



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.
and the medicine "Soliris"**

REASONS FOR DECISION

(Amount of Excess Revenue Payment)

Decided by the panel (the "**Panel**") of the Patented Medicine Prices Review Board (the "**PMPRB**" or the "**Board**") seized with this proceeding on the basis of written submissions.

1. In its decision on the merits, dated September 20, 2017 (the "**Decision**"), the Panel concluded that the price of Soliris (eculizumab) 10mg/mL was and is excessive under sections 83 and 85 of the *Patent Act*. In the Decision, the Panel ordered Alexion to (i) pay to Her Majesty in right of Canada an amount calculated by the parties in accordance with Schedule A to the Decision, to be approved by the Panel, and (ii) lower the list price of Soliris in Canada as of September 20, 2017 to no higher than the lowest price in the seven comparator countries set out in the current *Patented Medicines Regulations*.

2. Schedule A to the Decision required the parties to file by October 20, 2017 a joint chart or, failing agreement, their own charts, setting out the calculation of the payment as specified by Schedule A. Schedule A further provided that the Panel would issue a decision confirming the amount of the payment, and that Alexion was required to make the payment within 30 days of that decision.

3. On October 18, 2017, Board Staff requested a five-day extension of the October 20 deadline to submit materials regarding its calculation of excess revenues as per Schedule A to the Decision in the event that Alexion disagreed with Board Staff's

calculations that had been provided to Alexion on October 13. Alexion advised the Board on October 18 that it did not oppose Board Staff's request for additional time.

4. By direction dated October 19, 2017, the Panel ordered and directed the parties as follows:

- i. Board Staff shall file as soon as possible and no later than the previously ordered deadline of October 20 its version of the chart required by Schedule A.
- ii. Also by October 20, Alexion shall either advise that it agrees with Board Staff's chart or shall file its own chart and identify where its chart differs from the chart filed by Board Staff.
- iii. If Alexion provides a chart that differs from that filed by Board Staff by the deadline of October 20, Board Staff shall have until 4 pm on October 23 to respond.
- iv. The Panel will make its determination based on the charts filed by the October 20 deadline and any response by Board Staff filed on or before October 23 (if relevant), subject to the Panel's discretion to order a case conference should the Panel deem it necessary.

5. Alexion responded to the Panel's October 19 direction by requesting the opportunity to file a brief reply to Board Staff's submissions. Board Staff objected to this request. Alexion's request became moot as matters unfolded and therefore was not ruled on by the Panel.

6. On October 20, 2017, both Alexion and Board Staff filed charts and submissions regarding the calculation of the excess revenue payment under Schedule A to the Decision. On October 23, Alexion filed amended charts (clarifying the titles to the charts to avoid any confusion) and Board Staff filed its reply submissions to Alexion's charts and submissions. The parties did not agree on the amount of the payment, having adopted different assumptions as to which international prices were relevant for the purposes of the analysis.

7. On October 25, 2017, the Panel issued a direction to the parties in order to correct any misunderstanding about what international prices were to be used to establish the benchmark for purposes of determining whether there were excess revenues in any given year. The substantive part of the direction provided:

Schedule A must be read in conjunction with the Decision. The Panel, in paragraphs 193 to 197 of the Decision, resolved any dispute about sources and back-up formulas for Block 5 international prices in Alexion's favour by requiring that "the parties use only the information provided by Alexion in its Form 2s (except for any claimed rebates to the provinces or Innomar) for the purpose of calculating excess revenues." The Block 5 prices to be used are the ones contained in the most up to date filing made by Alexion for any given filing period. The Panel directs the parties to file an amended chart(s) that complies with the Decision, as follows:

1. Board Staff is to provide Alexion with an amended chart by October 30, 2017, that complies with the Decision, and corrects the misunderstanding outlined above.
2. Alexion is to advise Board Staff by November 2, 2017 whether it agrees with Board Staff's amended chart. If Alexion agrees, counsel shall advise Mr. Couillard of the agreement and file the amended chart by November 3, 2017.
3. If Alexion does not agree, Alexion shall file its proposed amended chart and clearly indicate where its chart differs from Board Staff's, by November 3, 2017. Board Staff shall have the right to reply to Alexion's proposed amended chart (should there be one) by November 6, 2017.

8. On October 30, Board Staff filed its amended charts, in accordance with the Panel's October 25 direction. Table 4 contained Board Staff's calculation of Alexion's excess revenues for Soliris of \$4,245,329.60. Board Staff's calculation is based on applying the MIPC test to 2009 and the HIPC test to 2010 to 2017, and using Alexion's final revised Block 5 reported prices.

9. On November 2, 2017, Alexion advised that it agrees with the calculation of past excess revenues contained within Table 4 filed by Board Staff on October 30.

10. The Panel has reviewed the amended charts filed by Board Staff on October 30 and concludes that they accurately implement the Decision. Accordingly, the amount of the payment calculated in accordance with Schedule A to the Decision, and approved by this Panel, is \$4,245,329.60.

11. The Panel therefore orders Alexion to pay to Her Majesty in right of Canada the amount of \$4,245,329.60 on or before December 8, 2017.

Dated at Ottawa, this 8th day of November, 2017.

Original signed by

Signed on behalf of the Panel by
Dr. Mitchell Levine

Panel Members

Mitchell Levine
Carolyn Kobernick

Counsel for Alexion

Malcolm Ruby
David Woodfield
Alan West

Counsel for Board Staff

David Migicovsky
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Sandra Forbes
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