COMPLAINT NUMBER	21/339
APPEAL NUMBER	21/015
APPLICANT	Complainant
ADVERTISER	New Zealand Government
ADVERTISEMENT	Unite Against COVID-19, Print
DATE	7 October 2021
OUTCOME	Declined

SUMMARY

The Chair of the Complaints Board ruled on 2 August 2021, the complaint regarding a New Zealand Government newspaper advertisement about the Unite Against COVID-19 vaccination programme was No Grounds to Proceed.

The Complainant appealed the Decision. The appeal application was considered by the Chairperson of the Appeal Board. The Chairperson noted the Applicant's view that evidence had been misinterpreted to the extent that it affected the decision.

The Chairperson of the Appeal Board agreed with the Chair of the Complaints Board that the statements in the advertisement did not meet the threshold to mislead consumers.

The Chairperson noted the Complainant did not agree with the Decision, however, disagreement was not a ground on which an appeal could be accepted.

The Chairperson said none of the grounds for appeal had been met and ruled the appeal application was declined.

CHAIRPERSON'S RULING

The Chairperson viewed the application for appeal. She noted that there were five grounds upon which an appeal was able to proceed. These were listed at Clause 6(c) of the Second Schedule of the Advertising Standards Complaints Board Complaints Procedures and were as follows:

(a) The proper procedures have not been followed.

(b) There is new evidence of sufficient substance to affect the decision.

(c) Evidence provided to the Complaints Board has been misinterpreted to the extent that it has affected the decision.

(d) The decision is against the weight of evidence.

(e) It is in the interests of natural justice that the matter be reheard.

The Complainant appealed the Decision from the Chair of the Complaints Board which ruled the complaint had No Grounds to Proceed. (A full copy of the appeal is in Appendix 2 and a full copy of the Chair's ruling is in Appendix 3).

The Applicant appealed under Ground (c) - Evidence provided to the Complaints Board has been misinterpreted to the extent that it has affected the decision.

The Chairperson of the Appeal Board reviewed the complaint, the advertisement, the Ruling from the Chair of the Complaints Board, and the Complainant's appeal application to assess whether there is a possible breach of the Advertising Standards Code.

The Chairperson agreed with Chair of the Complaints Board that the identity of the Advertiser was sufficiently clear and the advertisement complied with the identity requirements of Rule 2(e) of the Advertising Standards Code concerning advocacy advertisements. As the Advertiser's identity was clear, a more liberal interpretation of the Advertising Standards Code applied.

Role of the ASA
The Chairperson confirmed the ASA's position with regard to assessing advertisements from expert bodies. The agencies supporting the Government's COVID-19 approach included the Ministry of Health, an expert body with regard to its statutory role relating to public health matters. The role and jurisdiction of the ASA in assessing advertising from expert bodies is addressed in *Electoral Commission v Cameron* [1997] 2 NZLR 421. In accordance with the findings of the Court of Appeal, the Advertising Standards Authority was required to "tread carefully" and ensure that it did not substitute its opinion for that of the expert body.

Was the advertisement likely to mislead or deceive consumers?
The Chairperson of the Appeal Board agreed with the Chair of the Complaints Board that the statements regarding the safety of the vaccine in the advertisement did not meet the threshold to mislead consumers under the Advertising Standards Code.

The Chairperson confirmed the issue raised by the Applicant about vaccine efficacy and vaccine approval were matters for the Government agency which is empowered by law to make those decisions. The Chairperson agreed with the original ruling that Medsafe's processes relating to vaccine approval were outside the jurisdiction of the ASA.

The Chairperson noted the Applicant's view about the reference to "a vaccine" in the advertisement, and that it meant the statement was not specifically about the COVID-19 vaccine. The statement says: "*How do we know it's safe? Medsafe (New Zealand's medicines safety authority) only grants consent for a vaccine to be used in Aotearoa once they're satisfied it's safe and effective to use"*.

The Chairperson considered the likely consumer take-out of the advertisement. She noted it uses a number of identifiers to link the content to COVID-19, including the heading which states "Answers to your COVID-19 vaccine questions", the colours of the Government COVID-19 advertising campaign, and the campaign logo "Unite against COVID-19". In the Chairperson's view, the consumer take-out of this statement in the advertisement is the Government chose the Pfizer vaccine and the Government's medicines safety regulator is satisfied that it is "safe and effective to use."

The Chairperson said the Ministry of Health has clearly laid out the approval process on its website stating that short cuts had not been taken in assessing the Pfizer COVID-19 vaccine. The website makes it clear Medsafe streamlined its assessment and approval process to meet the unique situation presented by the pandemic.

The Chairperson noted the Applicant disagreed with the Advertiser's characterisation of the vaccine approval process for the COVID-19 vaccines. She noted the expert body's reference to a more efficient safety monitoring is considered by the Applicant to be short cuts in the approval process.

The Chairperson noted the Complainant did not agree with the Decision, however, disagreement was not a ground on which an appeal could be accepted.

The Chairperson said none of the grounds for appeal had been met and ruled the appeal application was declined.

Chairperson's Ruling: Appeal application **Declined** Complaint **No Grounds to Proceed**

APPENDICES

1. **Description of Advertisement**
2. **Appeal Application from Complainant**
3. **Chair Of Complaints Board No Ground to Proceed Decision**

Appendix 1

DESCRIPTION OF ADVERTISEMENT

The New Zealand Government advertisement in the Waitako Times newspaper is a full-page and in a question and answer style with "frequently asked questions" about the COVID-19 vaccine. The advertisement addresses six questions about supply of the vaccine, the vaccination rollout, and the safety and efficacy of the vaccine. At the bottom of the page, there is a URL where people can find more information as well as the New Zealand government and "Unite Against COVID-19" logos.

Appendix 2

APPEAL APPLICATION FROM COMPLAINANT

The Advertisement in question stated:

> *"How do we know it's safe? Medsafe (New Zealand's medicines safety authority) only grants consent for a vaccine to be used in Aotearoa once they're satisfied it's safe and effective to use. All COVID-19 vaccines go through the same safety steps, and must meet the same robust standards. There have been no shortcuts taken in granting approval.".*

This Appeal is made on the basis that, at the very least, evidence provided to the Complaints Board has been misinterpreted to the extent it has affected the decision (i.e., at least ground (c)).

The Decision states, in relation to the above claim:

> *"The Chair noted that Complainant raised two issues that she considered under Principle 2 of the Advertising Standards Code, relating to truthful presentation. The Complainant said the advertisement overstated the effectiveness of the vaccine to reduce transmission and noted it only has provisional approval from Medsafe.*
>
> *The Chair said these issues related to the efficacy of the vaccine. The Chair confirmed the efficacy of the vaccine was not a matter for the ASA. The vaccine referred to in the advertising had received approval from Medsafe, the Government regulator for prescription medicines. The Chair noted the Datasheet which sets out all the relevant information for the vaccine, under Medsafe's approval process is available on the Medsafe website"*.

Firstly, the statement "*The Chair said these issues* [i.e., (1) effectiveness and (2) provisional approval] *related to the efficacy of the vaccine*" is incorrect. Thus, dismissing this part of the claim because "*efficacy of the vaccine was not a matter for the ASA*" was an error.

Whilst the first issue (effectiveness) clearly relates to the efficacy of the vaccine, the second issue (provisional approval) is a different matter altogether, which is unrelated to vaccine efficacy.

The statement "*How do we know it's safe? Medsafe (New Zealand's medicines safety authority) only grants consent for a vaccine to be used in Aotearoa once they're satisfied it's safe and effective to use"* refers only to consent being granted for "a vaccine", not to "a COVID-19 vaccine". The Decision refered me to the Medsafe article COVID-19 Vaccine Evaluation and Approval Process but this is irrelevant to the above statement. Medsafe also has an article entitled Medsafe's Evaluation and Approval Process, which relates to all medicines, including vaccines. The article referred to in the Decision relates specifically to COVID-19 vaccines but, as mentioned above, the statement in the Advertisement is not limited to COVID-19 vaccines.

The Advertisement claims that "*Medsafe (New Zealand's medicines safety authority) only grants consent for a vaccine to be used in Aotearoa once they're satisfied it's safe and effective to use*". The general public would interpret "*once they're satisfied it's safe and effective to use"* as "*once they're fully satisfied it's safe and effective to use".* However, Medsafe's own COVID-19 Vaccine Evaluation and Approval Process, referred to in the Decision, states "*We expect that most vaccines will be granted provisional consent because data to support the longer-term safety and efficacy of COVID-19 vaccines is not yet available*". Accordingly, full consent can only be granted when data to support the longer-term safety and efficacy of a COVID-19 vaccine is available. It is therefore simply untrue and misleading to state that Medsafe has been satisfied of the safety and efficacy of a provisionally approved COVID-19 vaccine – Medsafe has only been preliminarily satisfied, on the basis of only very short-term safety and efficacy data. For that very reason, Medsafe "*imposes conditions on the vaccine, restricting its use by healthcare professionals according to the data available at the time of approval*". Provisional approval is therefore best described as a shortcut in granting approval, or as explained in Medsafe's own words "*Provisional consent was included in the Medicines Act to allow New Zealand patients to have early access to medicines with a significant unmet clinical need*". A further Medsafe explanation of provisional consent is provided under "Timeframes for Provisional Consent" where it is stated that "*Provisional consent is ideally suited to medicines still undergoing clinical assessment but where it is desirable that patients have early access. It is anticipated that the medicine will be used on a restricted basis* ***until the risks and benefits have been quantified and full consent has been granted****.*" [emphasis added]. Accordingly, it is possible that Medsafe will grant consent (that is, provisional consent) for a vaccine even before they are fully satisfied that it is safe and effective to use, contrary to the statement in the Advertisement.

The general public, reading the statement "*Medsafe only grants consent for a vaccine to be used … once they're satisfied it's safe and effective to use*" would assume that the words "grants consent" mean "*grants full consent*". The general public reading this statement in the Advertisement would not appreciate that the vaccine approval process includes a provisional consent option and that the COVD-19 vaccine which is the subject of the Advertisement has only been granted provisional consent, and so its safety and efficacy have not yet met standards expected of the vast majority of medicines and vaccines approved by Medsafe. Note that of the 14,702 products (as of 13 September 2021) listed in Medsafe's approval database, only 62 have been granted provisional consent. Of those 14,702 products, 152 are vaccines and of those 152 vaccines, only 5 have been granted provisional consent (three COVID-19 vaccines and two pandemic influenza vaccines).

The statement "*All COVID-19 vaccines go through the same safety steps, and must meet the same robust standards*" refers specifically to "COVID-19 vaccines", unlike the previous

sentence that referred only to “a vaccine” (that is, any vaccine). While it is true that all COVID-19 vaccines go through the same approval process as all other COVID-19 vaccines, because this sentence follows on from a sentence specific to any vaccine (and which will be interpreted by the general public as relating to the granting of full consent) there is a misleading implication that “All COVID-19 vaccines” go through the same safety steps and meet the same robust standards as any medicine that has been granted full consent.

Appendix 3

CHAIR OF COMPLAINTS BOARD DECISION

COMPLAINT NUMBER	21/339
ADVERTISER	New Zealand Government
ADVERTISEMENT	Unite against COVID-19, Print
DATE OF MEETING	2 August 2021
OUTCOME	No Grounds to Proceed

Advertisement: The New Zealand Government advertisement in the Waitako Times newspaper is a full-page and in a question and answer style with "frequently asked questions" about the COVID-19 vaccine. The advertisement addresses six questions about supply of the vaccine, the vaccination rollout, and the safety and efficacy of the vaccine. At the bottom of the page, there is a URL where people can find more information as well as the New Zealand government and "Unite Against COVID-19" logos.

The Chair ruled there were no grounds for the complaint to proceed.

Complaint: The ad states "That means, if you do catch COVID-19, you are far less likely to fall seriously ill or transmit the virus to others". The Pfizer vaccine has been studied in relation to whether it will reduce serious symptoms, but not in relation to whether it will reduce transmission to others. The ad also states "How do we know it's safe? Medsafe (New Zealand's medicines safety authority) only grants consent for a vaccine to be used in Aotearoa once they're satisfied it's safe and effective to use. All COVID-19 vaccines go through the same safety steps, and must meet the same robust standards. There have been no shortcuts taken in granting approval". In fact, the Pfizer vaccine has only been granted "provisional consent" for 9 months (see https://medsafe.govt.nz/COVID-19/Comirnaty-Gazette.pdf). Provisional approval of the vaccine was granted under Section 23(1) of the Medicine's Act 1981 "to address an urgent clinical need". Clearly, it did not "go through the same safety steps" nor "meet the same safety standards" as other vaccines, which do not routinely obtain provisional consent. The Pfizer vaccine's provisional consent was granted with a list of 58 "obligations" placed upon Pfizer, relating to additional evidence or information that Pfizer must provide Medsafe by certain dates. Clearly, Medsafe has not yet been "satisfied it's safe and effective", otherwise, what are the obligations for? The statement "There have been no shortcuts taken in granting approval" is clearly false - a shortcut is precisely what provisional consent is as it is only granted "on a restricted basis for the treatment of a limited number of patients" (see Section 23(1) of the Medicines Act 1981).

The relevant provisions were Advertising Standards Code - Principle 2, Rule 2(b), Rule 2(e);

> **Principle 2: Truthful Presentation:** Advertisements must be truthful, balanced and not misleading.

> **Rule 2(b) Truthful Presentation:** Advertisements must not mislead or be likely to mislead, deceive or confuse consumers, abuse their trust or exploit their lack of knowledge. This includes by implication, inaccuracy, ambiguity, exaggeration, unrealistic claim, omission, false representation or otherwise. Obvious hyperbole identifiable as such is not considered to be misleading.
>
> **Rule 2(e) Advocacy advertising:** Advocacy advertising must clearly state the identity and position of the advertiser. Opinion in support of the advertiser's position must be clearly distinguishable from factual information. Factual information must be able to be substantiated.

About Advocacy Advertising under the Advertising Standards Code
The Chair confirmed the advertisement from the New Zealand Government on matters relating to the COVID-19 vaccination programme was advocacy advertising under the Advertising Standards Code.

Complaints about advocacy advertising are considered differently to complaints about advertising for products and services.

In assessing whether an advocacy advertisement complies with the Advertising Standards Code, the freedom of expression provisions under the Bill of Rights Act 1990 must also be considered.

Section 14 of the Act says: “Everyone has the right to freedom of expression, including the freedom to seek, receive, and impart information and opinions of any kind in any form.” This freedom of expression supports robust debate on current issues in a democracy.

The Chair observed that in a free and democratic society, issues should be openly debated without undue hindrance or interference from authorities such as the Advertising Standards Authority (ASA), and it should not unduly restrict the Government’s role in communicating public health information to the public.

Complainants sometimes ask the ASA to in effect decide which side in an advocacy debate is correct, but the Advertising Standards Complaints Board has consistently declined to have a view. The ASA is not an arbiter of scientific fact. The Complaints Board’s only role is to determine whether there has been a breach of the ASA Codes taking into account the Advocacy Principles. In the first instance the Chair’s role is to decide if there are any grounds for the complaint to proceed.

Under Rule 2(e) Advocacy advertising in the Advertising Standards Code:
- The identity of the advertiser must be clear
- Opinion must be clearly distinguishable from factual information, and
- Factual information must be able to be substantiated.

If the identity and position of the Advertiser is clear, a more liberal interpretation of the Advertising Standards Code is allowed.

The Chair confirmed the Advertiser’s identity was clear. The advertisement included logos for the New Zealand Government and the Unite against COVID-19 campaign seen throughout the pandemic response. The position of the Advertiser was also clear. It is an advertisement

to promote the vaccination rollout. The Chair said the advertisement complied with the identity requirements of Rule 2(e) of the Advertising Standards Code.

The Chair noted the advertisement had been approved by the New Zealand Government. The Chair confirmed the agencies supporting the Government's COVID-19 approach included the Ministry of Health, an expert body with regard to its statutory role relating to public health matters. The role and jurisdiction of the ASA in advertising from expert bodies in addressed in *Electoral Commission v Cameron* [1997] 2 NZLR 421.In accordance with the findings of the Court of Appeal, the Advertising Standards Authority was required to "tread carefully" and ensure that it did not substitute its opinion for that of the expert body.
Is the advertisement likely to mislead or deceive most consumers?

Advertisement claim: - "Medsafe…only grants consent for a vaccine…once they are satisfied it's safe and effective. There have been no shortcuts in granting approval."
The Chair noted that Complainant raised two issues that she considered under Principle 2 of the Advertising Standards Code, relating to truthful presentation. The Complainant said the advertisement overstated the effectiveness of the vaccine to reduce transmission and noted it only has provisional approval from Medsafe.

The Chair said these issues related to the efficacy of the vaccine. The Chair confirmed the efficacy of the vaccine was not a matter for the ASA. The vaccine referred to in the advertising had received approval from Medsafe, the Government regulator for prescription medicines. The Chair noted the Datasheet which sets out all the relevant information for the vaccine, under Medsafe's approval process is available on the Medsafe website.

Advertisement claim: "if you do catch COVID-19, you are far less likely to fall ill or transmit the virus to others."
The Chair noted there was information available on the Ministry of Health website at the time the advertisement was published which cited a number of international studies have shown that vaccination leads to a significant reduction in the rate of transmission of COVID-19.

Information on this was published by the Ministry on 7 May 2021.
https://www.health.govt.nz/our-work/diseases-and-conditions/covid-19-novel-coronavirus/covid-19-resources-and-tools/covid-19-science-news#updates

The Chair said within the context of advocacy advertising, the advertisement was unlikely to mislead or deceive consumers and was not in breach Principle 2 or Rules 2(b) or 2(e) of the Advertising Standards Code.

The Chair ruled there were no grounds for the complaint to proceed.

Chair's Ruling: Complaint **No Grounds to Proceed**