

CHPA Complaints Panel Final Determination 01/21

Meeting held on October 12, 2021

iNova Pharmaceuticals Pty Ltd (“iNova”)

v.

Care Pharmaceuticals Pty Ltd (“Care”)

Little Coughs Ivy Leaf (Hedera helix) range

1. iNova initiated this complaint formally by letter dated August 13, 2021. Care responded formally by letter dated August 27, 2021 and iNova referred the complaint to CHPA on September 8, 2021. iNova complains that Care has breached sections 4.1 and 5.1.4 of the ASMI/CHPA Code of Practice (“the Code”) in relation to the promotion of its Little Coughs™ Ivy Leaf (Hedera helix) range (“Little Coughs”) for use in children under 2 years of age.
2. The front labels of Care’s Little Coughs products prominently state “6 months +” and “For the soothing relief of coughs and chesty congestion”. The rear labels contain “Warnings” including, in fine print:

“Consult your healthcare professional:
*before using in children under 2 years of age...”

and “Directions for Use” including, also in fine print:

“Shake well before use
Use the enclosed dosing syringe to withdraw an accurate dose...”

Age	How much	How often
6 months – under 2 years	2.5ml	Once a day”

Section 4.1

3. Section 4.1 of the Code provides: “Members shall not engage in any unfair* or unconscionable conduct or commercial practice”. “Unfair” is defined in section 2 as “not equitable or honest or impartial or according to the Constitution”.
4. iNova contends that, based on its own literature searches, there is insufficient supporting evidence to justify the administration of the Little Coughs Hedera helix products to children in the 6 months to 2 years age group. Care contends that its literature review of Hedera helix in Little Coughs products establishes that Hedera helix can safely be provided to the 6 months – 2 year patient population.

5. In light of the Panel's decision below in relation to section 5.1.4 of the Code, the Panel will defer its consideration as to whether Care's promotion of its Little Coughs products for use in children aged 6 months to 2 years is justified and, if not, whether such promotion breaches section 4.1.

Section 5.1.4

6. Section 5.1.4 of the Code provides:

"5.1.4 Furthermore, information and claims must, when made, have been substantiated, such substantiation being provided without delay upon request. A member unable or unwilling to provide a reference in substantiation of a claim, should refrain from citing it. An abstract or summary of unpublished data should be identified as such when cited."

7. It is common ground that iNova requested Care to provide to it, in relation to Care's Little Coughs range:

"the evidence which you hold to substantiate the use of Hedera helix in the quantities and extract ratios used in each of your formulations for dosing in the 6 months – 2 years range".

8. Care has refused to comply with iNova's request, contending that the request (characterised by Care as its "Demand") is unclear, unreasonable and misconceived and that iNova has failed to state clearly whether it is seeking evidence to substantiate *dosing* or *supply* in the 6 months – 2 years age range.
9. Care states that its literature review of Hedera helix in Little Coughs establishes that Hedera helix can safely be provided to the 6 months – 2 year patient population and that iNova could discover the same data used in Care's literature review should iNova conduct its own literature review. iNova says it has conducted its own literature review and that the clinical studies that are available to support Hedera helix use in children in the relevant age group do not align with the extract quantities, nor ratios and doses specified on the label of Little Coughs products.
10. Care notes that its Little Coughs products compete with iNova's Duro-Tuss Children's Cough products, which state:

"Do not use this medicine in children under 2 years"

and contends that iNova's attempt to use the CHPA complaint process is a ruse to obtain Care's proprietary and confidential information, in breach of section 9.4.2.1 and 4.1 of the Code, which provide:

9.4.2.1 Industry-generated complaints should not be used simply as a competitive tool.

4.1 Members shall not engage in any unfair* or unconscionable conduct or commercial practice.

11. The Panel considers that iNova's request seeks the evidence held by Care to support the safety of Care's Little Coughs products when supplied to children in the 6 months

– 2 years age range at the dosages specified by Care, using the relevant ingredient, quantity and extract ratios. Accordingly, the Panel finds iNova's request is not unclear.

12. Further, in light of the results of iNova's literature review, the Panel finds iNova's request to be neither unreasonable nor misconceived, since Section 5.1.4 of the Code clearly requires Members to provide evidence to substantiate claims even when requested by competitors.
13. In its draft determination the Panel stated that Care's contention that iNova's use of the CHPA complaint process is a ruse to obtain Care's proprietary and confidential information is inconsistent with Care's contention that iNova could discover the same data used in Care's literature review should iNova conduct its own literature review. Care has since stated:

“By way of clarification, there is no single article which Care relies upon in respect to its evidence to support that Hedera helix can be safely provided to the 6 month to 2 year patient population. Care paid for the expertise of a third party to collate and analyse various information to reach a view. Accordingly, as stated...such information is propriety [sic] in nature and confidential to Care.”

14. The Panel considers that Section 5.1.4 of the Code requires members who choose to make claims based on confidential, proprietary information to provide that information without delay upon request. Accordingly, the Panel declines to find iNova's request to be in breach of Sections 9.4.2.1 and 4.1 of the Code.

Conclusion

15. The Panel finds Care to be in breach of section 5.1.4 of the Code in failing to comply with iNova's request. This is a Minor Breach, having no safety implications and no effect on how consumers or healthcare professionals will view the product or its competitors.
16. Pursuant to Section 10.2.1 of the Code, the Panel directs Care to provide to iNova, within 5 working days of receiving the Panel's Final decision in relation to Section 5.1.4, the evidence held by Care to support the safety of Care's Little Coughs products when supplied to children in the 6 months – 2 years age range at the dosages specified by Care, using the relevant ingredient, quantity and extract ratios.
17. The Panel requests iNova, within 5 working days of Care's compliance with this direction or within such further time as the Panel Chair may allow, to inform the Chief Executive Officer of CHPA and Care whether it wishes to proceed with its complaint of breach by Care of Section 4.1 and, if so, at the same time to provide to the Chief Executive Officer of CHPA and to Care:
 - (i) a copy of the evidence received from Care pursuant to the direction made under Section 10.2.1, and
 - (ii) any further submission iNova wishes to make in relation to its Section 4.1 complaint.
18. Should iNova wish to proceed with its Section 4.1 complaint, within 5 working days of Care's receipt of any further submission by iNova or within such further time as the

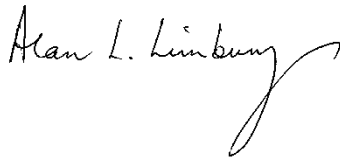
Panel Chair may allow, Care may provide to the Chief Executive Officer of CHPA and to iNova any response to iNova's further submission.

19. The Panel makes no determination to alter the usual operation of section 9.4.2.2 of the Code in relation to the Section 5.1.4 Complaint.

20. Any consideration of the substance of the Section 4.1 Complaint will take place on a date to be fixed.

Dated: October 19, 2021.

For the CHPA Complaints Panel

A handwritten signature in black ink, reading "Alan L. Limbury". The signature is written in a cursive style with a long, sweeping tail that loops back under the name.

Alan L. Limbury

Panel Chair

Note: although this is called a Final Determination, each party has a right of appeal to the Arbiter. If no appeal is lodged this determination will be published on the CHPA website once the time for lodging an appeal has expired. If there is an appeal, the Arbiter's determination will be published on the CHPA website together with this determination. Until publication on the website, parties and their representatives should maintain the privacy of these proceedings.