Patented Medicine Prices Review Board Canada
Conseil d'examen du prix des médicaments brevetés Canada

IN THE MATTER OF the Patent Act, R.S.C. 1985, c. P-4, as amended

AND IN THE MATTER OF Horizon Pharma (the "Respondent") and the medicine Cysteamine Bitartrate sold by the Respondent under the trade name Procysbi

DECISION ON REQUESTS FOR CONFIDENTIALITY MADE BY THE RESPONDENT ON FEBRUARY 12, 2021 AND BOARD STAFF ON MARCH 5, 2021 IN RESPECT OF CERTAIN HEARING DOCUMENTS

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

A. THE RESPONDENT'S REQUEST FOR CONFIDENTIALITY

(i) Initial Submissions

1. On February 12, 2021, the Respondent filed a request for confidentiality with the Board in respect of certain documents referred to during the evidentiary phase of this hearing (the "**Respondent's Request**").

2. On March 5, 2021, Board Staff filed a reply to the Respondent's Request ("**Board Staff's Reply**").

3. The Respondent's Request and Board Staff's Reply were made pursuant to the confidentiality protocol issued by this Panel on October 29, 2019 (the "**Confidentiality Protocol**"), as well as the Panel's Directions of November 26, 2020, January 20, 2021, and February 22, 2021.

4. The Respondent's Request proposes certain redactions to the version of the Exhibits Briefs that will be filed on the public record. In support of its Request, the Respondent filed a redaction chart that lists each requested redaction and provides

reasons for why each redaction should be permitted in accordance with the Confidentiality Protocol (the "**Respondent's Redaction Chart**").

5. In its Reply, Board Staff objects to the redaction of documents on the basis that they are publicly available – either because the documents were made public prior to the hearing, or because the documents were referred to during a public section of the hearing. Specifically, Board Staff objects to item 9 of the Respondent's Redaction Chart because the document heading states that the information is "publicly available".

(ii) Supplementary Submissions

6. On March 23, 2021, the Panel issued a request for clarification in respect of items 140, 141, 148, 152-154 and 156-160 of the Respondent's Redaction Chart.

7. On April 1, 2021, the Respondent delivered a response to the Panel's request for clarification, in which it:

(a) Withdrew its request for confidentiality over items 152-154 of the Respondent's Redaction Chart on the basis that those items had been inadvertently included in error; and

(b) Amended its request with respect to items 140, 141, 148 and 156-160 (collectively, the "**RP103 Reports**") by replacing its original request to redact those documents in their entirety with a request to redact them only in part, by applying specific and targeted redactions.

8. In its amended request, the Respondent submits that portions of the RP103 Reports should be redacted because they contain sensitive patient information. In support of this position, the Respondent notes that redacted versions of the RP103 Reports (except for the clinical study report for RP103-08) had previously been provided to Health Canada as part of a Public Release of Clinical Information ("**PRCI**") Submission – the purpose of which was to identify and redact sensitive patient information so that the RP103 clinical trial studies could be made available to certain

members of the public (who certify that they will use the reports for non-commercial purposes) without compromising patient privacy.

9. Accordingly, the Respondent proposes two alternative methods for filing public versions of the RP103 Reports:

(a) First, the Respondent proposes to only file specific extracts from the RP103 Reports that were put to witnesses during the hearing. The extracts of the RP103 Reports (except for the RP103-08 report) would be pulled from the redacted versions of the RP103 Reports that were provided to Health Canada, and the Respondent would propose its own redactions to the extract of the RP103-08 report.

(b) Alternatively, the Respondent proposes to file full copies (not extracts) of the redacted versions of the RP103 Reports (except for the RP103-08 report) that were provided to Health Canada, and the Respondent would propose its own redactions to the full copy of the RP103-08 report.

10. By letter dated April 8, 2021, Board Staff objected to the Respondent's request to redact the RP103 Reports. Board Staff submits that the RP103 Reports are not confidential because the Respondent has not established that it would suffer specific, direct and substantial harm following the disclosure of the RP103 Reports. Moreover, Board Staff submits that these Reports were referred to during public portions of the hearing, with no objection from the Respondent.

11. On April 12, 2021, the Respondent replied to Board Staff's April 8, 2021 letter, maintaining that the RP103 Reports should be redacted in order to protect sensitive patient information.

(iii) Decision

12. After carefully reviewing and considering all of the materials filed by the Respondent and Board Staff, the Panel grants the Respondent's Request in part, as follows:

(a) The Panel denies the proposed redactions in items 4-6, 9, 132, 145-147 and 149 of the Respondent's Redaction Chart in their entirety;

(b) The Panel grants the proposed redactions in items 1-3, 8, 10-14,16-131, 133-144, 148, 150-151, 156-168, 170-174 and 176-211 of the Respondent's Redaction Chart in their entirety; and

(c) The Panel grants the proposed redactions in items 7, 15, 155, 169 and 175 of the Redaction Chart in part.[1]

13. The Panel has provided a copy of the Respondent's Redaction Chart to the parties with this Decision. This Redaction Chart identifies whether a request was granted, denied or granted in part.

14. Where a request was granted in part, the Panel used red underlining (and in some instances, red boxes) to identify the portions of the document that it accepts are confidential and should be redacted from the public record. For greater clarity, where a request was granted in part, the Panel only permits the redaction of the portions of the documents that are underlined in red (or contained within a red box) in the Respondent's Redaction Chart.

15. With respect to the RP103 Reports (*i.e.*, items 140, 141, 148 and 156-160), the Panel directs the Respondent to:

(a) File with the Board full copies (not extracts) of the redacted versions of the RP103 Reports that were provided to Health Canada; and

(b) File with the Board a full copy (not an extract) of the RP103-08 clinical study report (*i.e.*, item 160 of the Redaction Chart), in which, following the approach taken to redactions during the PRCI Submission process, only sensitive patient information is redacted.

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[1] The Panel has not addressed the proposed redactions in items 152-154 of the Respondent's Redaction Chart because, as noted above, the Respondent has withdrawn its request for those redactions.

16. While the versions of the RP103 Reports described in paragraphs 15(a) and 15(b) above shall form part of the public record, access to them shall be restricted to those persons who certify agreement with the Terms of Use governing access and use of Clinical Information by Health Canada for non-commercial purposes.

(iv) Reasons

17. The Panel repeats and relies on the legal principles and findings set out in its previous confidentiality decisions in this matter[2] (the "**Initial Confidentiality Decisions**"), which are incorporated by reference into this Decision.

18. The Panel grants the requests or portions of the requests noted in paragraphs 12(b) and 12(c) above because they are (i) consistent with the Initial Confidentiality Decisions, (ii) justified based on the test for confidentiality set out in the Confidentiality Protocol, and/or (iii) necessary in order to protect patient privacy.

19. For example, the Panel grants the Respondent's amended requests regarding the RP103 Reports in order to prevent the public disclosure of sensitive patient information, which is particularly important given the limited number of participants in the RP103 clinical trial studies. The Panel accepts the Respondent's submission that the purpose of the PRCI Submission process with Health Canada was to identify and redact sensitive patient information. In these circumstances, the Panel agrees that it is appropriate for the Respondent to (i) file the redacted versions of the RP103 Reports that were provided to Health Canada, and (ii) following the approach taken to redactions

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[2] Decision on Confidentiality Requests Made in Respect of Materials Filed for Board Staff's Bifurcation/Production Motion (February 24, 2020), online: <https://www.canada.ca/en/patented-medicine-prices-review/services/hearings/status-ongoing-proceedings/decision-confidentiality-requests.html>; Decision on Confidentiality Request Made in Respect of Materials Filed for the Production of Documents (July 21, 2020), online: <https://www.canada.ca/en/patented-medicine-prices-review/services/hearings/status-ongoing-proceedings/procysbi-decision-production-documents.html>; Decision on Confidentiality Requests Made by the Respondent in Respect of Certain Expert Reports (December 2, 2020), online: <https://www.canada.ca/content/dam/pmprb-cepmb/documents/hearings/status-ongoing-proceedings/2020-12-02%20-%20Decision%20on%20Confidentiality%20-%20Respondent%20Requests%20of%20Certain%20Expert%20Reports.pdf>.

during the PRCI Submission process, apply redactions to the RP103-08 report that are required to protect patient privacy.

20. For greater clarity, the Panel only permits sensitive patient information to be redacted from the RP103 Reports. The Respondent has not satisfied the Panel that specific, direct and substantial harm will be caused by publicly disclosing the information (other than sensitive patient information) contained in the RP103 Reports. Accordingly, there is no basis for the Respondent to only file extracts of the RP103 Reports on the public record. This is consistent with the Panel's Direction of November 24, 2020, in which the parties were directed to publicly file all documents (not extracts of documents) that were admitted into evidence during the hearing.[3]

21. The Panel denies the redaction requests set out in paragraph 12(a), and grants the redaction requests set out in paragraph 12(c) in part only, for one or more of the following reasons:

(a) The information is already in the public domain and therefore is not confidential pursuant to paragraph 12 of the Confidentiality Protocol. For example, the Panel denies the redactions proposed in items 4-6 of the Respondent's Redaction Chart because these documents were discussed in great detail during public portions of the hearing, with no objection from the Respondent.[4] Notably, item 6 concerns the Respondent's Draft Voluntary Compliance Undertaking. When this document was screen-shared during a public portion of the hearing, the Panel asked counsel whether the document was confidential, and counsel confirmed that it was not.[5]

(b) The requested redaction is over-inclusive and inconsistent with the Panel's Initial Confidentiality Decisions in which the Panel directed the

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3 Hearing Transcript, November 24, 2020, pp. 197-199.

4 Hearing Transcript, November 24, 2020, pp. 234-238, 248-253, 259-264.

5 Hearing Transcript, November 24, 2020, pp. 261-263.

parties to propose thoughtful, justified and precise redactions. In a number of instances, the Respondent proposes to redact a document in its entirety, when only a portion of the document contains confidential information. In those circumstances, the request was granted in part. For example, in item 7 of the Respondent's Redaction Chart, the Respondent proposes to redact the document in its entirety when the only confidential information contained in the document are the precise figures related to units sold and revenues. Accordingly, the Panel only grants the request in item 7 of the Respondent's Redaction Chart in part – the Respondent may only redact the precise figures and dollar values underlined in red.

(c) The requested redaction is over-inclusive and inconsistent with other requests in the Respondent's Redaction Chart. For example, in item 175, the Respondent proposes to redact the following three phrases: (i) "of Raptor Acquisition Cost to Canada"; (ii) "worldwide marketing rights"; and (iii) "allocating it by region". Item 174 of the Respondent's Redaction Chart contains these identical phrases in a similar context, however, the Respondent did not claim confidentiality over them. Accordingly, the Panel only grants item 175 of the Respondent's Redaction Chart in part – those three phrases shall not be redacted.

B. BOARD STAFF'S REQUESTS FOR CONFIDENTIALITY

(i) Background

22. On March 5, 2021, Board Staff filed a request for confidentiality in respect of the parties' written closing submissions ("**Board Staff's First Request**").

23. On March 23, 2021, the Panel issued a request for clarification with respect to paragraph 6 of Board Staff's First Request. In addition, the Panel, *inter alia*, (i) directed the parties to file any confidentiality requests with respect to the Amended Report of Professor Schwindt dated November 26, 2020 (the "**Amended Schwindt Report**") by

April 1, 2021, and (ii) directed the Respondent to file any written reply submissions to Board Staff's First Request by April 1, 2021.

24. On March 26, 2021, Board Staff delivered a written response to the Panel's request for clarification in which it confirmed that Board Staff's First Request did not propose any redactions to the Respondent's reply submissions dated March 5, 2021. In addition, Board Staff filed a request for confidentiality with respect to the Amended Schwindt Report ("**Board Staff's Second Request**").

25. On April 1, 2021, the Respondent filed its reply to both of Board Staff's Requests (the "**Respondent's Reply**").

26. Board Staff's Requests and the Respondent's Reply were made pursuant to the Confidentiality Protocol and the Panel's Directions of February 22, 2021 and March 23, 2021.

(ii) Positions of the Parties

27. Both of Board Staff's Requests propose to redact all references in the parties' written closing submissions and the Amended Schwindt Report to data generated by IQVIA Solutions Canada Inc. ("**IQVIA Data**").

28. In support of these Requests, Board Staff relies on its written submissions that were filed in support of its request for confidentiality dated November 9, 2020. Board Staff's November 9th confidentiality request concerned a data report generated by IQVIA Solutions Canada Inc. and a table in the original expert report of Professor Schwindt dated September 6, 2019, which Board Staff submitted contained IQVIA Data. The Respondent consented to the November 9th confidentiality request, and the Panel granted that request on November 23, 2020.[6]

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6 Hearing Transcript, November 23, 2020, Volume 1, pp. 6-7.

29. In its Reply, the Respondent raises three categories of objections to Board Staff's Requests.

30. First, the Respondent objects to the requested redactions set out in paragraphs 4(a), 5(a), 5(c), 5(e) and 5(f) of Board Staff's First Request because "18.25%" is a reference to Board Staff's calculations – not IQVIA Data. Moreover, the Respondent notes that this figure is already a matter of the public record because the reference to "18.25%" appears multiple times in Board Staff's Statement of Allegations which have been available on the PMPRB website since early 2018, and because the reference to "18.25%" was frequently discussed during public portions of the hearing.

31. Second, the Respondent objects to the requested redaction set out in paragraph 5(d) of Board Staff's First Request because it does not reference specific IQVIA Data, and simply reflects Dr. Hay's expert opinion on IQVIA Data generally.

32. Third, the Respondent objects to the proposed redactions to the Amended Schwindt Report set out in Board Staff's Second Request because the redactions are not of IQVIA Data.

(iii) Decision

33. As described above, the Panel repeats and relies on the legal principles and findings set out in its Initial Confidentiality Decisions which are incorporated by reference into this Decision.

34. After carefully reviewing and considering the materials filed by Board Staff and the Respondent in respect of Board Staff's Requests, the Panel grants Board Staff's First Confidentiality Request in part, as follows:

(a) The Panel grants the redaction proposed in paragraph 5(b) because this sentence contains confidential IQVIA Data;

(b) The Panel denies the redactions proposed in paragraphs 4(a), 5(a), 5(c), 5(e) and 5(f) because the "18.25%" figure is already in the public domain

and therefore is not confidential pursuant to paragraph 12 of the Confidentiality Protocol; and

(c) The Panel denies the redaction proposed in paragraph 5(d) because this sentence simply reflects Dr. Hay's expert opinion and does not contain confidential IQVIA Data.

35. The Panel also grants Board Staff's Second Request in part, as follows:

(a) The Panel grants Board Staff's request to redact rows 1 through 4 of the first column of Table 5 of the Amended Schwindt Report because this is consistent with Board Staff's request for confidentiality dated November 9, 2020 (which the Respondent consented to, and the Panel granted on November 23, 2020); and

(b) The Panel denies Board Staff's request to redact (i) the remaining numerical data in the first column of Table 5, (ii) the numerical data in rows 5 through 9 of the second column of Table 5, and (iii) the numerical data in the paragraph preceding Table 5 because these figures do not disclose confidential IQVIA Data.

C. DISPOSITION

36. For the foregoing reasons, the Panel hereby orders the parties to file with the Board public and confidential versions of the Exhibits Briefs no later than July 30, 2021. For greater clarity, in accordance with the Panel's Direction of November 24, 2020,[7] the Exhibits Briefs shall only contain those documents that were (1) admitted into evidence by a witness, or (2) agreed by the parties to be admitted into evidence. It is the parties' responsibility to remove any documents from the Exhibits Briefs that were not admitted into evidence. The public version of the Exhibits Briefs shall only contain redactions to

[7] Hearing Transcript, November 24, 2020, pp. 197-199.

the extent that they were granted by this Panel. The confidential version of the Exhibits Briefs shall be un-redacted.

37. For the foregoing reasons, the Panel hereby orders Board Staff to file with the Board a public version of the Amended Schwindt Report redacting only the portions of the Report identified in paragraph 35(a) above.

38. The Panel's Direction of February 22, 2021 granted the Respondent's request to defer filing a confidentiality request in relation to the written closing submissions until after the Panel had ruled on its Request for Confidentiality dated February 12, 2021 (defined above as the "Respondent's Request"). Now that the Panel has ruled on the Respondent's Request, the Panel hereby orders the Respondent to file with the Board its request for confidentiality in respect of the parties' written closing submissions and reply submissions, no later than June 30, 2021. The Panel's decision on that request for confidentiality will contain a deadline by which the parties shall file public versions of the written closing submissions and reply submissions.

Dated at Ottawa, this 15th day of June, 2020.

E-SIGNED by Carolyn Kobernick
on 2021-06-15 08:05:09 EDT

Signed on behalf of the Panel by
Carolyn Kobernick

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