine Prices Review Board ("PMPRB").

THE MOTION IS FOR an order granting the CLHIA intervener status in this matter in order to permit the CLHIA to make written submissions to the PMPRB regarding its position and that of its members on this hearing.

THE GROUNDS FOR THE MOTION ARE:

(1) The CLHIA, on behalf of its member companies, has an interest in the subject matter of this proceeding;

(2) The CLHIA represents the interests of 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;

(3) The CLHIA, on behalf of its member companies, is in a position to provide information that is relevant to these proceedings; and

(4) Section 20 of the *Patented Medicine Prices Review Board Rules of Practice and Procedure Regulations*, SOR 2012-247.

Background

1. Established in 1894, the CLHIA is a voluntary industry trade 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 2013, private supplementary health care

benefit plans covered over 24 million Canadians and reimbursed roughly $10.1 billion in prescription drug costs.

2. The provision of prescription drug coverage in Canada is shared between the public and private sectors. The majority of Canadians rely on private drug coverage, with more than 65 per cent of Canadians having prescription drug coverage through workplace benefit plans. An additional 1.8 million Canadians have individual supplemental health coverage. This Motion focusses on the group benefit plan business in Canada given that over 90% of individuals with supplemental health coverage are covered through a group plan.[1] However, all the matters listed below will equally impact Canadians with individual coverage.

3. The PMPRB's Highest International Price Comparison test, which compares the price of a patented drug to the publicly available list prices for that drug in certain comparator countries, disproportionately impacts Canadians covered by private insurance or paying out-of-pocket for their drugs. This is due to the fact that public drug benefit plans have made widespread use of confidential product list agreements (PLAs), which provide a discount to the list price of certain high cost drugs (including Soliris). Private payors have been unable to benefit from any discounts that may have been negotiated between governments and Alexion. This was noted in the Affidavit of Eric Lun dated April 1, 2015 that was filed by the Minister of Health for British Columbia with the PMPRB, in which Mr. Lun stated the following at paragraph 17:

> Although provincial governments pay for a significant proportion of Soliris treatments, there are other payors as well – hospitals (which may provide funding independently of public drug plans), drug benefit insurers and private payors. These payors are not able to benefit from any negotiated agreements that the provincial governments may have with the Respondent. These other payors would need to pay the full list price of the product unless there was an agreement in place between the payor and the Respondent.

4. A common justification for high prices for drugs that can treat rare diseases is that manufacturers need high prices due to the low number of potential patients to recoup the costs associated with bringing these drugs to market. We would note, however, that there appears to be no process for

[1] CLHIA survey of member companies and as reported in CLHIA's Health Insurance Benefits in Canada - 2013

the PMPRB to review the price of a drug over time if market conditions change, or even if the initial assumptions about the market for such drug materially change.

5. As noted in the PMPRB's Statement of Allegations, Soliris is the first and only treatment for patients with Paroxysmal Nocturnal Hemoglobinuria. Soliris became eligible for sale in Canada in June 2009. However, in 2013, Soliris was also approved for the treatment of Atypical Hemolytic Uremic Syndrome ("aHUS"). This has had the effect of expanding the market for Soliris in Canada. However, it has not generated a second review by the PMPRB to ensure that the price of Soliris remains appropriate given the expanded market for the drug.

6. We also note that Soliris has been approved for 3 additional indications (listed below) in the U.S. and Europe which will again broaden its potential use. We expect these indications to be approved in Canada in due course as well.

- Typical hemolytic uremic syndrome
- Complication after organ rejection
- Myasthenia Gravis

The CLHIA's Interest in this Hearing

7. The CLHIA notes that, in the course of making a ruling on an intervener motion by GlaxoSmithKline Inc. (Decision: PMPRB-07-D1-QUADRACEL and PENTACEL) in a 2007 matter involving allegations of excessive pricing of the drugs Quadracel and Pentacel, the PMPRB stated the following general principles with respect to granting intervener status at paragraph 12 of the decision:

> 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.

[Emphasis added]

8. As the PMPRB noted in its 2013 Annual Report, Canadians pay some of the highest prescription drug prices in the world (third highest as compared to the comparator countries used by the PMPRB). Of particular concern is the increasing incidence of very high costs for relatively rare drugs. For example, as noted by Bill Bright, Pharmacy Practice Leader for Towers Watson Canada, high-cost or specialty drugs are typically used by fewer than 5% of employees, but can account for 15 to 25% or more of an employer's total drug spend and are forecast to account for close to 30% of drug plan expense within the next three to five years.[2] .

9. Private benefit plans incur significant costs for Soliris in Canada annually. In 2013 the CLHIA estimates, based upon a survey of its members, that private payers reimbursed more than $29 million for Soliris claims. This has increased roughly 38% from 2012, when private payers paid approximately $21.6 million for Soliris claims.

10. The majority of private drug benefit plans in Canada provide coverage for any drugs that have received a Notice of Compliance by Health Canada as eligible expenses. As such, private benefit plans can be expected to incur higher numbers of Soliris claims as the drug is approved for further indications.

11. In order to contain costs, many benefit plan sponsors have implemented cost sharing mechanisms, including co-payments and annual reimbursement maximums, which can result in high-cost, lifesaving drugs, like Soliris, becoming unaffordable to benefit plan members. These out-of-pocket costs can be very significant for high costs treatments. For example, a 20% co-payment could result in an individual plan member having to pay over $100,000 out-of-pocket per year for Soliris.

[2] Bill Bright, Towers Watson. December 4, 2014. http://www.towerswatson.com/en-CA/Press/2014/12/companies-using-pharmacy-management-strategies-see-savings

12. The CLHIA is seeing a greater trend in the market towards introducing more cost control measures by employers that result in an increase in the out-of-pocket expenses for individuals. According to TELUS Health data[3], private plan members' share of prescription drug costs has been increasing in recent years, reaching a record high of almost 25 per cent in 2013. As well, TELUS Health reports that an increasing share of plan members have annual or lifetime maximums on their plans. Such plans proportion of total plans on the TELUS block of business reached an all-time high of just over 17 per cent in 2012[4].

13. This is an issue with potentially significant repercussions. Individuals requiring very high cost prescription drug therapies, who are unable to afford their particular drug therapy because of cost sharing mechanism implemented by plan sponsors may be unable to access therapies required to allow them a reasonable quality of life or even to prolong their lives. Ultimately, in such cases, these individuals tend to fall onto government provincial programs, which further strains the provincial treasury.

The Issues the CLHIA Intends to Address

14. The CLHIA intends to address the types of remedies being sought by the PMPRB.

15. The Board Staff of the PMPRB are seeking issuance of an Order against Alexion, the terms of which include the following:

- Alexion shall offset the cumulative excess revenues it has received during the period of 1 January 2012 to 30 June 2014 by making a payment to Her Majesty in Right of Canada, within 30 days of the date of the Board's Order.

- Alexion shall offset the cumulative excess revenues it has received during the period of 1 July 2014 to the date on which the price reduction comes into effect 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.

[3] "Does Drug Plan Design Affect Patient Behaviour?" Presentation by Bryan Ferguson - TELUS Health Analytics, November 2014
[4] IBID

16. The above remedies will not assist Canadian benefit plan sponsors who have already borne a significant portion of the excessive pricing of Soliris. The CLHIA intends to request that the PMPRB exercise its discretion under paragraph 83(2)(a) of the *Patent Act* (Canada), and reduce the maximum price of Soliris to an amount that results, over a reasonable period of time, in an offseting of the excessive price charged by Alexion from January 1, 2012 to the date of the PMPRB's order, and thereafter to a price that is not excessive.

17. Further, the CLHIA intends to request that the PMPRB:

- in determining the non-excessive maximum price of Soliris, take into consideration the newly approved indication for aHUS. The CLHIA requests that the maximum price be adjusted if it is concluded that the new indication for aHUS will materially increase the market for Soliris in Canada, and
- conduct a similar review on each subsequent indication for Soliris that is approved by Health Canada.

Relief Sought

18. The CLHIA requests an Order granting the CLHIA leave to intervene in the Soliris hearing by permitting the CLHIA to file a written submission.

Dated at Toronto, Ontario this 12th day of May, 2015

ON BEHALF OF THE CANADIAN LIFE AND HEALTH ASSOCIATION INC.

Original signature redacted

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