CHPA Arbiter's Determination 01/21 (Part 2)

Hearing on April 26, 2022

Care Pharmaceuticals Pty Ltd- Appellant

vs

iNova Pharmaceuticals Pty Ltd- Respondent

Little Coughs Ivy Leaf (Hedera helix) range

1. This is an appeal from a determination made by the CHPA Complaints Panel dated 28 February 2022, pursuant to section 11 of the ASMI/CHPA Code of Practice (**Code**).

Procedural History

2. In a letter dated 8 September 2021, iNova complained that Care has breached sections 4.1 and 5.1.4 of the Code in relation to the promotion of its Little Coughs Ivy Leaf (Hedera helix) range in children between the age of 6 months and 2 years (**the Products**).
3. At a meeting on 12 October 2021, the Panel deferred its consideration of the substance of the section 4.1 complaint. The Panel found Care to be in breach of section 5.1.4 of the Code in failing to comply with iNova's request that Care provide to it in relation to the Products:

> "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".

4. The Panel found that Care's breach was a Minor breach having no safety implications
5. In response to the Panel's draft determination in relation to the section 5.1.4 complaint, Care advised the Panel that there was **no single article upon which Care relied** in respect to its evidence to support its claim that the Products can be safely provided to the 6 months to 2 year patient population. It advised that it had paid for

the expertise of a third party to collate and analyse "various information" to reach a view. It asserted that that information was proprietary in nature and confidential to Care.

6. Pursuant to section 10.2.1 of the Code, the Panel directed Care to provide to iNova within five working days of receiving the Panels 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 (**the Panel's Direction**).
7. Care appealed to the Arbiter from the Panel's decision. On 7 December 2021, the Arbiter rejected Care's appeal and confirmed the Panel's Direction to Care pursuant to section 10.2.1 of the Code to provide the evidence.
8. The Arbiter found that there were two representations made by Care concerning the Products. Firstly, that they can be used by children between 6 months and 2 years in the dosage recommended by Care, subject to obtaining advice from a healthcare professional. Secondly, an implied representation that it was safe to use the Products, in the dosage recommended for children between the age of 6 months and 2 years (**the Claims**).[1] The Arbiter found that the Claims had not been substantiated and that this was in breach of section 5.1.4 of the Code.
9. The Arbiter found this breach to be a Severe Breach, having safety implications, and imposed a fine of $25,000. This fine was payable if Care did not provide the evidence which it was directed to provide to iNova or, if following the provision of the evidence, iNova pursued its appeal and the Panel determined that the Claims made by Care were unsafe and further if the Panel's decision was appealed, the Arbiter determined that the Claims made by Care were unsafe[2]
10. In response, by letter dated 15 December 2021, Care provided to iNova, with a copy to CHPA, "… the attached list of references on which Care relies to support the claims we make about Care Little Coughs…".
11. Care did not provide the third-party study on which it relied to formulate its view that it was safe to make its claim concerning the Products. The list containing 47 references which it provided, contained citations only and full copies of the references were not provided.[3]

Further Appeal

12. In a letter dated 17 December 2021, iNova notified CHPA that it wished to pursue its section 4.1 complaint and made submissions. On 20 January 2022, Care provided further submissions to the Panel.

[1] Arbiters Determination para 23.
[2] Arbiters Determination para 69.
[3] iNova's letter dated 17 December 2021 (p1)

The Panel's Reasoning

13. In its reasoning, the Panel said that the issues to be determined by it were whether the references provided by Care to iNova pursuant to the direction of the Arbiter in relation to the section 5.1.4 complaint, support the efficacy and safety of the Products in the 6 months – 2 years age range at the dosages specified by Care, using the relevant ingredient, quantity and extract ratios and, if not, whether Care is in breach of section 4.1 of the Code. That section 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".*

14. The front labels of the Products include the statements "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…".

15. The "Directions for Use" are also in fine print. They prescribe 2.5 mL for children of the age 6 months – under 2 years to be taken once a day.
16. The Panel accepted Care's contention that the use of the words "*consult your healthcare professional: before using in children under two years of age"* (**the Healthcare warning**) was important because they qualified the suitability of use for children under two years and made it clear that the parent or consumer should consult a healthcare professional first before using it. However, it pointed out that the issue to be determined by it was whether the evidence on which Care relies supports the efficacy and safety of the Products in children under 2 years. This became a central focus of Care's appeal because it asserted that the Panel misdirected itself in asking this question.[4]
17. The Panel then went on to examine the evidence provided by Care. It referred initially to the European Medicines Agency Monograph ("the Monograph") which was the first reference in Care's list. It accepted Care's contention that the Monograph was not binding in Australia but said that it was nevertheless a useful document when considering claims that can be made. It noted that the Monograph determined the use of Hedera helix in children under 2 years of age was contraindicated due to the risk of respiratory congestion and rising bronchiolitis in infants as a result of the

[4] Determination para 11.

functional features of their passages and thoracic cavity (small calibre bronchi on immature bronchial surfaces that limit the lungs capacity to remove mucus flow).[5]

18. The Panel further noted that the EMA Assessment report on Hedera helix which was included in the Care's list of references (reference 13) cited 17 of the references included in Care's list. That report stated that "**The use in children under 2 years is contraindicated due to possible aggravation of respiratory symptoms."[6]**

19. The Panel noted Care's contention that because the contraindication for children under 2 years of age in the Monograph was not specific for Hedera helix and was instead a more general contraindication for the use of mucolytics in this population, it was not relevant for Care's product range because of the availability of supporting studies indicating the safety and efficacy of Hedera helix in this population.[7]
20. The Panel, however, went on to find that the references on which Care relies do not support the safety and use of the Products in children between 6 months and 2 years. It pointed out that many of the references provided by Care were unsuitable for use as evidence to support its claim because they were in a different language and neither iNova nor the Panel were provided with translations; many related to a serious disease condition ailment or defect; many did not relate to the relevant age group. Further, Care had not provided justification for differences between study and target population and many of the papers used a dosage of active ingredient which was higher than that used in Care's products.[8]
21. The Panel noted that it had reviewed a selection of papers which were included in Care's references and found 4 which did not justify the claims made by Care. This demonstrated that the body of evidence which Care had provided in relation to the use of the substance contained evidence that was contrary to Care's claims. Care had not provided any justification for how the papers which were contrary to its claims fit into the context of the broader scientific literature particularly having regard to the fact that the references had been provided by Care to support its claims.[9]
22. The Panel accordingly found that the references provided by Care and on which it relied to support its claim did not in fact support the efficacy and safety of the Products 6 months – 2 years age range at the dosages specified by Care, using the relevant ingredient, quantity and extract ratios.[10]
23. The Panel then concluded that in promoting the Products for use in children in that age group, Care had engaged in unconscionable commercial practice, in breach of section 4.1 of the Code.
24. It noted that Care's breach of section 5.1.4 was determined by the Arbiter to be a Severe Breach having safety implications and directed that if the claims remained unsubstantiated, as the Panel had now found, a fine of $25,000 should be imposed.[11]

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[5] Determination para 12.
[6] Determination para 13.
[7] Determination para 15.
[8] Determination para 17
[9] Determination para 18.
[10] Determination para 19.
[11] Determination para 22.

25. The Panel then imposed a further fine of $25,000 for Care's breach of section 4.1 in addition to the fine imposed by the Arbiter.[12]

Care Submissions on Appeal

26. Care's submissions commence by referring to its letter of the 15 October 2021 addressed to the Panel in which it explained that there is no single article upon which Care relies to support its claim that the Products can be safely provided to the 6 month to 2 year patient population.[13] It goes on to say that it had paid for a third party to collate and analyse "various information" to reach a view. Such information is proprietary in nature and confidential to Care. I note in this regard, that Care does not advise whether the third-party view was based upon the list of references provided by it pursuant to the Aribiter's direction.
27. It asserts that in response to the Arbiters direction, it provided by letter dated 15 December 2021, the evidence held by to support the claim for the safety of the use of the Products in children in the 6 months to 2 years age range at the dosages specified by Care. That was a list of 47 scientific articles[14](**the Evidence**).
28. Care says that it is not its case that every single one of the articles supports its claim for the Products, rather that those are the articles which "are relevant" to this issue and which it relies upon **as a whole in support of the use of its products in the relevant age group** (emphasis supplied).[15]
29. Care says that because the Panel and the Arbiter had already dealt with the substantiation of claims under section 5.1.4 of the Code, it was not correct for the Panel to conflate section 5.1.4 and section 4.1 of the Code by asking whether the Evidence constituted a sufficient substantiation of Care's claims and if not whether Care was in breach of section 4.1 of the Code.[16]
30. It said that the only question for determination was whether iNova had shown that Care had breached section 4.1 of the Code in relation to the Products. It asserted that the Panel had incorrectly focused on whether Care had provided some kind of justification for its reliance upon the Evidence.[17]
31. Care further submitted that in determining whether section 4.1 had been breached, the Panel erred in asking whether the Evidence supported the use of the Products in the 6 months to 2 years age group. The Panel also erred in finding that Care had breached section 4.1 of the Code because there were some articles which did not support such use .[18]

[12] Determination para 24.
[13] Care submissions para 3.
[14] Care submissions para 6.
[15] Care submissions para 15.
[16] Care submission para 18 and 19.
[17] Care submission para 21 and 22.
[18] Care submission para 23.

32. Care says that it was not correct for the Panel to select 4 out of a total of 47 articles which did not support its claims because it should have asked whether there was a measure of support for Care's representations as to the use of the Products.[19]
33. It then submitted that the Panel was not obliged to undertake a detailed review of every single one of those articles. It suggests that the Panel ought to have asked simply whether the totality of the articles provided by Care showed a sufficient basis for Care's representations.[20]
34. Care also submited that in answering the question whether there was a measure of support for its Claim, the Panel should have taken into account the context in which the representation was made namely, that the packaging contained the warning "Consult your healthcare professional: before using in children under 2 years of age".[21]
35. Care says that the substance of the allegation that it breached section 4.1 of the Code is that the representation made by it concerning the suitability of the Products for use in children aged 6 months to 2 years, lacks a sufficient basis. It says that although section 4.1 of the Code does not speak expressly in terms of misleading or deceptive conduct, it is appropriate to consider the complaint by asking whether the representation is misleading or deceptive to consumers of the Products. It then goes on to suggest that the general approach taken by the courts in relation to whether a representation is misleading or deceptive should be applied.[22]
36. Care also says that the representations must be understood in their context. The effect of the Healthcare warning is that the representation that the Products can be used safely for children in the age group 6 months to 2 years is neither unqualified nor unconditional. It would therefore be wrong to ask whether the evidence supports a claim that Care's products are suitable for children in that age category.
37. The correct question is whether iNova has established that there is no reasonable basis for the representation made by Care. It says that because the representation is qualified, it is not necessary to show that the medical evidence in existence is unanimous or overwhelming in supporting its claim. The question is whether there is a sufficiently sound basis for Care's conduct, which it says is readily established by reference to the Evidence.[23] (I note however, that it does not seek to identify which of the studies in the 47 references it has produced, in fact support its claim.)
38. Care says that having accepted the importance of the Healthcare warning, the Panel misdirected itself by asking whether the evidence upon which Care relied, supported the efficacy and safety of the Products in children under two years.
39. The Panel should rather have asked whether there was a reasonable basis for the qualified representation that was in fact made or, asking whether there was evidence which did support it despite a lack of unanimity. It asserts that the Panel misdirected itself in considering whether there was evidence which did not support the use of the products in children in the age group. It was wrong to assume or decide that the

[19] Care submissions para 26.
[20] Care submissions para 29.
[21] Care submissions para 32 to 34.
[22] Care submissions para35 to 41.
[23] Care submissions para 46 t0 52.

existence of differing opinions in the evidence undermined Care's case and to assume that Care bore some kind of onus to explain away those differing opinions.[24]

40. Care submitted that in advancing the section 4.1 complaint, the onus was on iNova to establish that there was something wrong in the limited and qualified representation made by Care. It asserted that iNova had failed to advance any evidence in support of that case.
41. It then submitted that it was sufficient for Care to demonstrate that there was a reasonable basis for the qualified representation it had made because it was supported by evidence, albeit that that evidence was not unanimous. It suggested that the very fact that the products required consultation with a healthcare professional was consistent with there being a difference in medical opinion in respect of that age group.
42. Finally, it asserted that there was nothing misleading or deceptive or anything unfair or unconscionable in Care relying upon evidence (albeit evidence that is not unanimous) which supports the administration of the products to children between 6monts and 2 years, provided that Care makes it clear that the products should only be administered to children in that age group after prior consultation with a healthcare professional.
43. It says that iNova accepts there is evidence which supports the use of Care's product and says that iNova's complaint appears to be that the evidence in support of such use is insufficient or has not been "justified".
44. To put the issue in that way is to invite error. Care need only show a reasonable basis for the qualified representation made and the fact that iNova has accepted there is evidence supporting the use of the product, ought to be determinative of the complaint.[25]

iNova submissions on Appeal

45. iNova supports the Panel's findings. It submits that Care has not identified any evidence that supports the efficacy and safety of the Products when supplied to children in the age group and using the quantity and extract ratios specified.[26]
46. It points out that the Healthcare warning appears in fine print on the back label. It submits that it is reasonable to assume that the vast majority of consumers acting in reliance on the dominant representations would not read all the safety warnings on the back of the pack and even if they did, take the intervening step of consulting a healthcare professional prior to purchase (or after purchase).[27]
47. INova submits that the correct question must be whether Care has provided evidence to support the efficacy and safety of the Products for the age range because

[24] Care submissions para53 to 58.
[25] Care submissions para 59 to 66.
[26] iNova submissions para 1
[27] iNova submissions para 6.

consumers will draw that conclusion when they read the pack, that it contains a clear representation to that effect.[28]

48. iNova stresses that whilst it has acknowledged that some evidence exists for the ingredient Hedera helix, it continues to assert that this evidence does not align with Care's formulations with regard to the herbal ingredient, quantity and extract ratios. It points out that Care has not provided any justification for these differences.
49. It submits that Care has not provided any basis for the efficacy and/or safety of the Products and at that the dosages specified by Care.[29]
50. iNova strongly supports the conclusion that there are safety implications for children in the 6 months to 2 years age group. This is based on the EMA assessment report which concluded that the use of Hedera helix in children under two years is contraindicated due to possible aggravation of respiratory systems.[30]

Analysis

51. The genesis of this appeal lies in the complaint made by iNova that Care had failed to provide substantiation for its claim that the Products can be used safely for children in the in the 6 months to 2 years age category at the doses specified by Care, using the relevant ingredient, quantity, and extract ratios.[31]
52. In defending the complaint, Care had in essence, contended that it was not obliged to provide the references upon which it relied to support its claim. That argument was rejected by the Panel in its original Determination of 19 October 2021 and also rejected by the Arbiter in his Determination of 7 December 2021.
53. In considering the effect of sections 5.1.3 and sections 5.1.4 of the Code, the Arbiter's Determination concluded that:

> "*Section 5.1.4 requires that information and claims about non-consumer healthcare products must be substantiated, clearly with the express purpose of ensuring they are not misleading or otherwise in breach of section 5.1.3. It also provides that the substantiation be provided to the requesting member, so that the information and claims can be examined by that member to see whether they comply with section 5.1.3. This requirement is consonant with the objectives set out in section 3 of the Code, namely, to assist Members to ensure that claims made for products are "accurate, balanced and based on sound and objective scientific considerations*."[32]

54. Further, as was pointed out at paragraph 51 of the Arbiter's Determination, "*It is not sufficient that the member making the claim believes that the evidence it has is*

[28] iNova submissions para 3
[29] iNova submissions para 4.
[30] iNova submissions para 5.
[31] iNova letter dated 13 August 2021.
[32] Arbiter's Determination para 45.

sufficient to substantiate it. This has to be demonstrated to the satisfaction of the member requesting the substantiation."

55. It was in this context that the Arbiter confirmed the Panel's Direction.
56. In considering the scenarios which might arise as a result of the Direction, the Arbiter pointed out that Care might provide evidence which satisfied iNova's concerns and it might withdraw its complaint. If the evidence provided by Care did not satisfy iNova that the Claims are safe, this issue would then be determined by the Panel or finally upon appeal.[33]
57. In its submissions, Care accepted that it had been directed to provide "**the evidence** held by it to support the safety of the Products when supplied to children in the 6 months to 2 years age range at the dosages specified by Care, using the relevant ingredient, quantity and extract ratios."[34] It confirmed that the evidence upon which it relies to support the safety of the Claim made for the Products is the list of 47 scientific articles (paragraph 6).
58. It does not rely on any single article, but it says rather that it has put together the articles which it has obtained which are relevant and which it relies upon as a whole in support of the use of its products in the relevant age group (paragraph 15).
59. Having regard to the fact that both the Panel's Direction and later the Arbiters direction, were specifically made to provide Care the opportunity to supply the evidence upon which it relied to substantiate its Claim, the Panel was in my view correct in stating that the first issue to be determined by it was whether the references provided by Care did in fact substantiate the Claim.
60. Consistently with the analysis of section 5.1.3 and 5.1.4 set out in the Arbiter's Determination, the direction required Care to provide the Evidence to enable iNova to satisfy itself that the Evidence substantiated the Claim. If it was not satisfied, then the Panel and thereafter if appealed, the Arbiter, was to determine whether the Claim was substantiated by the Evidence. This would have been clear to Care upon reading the Arbiter's Determination.
61. It follows that Care's submission that, once the Panel and thereafter the Arbiter had determined that it was obliged to provide substantiation of its claims under section 5.1.4 of the Code, it was no longer necessary for the Panel to consider whether Care had in fact complied with the direction is incorrect. It overlooks the very reason for the direction.
62. If the Panel then found that Care had not substantiated its Claim, the Panel was then required to determine whether Care's conduct in making the Claim constituted a breach of section 4.1 of the Code. Accordingly, the question of whether the Evidence supplied by Care in fact substantiated its Claim was directly connected to and consequent upon the enquiry as to whether Care had breached section 4.1.
63. In my view therefore, the submissions made by Care to the effect that the Panel posed itself the incorrect questions which it outlined in paragraphs 18 to 22 of its submissions are misconceived.

[33] Arbiter's Determination para 63.
[34] Care submission para 4.

Compliance with section 5.1.4 of the Code

64. In complying with the direction to produce the Evidence upon which it relied to substantiate its Claim, it was open to Care to provide the third-party analysis which it said it had commissioned. It declined to do so.
65. Instead, Care chose merely to supply the list of references without identifying which of them it relied upon. It does not challenge the Panel's finding that many of the references provided by Care are unsuitable for use as evidence to support a claim for a listed medicine. Care also accepts that 4 of the articles do not in fact support Care's Claim (paragraph 26 of Care's submissions).
66. Rather than taking the opportunity to identify those studies which do support its Claim, Care criticises the Panel for not asking whether there was a measure of support for Care's Claims amongst the Evidence. It goes on to say that it would not have been appropriate for the Panel to review the collection of 47 scientific papers because it is not scientifically or medically trained to review a collection of 47 scientific papers and make an assessment in respect to whether they collectively substantiate Care's Claims.[35]
67. It says the Panel should simply have asked whether the totality of articles showed a sufficient basis for Care's representations (Para 28 of Care's submissions). It does not say how the Panel was meant to do this without reviewing the 47 papers.
68. Other than providing a list which contained references that it admits did not support its Claims and which contained other references which were unsuitable, Care has done nothing to establish that its Claims are substantiated.
69. It's conduct in supplying its so-called "evidence" without identifying which of the references it asserts supports its Claims and in a context in which it says that the Panel is incapable of making an analysis of that evidence, is in my view open to the inference that Care has deliberately chosen to breach section 5.1.3 and 5.1.4 of the Code by making unsubstantiated Claims.
70. In effect it is saying that iNova, the Panel and the Arbiter should just accept its assertion that the list it has provided substantiates its Claims without examining the references in that list. This ignores the Panels' first determination and the Arbiters determination as to the effect of sections 5.1.3 and 5.1.4 of the Code.
71. It was clear from both the Panel's Direction and the Arbiters Determination that Care had to demonstrate that the evidence on which it relied supported its Claims. In those circumstances, its submission that the onus was upon iNova to establish that the representations made by Care were misleading or deceptive in the context of the Healthcare warning, is not correct. Those submissions ignore the purpose of section 5.1.3 and 5.1.4 of the code.
72. Further, if Care failed to substantiate its Claim, the Healthcare warning had no relevance because the Claims would be in breach of section 5.1.3 and 5.1.4 and could not be justified by a qualification of that nature.

[35] Care submissions (para 28).

73. For the above reasons, I agree with the Panel's conclusion that the Evidence supplied by Care did not support the efficacy and safety of the claims made by it for the Products.

Section 4.1 of the Code

74. The Panel then went on to conclude that in promoting the Products for use in children in that age group, Care had engaged in unconscionable commercial practice in breach of section 4.1 of the Code.
75. Care criticised the Panel for conflating a breach of section 5.1.4 of the Code with a breach of section 4.1 of the Code (paragraph 19 of Care's submissions). For the reasons set out above, I believe the Panel was correct in its approach.
76. The Claims represent that it is safe to use the Products on children in the age group 6 months to 2 years at the dosages specified, using the relevant ingredients, quantity, and extract ratios.
77. The evidence before the Panel and the Arbiter, includes the Monograph published by the European Medicines Agency which determined that the use of Hedera helix in children under two years of age to be contraindicated due to the risk of respiratory congestion and rising bronchiolitis in infants. Further, the EMA Assessment Report, which was one of the studies relied upon by Care, says that the use of Hedera helix in children under two years is contraindicated due to possible aggravation of respiratory symptoms.
78. In those circumstances, Care has deliberately represented to consumers that the Products are safe for use on children in the 6 months to 2 years age group when in fact they are not safe. I agree with the Panel that Care's conduct in making the representation, which is on the available evidence, false and unsubstantiated, is unconscionable within the meaning of section 4.1 of the Code.
79. I note also that section 5.1 of the Constitution provides that the Code is binding on all Members as a condition of membership. Section 2.8 of the Code also records that acceptance and observance of its provisions are binding and a condition of membership.
80. Section 4.1 of the Code provides that members shall not engage in any unfair conduct. The definition of "Unfair" includes conduct "not… according to the Constitution."
81. In my view, the deliberate failure of Care to provide substantiation for the Claims as required by sections 5.1.3 and section 5.1.4 of the Code, is not according to the Constitution and is therefore and in that respect also, a breach of section 4.1 the Code.
82. Having regard to the safety issues, I agree with the Panel's finding that Care's breach of section 4.1 is a Severe Breach within the meaning of section 10.1.1 of the Code.

Directions

83. I note the matters taken into consideration by the Panel in paragraph 23 of its Determination and confirm that within 10 days of this decision:

a. Pursuant to section 10.2.1 of the Code, Care is to give an undertaking in writing to CHPA:
    i. immediately to discontinue making the claims that it's Little Coughs products can be used by children between the age of 6 months to 2 years either in the dosages recommended or at all, or that it is safe to do so; and
    ii. immediately to cease distribution of little Coughs products bearing labels representing that they can be used by children between the age of 6 months to 2 years either in the dosages recommended or at all, or that it is safe to do so; and
b. Care is to pay a total fine of $50,000 to CHPA.

84. I confirm the Panel's decision to make no determination to alter the usual operation of section 9.4.2.2 of the Code in relation to the section 4.1 complaint.
85. I make no order to alter the usual operation of section 9.4.2.2 of the Code in relation to this Appeal.

Dated 9 May 2022

Arbiter: Harold Werksman.