CHPA ARBITER'S Determination 01/21

Hearing on 25 November 2021

Care Pharmaceuticals Pty Ltd ("Care") – Appellant

vs

iNova Pharmaceuticals Pty Ltd ("iNova") - Respondent

Little Coughs Ivy Leaf (Hedera helix) range

1 This is an appeal from a determination made by the CHPA Complaints Panel dated 19 October 2021 pursuant to section 11 of the ASMI/CHPA Code of Practice (**Code**).

2 The Complaint was initiated by iNova by letter dated 13 August 2021 and Care responded by letter dated 27 August 2021. iNova complained that Care had 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 for use in children under two years of age (**the Products**).

3 The front labels on the Little Coughs Products prominently state "6 months +" and the rear labels contain "Warnings" including "Consult your healthcare professional before using in children under 2 years of age" . They also contain "Directions for Use" which indicate that the Products can be used in the age group 6 months to two years in a dosage of 2.5 ml, once a day.

4 iNova, in its Complaint, asserted that it had performed its own literature searches and had come to the conclusion that there was insufficient supporting evidence to justify the administration of the Products to children in the six-month to 2 year age group. It pointed out that evidence from a reputable source, being an EMA Monograph for Hedera helix, specifically contraindicates use in this population due to the risk of aggravation of respiratory symptoms.[1] It acknowledged that the Monograph was not a binding document in Australia but asserted that it presented a strong and reputable source of supporting reference material.

5 iNova contended that this was a breach of section 4.1 of the Code and was a Severe Breach as it related to safety in the population using the product. iNova also complained that Care's refusal to provide substantiation for its claims was a breach of section 5.1.4 of the Code which it contended was a Minor Breach.

6 Care, in its response to the Complaint, said that it had performed its own literature review which established that the Products could safely be provided to the six-month – two-year patient population. It asserted that its review was paid for and analysed by Care and that that information was proprietary in nature and confidential to Care[2]. It alleged that iNova was using the complaints process in the Code as a competitive tool in breach of section 9.4.2.1 of the Code and declined to provide the review to iNova.

7 The Panel decided to defer its consideration of whether Care's promotion of the Products for use in children aged six months to 2 years is justified and if not, whether such promotion breaches section 4.1. It did so, because it ultimately directed Care to provide to iNova the evidence upon which it relied to support the safety of the Products when supplied to children in the age category, six months to 2 years at the dosages specified using the relevant ingredient, quantity and extract ratios[3].

[1] Page 1 of the Complaint.
[2] Para 2.5 and 2.8 of Care's response.
[3] Para 5 and 16 of the Determination.

The Panel's Determination on Section 5.1.4 of the Code.

8 Section 5 of the Code applies to members whose non-prescription consumer healthcare products are promoted to consumers and healthcare professionals.

9 Section 5.1.3 of the Code says that "Information and medical claims about non-prescription consumer healthcare products must be current, accurate, balanced, and must not mislead either directly, by implication, or by omission."

10 Section 5.1.4 of the Code goes on to say "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."

11 The Panel noted Care's contention that iNova's Duro-Tuss Children's Cough products, which competed with Care's Products stated that they should not be used in children under two years.[4] It also noted Care's contention that iNova's complaint was a ruse to obtain Care's proprietary and confidential information in breach of section 9.4.2.1 of the Code which provides that industry generated complaints should not be used simply as a competitive tool.

12 The Panel concluded that iNova's request for the evidence held by Care to support the safety of its Products when supplied to children in the six months to 2 years age range at the dosages specified, was not unreasonable because it came to the view that section 5.1.4 of the Code required members to provide evidence to substantiate claims even when requested by competitors[5].

13 The Panel went on to note that Care had stated that there was no single article upon which Care relied for its claims and that Care had paid for the expertise of a third party to collate and analyse various information to reach a view. It was that information which was proprietary and confidential to Care.[6]

14 The Panel considered that section 5.1.4 of the Code required members who choose to make claims based upon confidential or proprietary information to provide it without delay upon request. It therefore declined to find that iNova's request was a breach of section 9.4.2.1 of the Code.[7]

15 The Panel then concluded that Care was in breach of section 5.1.4 of the Code by failing to comply with iNova's request and classified that as a Minor Breach having no safety implications.[8]

16 After directing iNova to provide the evidence upon which it relied to support the safety of the Products, within five days of the Panels Final decision, the Panel requested iNova within a further period of five days to inform the Chief Executive Officer of CHPA and Care whether it wished to proceed with its complaint under section 4.1 and if so to provide a copy of the evidence received from Care and any further submission iNova wished to make in relation to its section 4.1 complaint. It then allowed Care, a further five days to provide a response to iNova's further submission.[9] It deferred any further consideration of the substance of the section 4.1 Complaint to a date to be fixed.[10]

The Appeal.

17 Care now appeals the determination of the Panel and specifically challenges the Panel's findings that section 5.1.4 of the Code requires Members to provide evidence to substantiate claims even when requested by competitors and that members who choose to make claims based upon confidential, proprietary information are required to provide that information without delay upon request.[11]

[4] Para 10 of the Determination.
[5] Para 12 of the Determination.
[6] Para 13 of the Determination.
[7] Para 14 of the Determination.
[8] Para 15 of the Determination.
[9] Para 17 and 18 of the Determination.
[10] Para 20 of the Determination.
[11] Paras 12 and 14 of the Determination.

18 Care submits that section 5.1.4 is to be construed in the light of the Code generally and its objectives including provisions such as 9.4.2.1. It says that section 5.1.4 is not a vehicle by which a competitor may demand delivery up of scientific evidence or other such material held by the recipient of a request concerning a claim which contains or comprises the commercially sensitive or confidential proprietary information of a recipient.[12]

19 iNova generally supports the Panel's determination and persists in its request for the evidence relied upon by Care.

Context.

20 iNova's complaint raised squarely its concern that its researches had shown there was insufficient evidence to justify the administration of the Products to children in the six months to 2 years age group. To the contrary, the EMA Monograph it had found, specifically contraindicated use in this population. It acknowledged that this monograph was non-binding in Australia but asserted that it was nevertheless a strong and reputable source of supporting reference material[13].

21 It was clear from iNovas complaint that it had a safety concern regarding the use of the Products in the age group 6 months to 2 years. During the course of argument at the hearing of the appeal, iNova again stated its concern regarding the safety of the claim.

22 In the course of oral argument on behalf of Care, Senior Counsel, Mr Andrew Fox SC, accepted that the "claim" which is the subject matter of the Complaint, is that the Products can be used by children between six months and two years in the dosage recommended by Care, subject to obtaining advice from a healthcare professional.

23 He also accepted, in my view and with respect, correctly, that the claim contained the implied representation that it was safe to use the Products, in the dosage recommended for children between the age of six months and two years. (I refer to both claims, including the implied claim as "**the Claims**").

24 It is in this context then that it is necessary for me to determine whether Care is in breach of the Code, by refusing to provide the source material upon which it relies, to substantiate the Claims.

Contentions regarding Section 5.1.4

25 In making its case that it is not obliged to provide the proprietary information, Care relies upon a narrow interpretation of clause 5.1.4 of the Code.

26 Care submitted that the term "substantiation", where it is used in section 5.1.4 means that a member who receives a request must provide sufficient information to inform the requestor of the grounds relied upon by the recipient to support the claim made. It does not require the recipient of a request to deliver up to a competitor, scientific evidence or such other material of a proprietary nature held by the recipient to justify, scientifically, a claim made.[14] All that was required was that Care was able to substantiate the claim made at the time when its Product was labelled.[15]

27 Care also submitted that the second sentence of section 5.1.4 which reads "A member unable or unwilling to provide a reference in substantiation of a claim, should refrain from citing it." means that the recipient of a request is entitled to refrain from citing the scientific work or a report in the possession of the recipient in a "fulsome manner".[16]

28 Care says that the third sentence of section 5.4.1 contemplates that an abstract or summary of unpublished data may be referred to in a recipient's response and that it should be identified as

[12] Para 25 of Care's submissions.
[13] Para 1 on page 3 (Appendix 1)
[14] Para 27 of Care's submissions

[15] Para 20 of Care's submissions.
[16] Para 23 of Care's submissions.

such when responding. It does not however, require a recipient to deliver up any such material in response to a request. [17]

29 It contended that, having informed iNova that the claim was based upon a confidential and proprietary analysis conducted by third party, the Panel ought to have found that the information provided by Care was sufficient to discharge its obligations under section 5.1.4 when responding to a request from a competitor.[18]

30 Care says that it is inconsistent with the Code that it be construed in a manner which results in a party's membership of and participation in ASMI/CHPA constituting an implicit waiver of a member's rights to highly commercially sensitive and confidential proprietary information. During oral submissions, Senior Counsel said that if it was requested by the TGA to provide the information, Care would do so. It was not the function of the Code to replace the TGA.

31 iNova supported the findings of the Panel and pointed out that there was a long established practice of CHPA members being compelled to provide substantiating evidence in relation to product claims. Senior Counsel for Care, during oral argument, distinguished the previous determinations relied upon by iNova on the basis that they were claims in relation to advertising and were different in nature, from the Claims here under consideration.

Analysis

32 Care's submissions attempt to isolate section 5.1.4 from 5.1.3**.** It submits that it is not without significance that iNovas Complaint does not contend that Care has breached section 5.1.3 by the Claims[19]. For the reasons set out below, I believe sections 5.1.3 and 5.1.4 are to be read together.

33 Although Care submits that section 5.1.4 is to be construed in the light of the Code generally and its objectives (including section 3.2.3) its construction is highly technical and in my view, does not properly take into account the objectives of the Code and the context in which section 5.1.4 is contained in the Code.

34 In essence, Care's submissions are an attempt to justify the proposition that if a member making a claim believes it has material which substantiates that claim but which it does not wish to disclose because that material is proprietary and confidential to the claiming member, then the judgement as to whether the material in fact substantiates the claim is to be left to that member. The effect of this interpretation is that it is left to the member making the claim to determine whether the claim is accurate, balanced and based on sound and objective scientific considerations and is not misleading. For the reasons below, I believe that proposition is incorrect.

35 The fact that as was submitted by senior counsel for Care, the member may be willing to provide the substantiating material to the TGA if requested to do so is, in my view, irrelevant. The question to be determined is whether the Code requires the claimant to deliver the substantiating material to the requesting member even if that material is commercially valuable to the claimant.

Objectives of the Code

36 Section 2.8 of the Code makes acceptance and observance of its provisions binding and a condition of membership of CHPA.

37 Section 2.9 of the Code provides that the members acknowledge that the Code is to be applied in spirit, as well as in the letter, so that high ethical standards are followed throughout the industry. The Code is therefore to be interpreted broadly so that its objectives can be achieved.

38 The objectives of the Code are set out in section 3 which states that the Code is intended to establish the basic parameters which guide members in the conduct of their businesses and particularly in matters of advertising and promotion of non-prescription consumer healthcare products. [20]

[17] Para 23 of Care's submissions.
[18] Para 31 of Care's submissions.
[19] Para 17 of Care's submissions.
[20] Section 3.1 of the Code.

39 Section 3.2 of the Code states that in relation to non-prescription consumer healthcare products, the Code seeks to assist Members to ensure that all claims made for the products are accurate, balanced and based on sound and objective scientific considerations. A Member includes any Ordinary or Associate member as defined by the Constitution.

40 The Code is therefore predicated upon the Members as a general body, being assisted by the Code to ensure that claims made by a particular member for its products, are accurate, balanced and based on sound and objective scientific considerations. This is consistent with the proposition that it is not to be left solely to the judgement of a particular member making a claim to determine whether that claim is properly substantiated.

41 Section 4 then sets out the principles of practice which bind all members. This includes the requirement that members not engage in any unfair or unconscionable conduct. Unfair conduct is defined to mean conduct which is not equitable or honest or impartial or according to the Constitution.

Section 5

42 One then comes to section 5 of the Code, which applies to members whose non-prescription consumer healthcare products are promoted to consumers. Relevantly, section 5.1.3 then provides that "Information and medical claims about non-prescription consumer healthcare products must be current, accurate, balanced, and must not mislead either directly, **by implication**, or by omission." (emphasis supplied). The implied claim made by Care for the safety of the Products in the age group specified, is therefore clearly covered by this section.

43 The Explanatory Notes to section 5.1.3 [21] provide the guidance that information that may be considered false or misleading, includes claims that are "more favourable than has been demonstrated by the body of clinical evidence or experience" or information from a study that is clearly inadequate in design, scope or conduct to furnish support for such information.

44 The Code therefore expressly recognizes that there may well be circumstances in which claims made by members are sought to be supported by evidence which does not justify those claims. Clearly, a member seeking to determine whether information is false or misleading within the meaning of the Explanatory Notes, would need to have access to the material relied upon by the claimant to support the claim. The Code accordingly provides a mechanism which assists other members to obtain that material.

45 This is achieved by the addition of clause 5.1.4 which opens with the word "Furthermore…" indicating that Clauses 5.1.3 and 5.1.4 are to be read together and to complement each other. Section 5.1.4 requires that information and claims about non consumer health care 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." [22]

46 Although clause 5.1.3 refers to "medical claims" and 5.1.4 refers to "claims", the effect appears to broaden the operation of clause 5.1.4 to claims which are not only of a medical nature. Care did not suggest that section 5.1.4 did not apply to its Claims. In any event, both sections refer to "information". The Claims made by Care would in my view, clearly fall within the definition of "information" because they inform readers of the label contained on the Products, that they can be used safely at a certain dosage level on children between six months and two years.

47 A point was made by Care that there is a temporal difference between substantiating the claim at the time when the product was first labelled with the claim and later when the request for substantiation is made (para 20 of Cares submissions). This was used in support of a submission that the second sentence of 5.1.4 relieves the claimant from the obligation to supply the substantiation. In my view this argument is misconceived.

[21] At page 17 of the Code.
[22] Section 3.2.3 of the Code

48 Section 5.1.4 contemplates that the claimant must be able to demonstrate to the satisfaction of the member requesting substantiation of a claim, that the claim is based on "sound and objective scientific considerations" as required by section 3.2.3 and is therefore not misleading or otherwise in breach of section 5.1.3. Accordingly, although the term "substantiation" in the first sentence of section 5.1.4 is not defined, it clearly includes the citation of scientific material which will support a claim.

49 Substantiation can therefore be achieved by providing references to published scientific material which can be accessed by a member, so that the requesting member can be assisted to determine that the claim is accurate, balanced, based on sound and objective scientific considerations and is not misleading. In relation to material which is not publicly available, the material which is claimed to be the substantiation is to be supplied upon request, again so that the requesting member can be assisted to assess whether the claims are based on sound and objective scientific considerations and is not misleading.

50 The term "reference" where used in the second sentence of section 5.1.4, is in my view, broad enough to cover any material upon which a member seeks to rely to substantiate its claim. That would include the literature review carried out by the third-party contracted by Care as well as the supporting material upon that review relies. It was open to Care to provide the latter material i.e. the source material upon which the "literature review" was based. This was conceded by Senior Counsel in oral submission. He confirmed that Care declined to provide the source material as well.

51 The effect of the second sentence is that if a member making a claim is unwilling to supply the material it relies on to substantiate its claim, it cannot rely on that material to do so. It must find other references to substantiate its claim. If it does not do so its claim is unsubstantiated and in breach of section 5.1.4. It is not sufficient that the member making the claim believes that the evidence it has is sufficient to substantiate it. This has to be demonstrated to the satisfaction of the member requesting the substantiation.

52 The fact that the third sentence of 5.1.4 says that where an abstract or summary of unpublished data is cited to support a claim, it should be identified as such, does not relieve a member from providing the substantiation required in the first sentence. Its purpose is to ensure that the claimant must notify the reader that the material upon which the claimant relies to substantiate its claim is either an abstract or a summary of data which is not publicly available. There is nothing to suggest, in that sentence, that the member making the claim is to be relieved from providing the substantiating material. This would be contrary to the spirit and intent both of section 3.2 and section 5.1.3 of the Code.

Section 9 of the Code

53 In providing the mechanism by which a member requesting substantiation of the claim can be provided with the evidence relied upon by the claimant, section 5.1.4 is also consistent with the complaint mechanism which is set out in section 9 of the Code. This allows a member dissatisfied with the evidence supplied by the claimant to engage in a process which ultimately places the obligation to determine whether the claim made is misleading or deceptive, upon the Panel. The Code does not leave it simply to the claimant to determine that its claims are properly supported by evidence which it can withhold without disclosure.

54 Care further submitted that section 9.4.2.1 which states that industry generated complaints should not be used simply as a competitive tool. In oral submission, Senior Counsel said that this section was a provision which might assist in construing clause 5.1.4. He said that he did not suggest that there was evidence to show that iNova was in fact using this complaint as a competitive tool.

55 I would agree with the Panel that having regard to the fact that iNova has conducted its own literature review which does not support the Claims and that having regard to the above analysis, iNova is entitled to the information it sought, there is no substance for a finding that it is using this complaint as a competitive tool.

56 In summary therefore, I am of the view that Care was obliged to provide to iNova, the evidence upon which it relies to substantiate its Claim.

Classification of Breach

57 The Panel found that Care's failure to provide the information requested was a Minor Breach having no safety implications. Care, in its submissions emphasised that there was no finding that the claims made by Care gave rise to any safety implications.[23] The Panel did not provide any reasons for its finding on this issue. It appears to be based on the decision of the Panel not to make any determination in respect of the first complaint made by iNova which specifically raised safety issues, until Care had been given an opportunity to comply with the Panels direction to provide evidence to support the Claims.

58 In my view, the Panel was incorrect in coming to this finding. The Panel was obliged, before making its determination on this aspect, to take into account all the evidence which was available to it.[24] It is not clear whether the Panel contemplated that if ultimately it was required to make a determination in respect of the section 4.1 complaint, it would then revisit its classification of the section 5.4.1 breach. In my view, once it made its determination in relation to the section 5.1.4 complaint, the Panel has discharged its function in that regard and would not be able to revisit its decision on this issue.

59 The Claims with which the Panel was concerned, included the implied claim that it is safe to use the Products in the recommended dosages for the age group specified. In considering whether the failure to provide the evidence to support the Claims had any safety implications, the Panel in my view, should have taken into account that in the absence of any such evidence from Care, the implied claim has not been substantiated.

60 To the contrary, the Panel had evidence that iNova had conducted its own searches which had established no support for the Claims and that Inova had also, in the form of the EMA Monograph, found evidence which specifically contraindicated use in the six-month to 2 year population. The Panel was further aware that Inova, whose products compete with Care's, states that its medicine is not to be used in children under two years[25]. That recommendation is consistent with the view that the products are not safe for use in children in the 6 six-month to 2 year age group.

61 Accordingly, the evidence before the Panel established that there are serious concerns that it is not safe to use the Products for the age group specified and in the dosages recommended. In my view the breach should be classified as a Severe Breach that has safety implications, pursuant to section 10.1.1 of the Code.

Sanctions

62 In assessing the appropriate sanctions for this Breach, it is of course relevant to take into account that the Panel has directed Care to provide to iNova the evidence held by Care to support the safety of Cares Little Coughs products when supplied to children in the six-month to 2 years age range at the dosages specified by Care, using the relevant ingredient, quantity and extract ratios.[26]

63 The following scenarios may, amongst others, arise as a result of the Panels direction:

(a) Care may provide evidence to iNova which satisfies its concerns and it may withdraw its complaint under Section 4.1;

(b) The evidence provided by Care may not satisfy iNova that the Claims are safe and it proceeds with its complaint, which will then be determined either by the Panel or finally on appeal.

64 If it is ultimately accepted either by iNova upon receipt of the evidence or by the Panel or the Arbiter, that the Claims made by Care are safe then it is not appropriate to apply the sanctions which I consider would be appropriate now, having regard to the fact that the Claims are presently unsubstantiated for the purposes of the Code and for the reasons stated, carry safety implications.

[23] Para 29 of Cares submissions
[24] Section 9.5.2 of the Code.
[25] para 10 of the Panels determination.
[26] para 16 of the Panels determination.

65 If the Claims remain unsubstantiated, I believe that it would be appropriate to require Care to cease making the Claims. Further, given the seriousness of the breach, I would also impose a fine of $25,000 having regard to the fact that the Code envisages a maximum fine of $40,000 for a Severe Breach and that this is Care's first such Breach.

66 In the circumstances I confirm the Panel's direction to Care pursuant to section 10.2.1 of the Code, to provide INova, within five working days of receiving my determination, the evidence held by Care to support the safety of Cares Little Coughs products when supplied to children in the six month – to two year age range at the dosages specified by Care, using the relevant ingredient, quantity and extract ratios.

67 I also confirm the Panel's request to iNova, that if Care complies with this direction, then it is to inform the Chief Executive Officer of CHPA and Care within five working days, 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.

68 If iNova decides to proceed with its section 4.1 complaint, Care may provide to the Chief Executive Officer of CHPA and iNova any response to iNova's further submission, within 5 working days or such further time as the Panel Chair allows.

69 I direct that if:

(i) Care does not provide any evidence to iNova in compliance with the above direction; or

(ii) If, following the provision of that evidence to iNova, it pursues its section 4.1 complaint and the Panel determines that the Claims are not safe and the time for making an appeal against that decision has lapses; or

(iii) If an appeal is made from the Panels determination and the Arbiter determines that the Claims are unsafe;

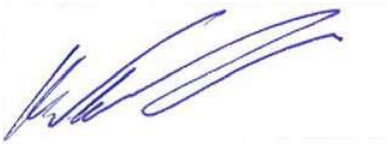
then, within 10 days of any of those events:

(a) pursuant to section 10.2.1 of the Code, Care must give an undertaking in writing to CHPA to discontinue making the claims that the Products can be used by children between the age of six 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 fine of $25,000 to CHPA.

70 I direct that pursuant to section 9.4.2.2 Care is to reimburse CHPA its out-of-pocket expenses associated with the determination of the section 5.4.1 complaint and this appeal.

Dated: 7 December 2021.



Arbiter: Harold Werksman