COMPLAINT NUMBER	17/348
COMPLAINANT	D Ryan
ADVERTISER	Zepter International New Zealand
ADVERTISEMENT	Zepter International New Zealand, Digital Marketing
DATE OF MEETING	28 November 2017
OUTCOME	Not Upheld

SUMMARY

The Bioptron Facebook page included therapeutic claims on its banner and in a video about the Bioptron device being “clinically proven” and that it was “effective across a broad range of conditions”; “accelerated wound healing” and provided “pain relief.”

The Complainant was concerned the Bioptron Facebook page banner and a video about the Bioptron device made unsubstantiated therapeutic claims.

The Advertiser said the claims were consistent with the medical device’s intended purpose as notified in the WAND notifications database required by Medsafe and provided substantiation to support the claims.

The Complaints Board said the claims made in the advertisement met the requirements of Rule 2(a) of the Therapeutic and Health Advertising Code with regard to consistency of notification for medical devices and had been substantiated. The Complaints Board said the advertisement was not misleading and had been prepared with a high standard of social responsibility and was not in breach Principles 1 and 2 and Rule 2(a) of the Therapeutic and Health Advertising Code.

The Complaints Board ruled the complaint was Not Upheld.

[No further action required]

Please note this headnote does not form part of the Decision.

COMPLAINTS BOARD DECISION

The Chair directed the Complaints Board to consider the advertisement with reference to Principles 1 and 2 and Rule 2 (a) of the Therapeutic and Health Advertising Code. This required the Complaints Board to consider whether the advertisement was truthful, balanced, misleading or likely to mislead, deceive or confuse consumers, abuse their trust, exploit their lack of knowledge or without justifiable reason, play on fear, whether by implication, omission, ambiguity, exaggerated or unrealistic claim or hyperbole. Statements and claims should be valid and able to be substantiated. Substantiation should exist prior to a claim being made and

any therapeutic claims must be consistent with the listed intended purpose for medical devices.

The Complaints Board was also required to consider whether the advertisement had been prepared with a high standard of social responsibility, particularly as consumers often rely on such products, devices and services for their health and wellbeing.

The Complaints Board ruled the complaint was Not Upheld.

The Complaint
The Complainant was concerned the Bioptron Facebook page banner and a video about the Bioptron device made unsubstantiated therapeutic claims.

The claims of concern to the Complainant on the Facebook page banner were:

> "Light Therapy System
> Clinically tested, proven and certified
> For long lasting, effective and natural healing"

The claims of concern in the video on the Facebook were:

> "clinically proven light therapy medical device"
> "Effective across a broad range of conditions"
> "Accelerated wound healing and pain relief"
> "Clinically proven in adults and children"

The Advertiser's Response
The Advertiser responded to the concerns raised by the Complainant stating, in part: "Both the Facebook banner and Facebook video have been created by Bioptron AG, the Swiss manufacturer, and have been, or are currently used, on the Facebook pages of Zepter companies worldwide. All and any advertising created by Bioptron AG is subject to rigorous checking and has to be in accordance with European advertising standards. In this respect, we are completely in line with a requirement of the NZ Commerce Commission as we are using "information provided by reputable suppliers or manufacturers". Bioptron AG is beyond any doubt a reputable, responsible, certified, award winning Swiss company.

The Advertiser supplied a copy of the DEKRA Clinical Data Summary signed by Prof. Dr. Med. Frank Duffner as evidence of compliance with the EU Medical Devices Directive 93/42/EEC (MDD) and the Web Assisted Notification of Devices (WAND) Medical Device Details which lists the 'Intended Purpose' of the device as required by Medsafe in New Zealand.

The Complaints Board Decision
The Complaints Board noted the concerns of the Complainant, the Advertiser's response and took into account the various precedent decisions referred to in the complaint.

The Complaints Board noted the Advertiser was required to demonstrate that there was suitable substantiation for the WAND listed intended purpose for Bioptron and therefore for the therapeutic claims made in the advertisement before it.

The Complaints Board considered the substantiation provided by the Advertiser, including the Clinical Summary supplied as evidence of the 93/42/EEC certification from DEKRA, an independent evaluation organisation. The Complaints Board said the notification of the intended purpose of the device required by Medsafe in New Zealand was consistent with the DEKRA evaluation and noted the Advertiser was entitled to use the information of the device's intended purpose in its advertising in a responsible manner.

The Complaints Board said the specific claims that light therapy could treat the conditions identified in the Facebook banner and video had been substantiated and were consistent with the device's intended purpose as notified in the WAND database required by Medsafe. Therefore, the Complaints Board said the advertisement met the requirements of Rule 2(a) of the Therapeutic and Health Advertising Code with regard to consistency of notification for medical devices.

The Complaints Board were also of the view the claim that the device was "clinically tested, proven and certified" and a "clinically proven light therapy device" was supported by the Clinical Summary and the DEKRA certification supplied to support the treatment indications in the advertisement and the reference was not misleading.

The Complaints Board said the advertisement was not misleading and had been prepared with a high standard of social responsibility. The Complaints Board ruled the advertisement was not in breach of Principles 1 and 2 and Rule 2(a) of the Therapeutic and Health Advertising Code.

Accordingly, the Complaints Board ruled the complaint was Not Upheld.

Decision: Complaint **Not Upheld**

DESCRIPTION OF ADVERTISEMENT

The Bioptron Facebook page banner and a video on the page made claims about the Bioptron medical Device.

The Facebook banner said:

> "Light Therapy System"
> "Clinically tested, proven and certified"
> "For long lasting, effective and natural healing"

The video on the Facebook said, in part:

> "Clinically proven light therapy medical device"
> "Effective across a broad range of conditions"
> "Accelerated wound healing and pain relief"
> "Clinically proven in adults and children"

COMPLAINT FROM D RYAN

Zepter International New Zealand highly likely breaks Therapeutic and Health Advertising Code PRINCIPLE 2, Rule their Bioptron product.
On their FB page banner they quote: "Light therapy system, Clinically tested, proven and certified. For long lasting, effective and natural healing"
https://www.facebook.com/101952946564156/photos/a.365225130236935.87098.101952946564156/567145250044921/
On one of their FB videos, it quotes: "The clinically proven light therapy medical device"
"Effective across a broad range of conditions"
"Accelerated wound healing and pain relief"
"Clinically proven in adults and children"
https://www.facebook.com/Zepter-International-New-Zealand-101952946564156/

Since 2015, there has been 6 upheld or settled ASA complaints against Bioptron. 15/352, 15/463, 15/462, 15/370, 15/353.

THERAPEUTIC AND HEALTH ADVERTISING CODE

> **Principle 1:** Therapeutic and Health advertisements shall observe a high standard of social responsibility particularly as consumers often rely on such products, devices and services for their health and wellbeing.
>
> **Principle: 2:** Advertisements shall be truthful, balanced and not misleading. Advertisements shall not mislead or be likely to mislead, deceive or confuse consumers, abuse their trust, exploit their lack of knowledge or without justifiable reason, play on fear. This includes by implication, omission, ambiguity, exaggerated or unrealistic claim or hyperbole.
>
> **Rule 2(a):** Advertisements shall be accurate. Statements and claims shall be valid and shall be able to be substantiated. Substantiation should exist prior to a claim being made. For medicines and medical devices, therapeutic claims must be consistent with the approved indication(s) (for medicines) or the listed intended purpose (for medical devices).

RESPONSE FROM ADVERTISER – ZEPTER INTERNATIONAL

We have received your letter dated 09.10.17 with details of complaint against the advertising for the Bioptron Light on www.facebook.com.

Please note the following points regarding this complaint.

Both the Facebook banner and Facebook video have been created by Bioptron AG, the Swiss manufacturer, and have been, or are currently used, on the Facebook pages of Zepter companies worldwide. All and any advertising created by Bioptron AG is subject to rigorous checking and has to be in accordance with European advertising standards. In this respect, we are completely in line with a requirement of the NZ Commerce Commission as we are using “information provided by reputable suppliers or manufacturers”. Bioptron AG is beyond any doubt a reputable, responsible, certified, award winning Swiss company.

This advertisement is also in line with the NZ Medicines Act 1981 Part 4 Medical Advertisements sections 57 and 58. It does not claim, indicate or suggests that Bioptron Light will prevent, alleviate or cure any disease, or prevent, reduce or terminate any physiological condition specified. It simply lists some of the facts about the product established over 29 years of testing and use.

In my fairly qualified opinion, this type of advertisement is truthful, balanced and not misleading. The wording used cannot deceive or confuse potential customers, abuse their trust, exploit their lack of knowledge or play on fear. We have had a number of complaints in the past against advertising for the Bioptron Light by the same individual/group of sceptics. The 6 complaints listed by the complainant were all upheld for different reasons. These advertisements were all unique and featured different wording. None of these advertisements were created by Zepter New Zealand, but rather by our local Agents and Distributors.

We believe at Zepter NZ that after going through this process in the past we have a proper understanding of the Code and its purpose. All Zepter New Zealand official advertising has always been done completely in line with instructions from the Swiss manufacturer. We do not create or interpret anything locally.

We trust the Chairman will exercise a common sense approach vested in the Code and disregard this particular complaint.

RESPONSE FROM MEDIA – FACEBOOK

We have investigated this matter and can advise that we did not detect any violations of our policies.