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| COMPLAINT NUMBER | 17/345 |
| 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 Go Green Expo website (www.gogreen.co.nz) 'Exhibitor Directory' page had links to information about various exhibitors, including Biopteron. The Biopteron listing said the device could provide in home treatment for: "Pain Relief; Wound Healing; Skin Problems; Sports Injuries and; Seasonal Affective Disorder (SAD)".

The Complainant was concerned that the Biopteron claims in the Exhibitor Directory contained "bad therapeutic claims" that were likely to mislead.

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 of 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 that claims made on the Go Green Expo website in the Exhibitor Directory the Biopton listing contained “bad therapeutic claims” that were likely to mislead.

The specific claims identified by the Complainant were:

“Biopton

THE MEDICAL INNOVATION WITH NATURAL HEALING POWER

The BIOPTON Light Therapy System is advanced system for simple and fast treatment at your home

- Pain Relief
- Wound Healing
- Skin Problems
- Sports Injuries
- Seasonal Affective Disorder (SAD)”

The Complainant also referred to several precedents decisions about advertisements for Biopton device that were Upheld or Settled (15/352, 15/463, 15/462, 15/370, 15/369, 15/353.)

The Advertiser’s response

The Advertiser responded to the complaint stating that “All Zepter New Zealand official advertising is completely in line with instructions from the Swiss manufacturer. We do not create or interpret anything locally. Biopton AG is a reputable, award winning company that has been advertising the Biopton Light worldwide for 29 years. All of their advertising is subject to a very high level of expert control in the European Union.”

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.

With regard to the information presented by the Complainant about previous Decisions where advertisements for Biopton were found in breach of the Advertising Codes, the Advertiser responded, in part: “The 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.”

The Advertiser referred to Complaints Board Decisions (10/228), (10/233) (14/249 Appeal 14/017) where it was found the claims, similar to the advertisement currently before the Complaints Board, were found to be consistent with the listed intended purpose on the WAND notifications database and had been substantiated.

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 following conditions identified in the advertisement: Pain Relief; Wound Healing; Skin Problems; Sports Injuries and; Seasonal Affective Disorder (SAD)" 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 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 Go Green Expo website (www.gogreen.co.nz) Exhibitor Directory page included links to information about various exhibitors, including Bioptron. The Bioptron listing said:

"Bioptron

THE MEDICAL INNOVATION WITH NATURAL HEALING POWER

The BIOPTON Light Therapy System is an advanced system for simple and fast treatment at your home

- Pain Relief
- Wound Healing
- Skin Problems
- Sports Injuries
- Seasonal Affective Disorder (SAD)"

COMPLAINT FROM D RYAN

Go Green Expo is highly likely breaking the Therapeutic and Health Advertising Code PRINCIPLE 2, Rule 2(a).

On their Wellington directory page (<http://www.gogreenexpo.co.nz/exhibitor-directory/>) they list a number of products with bad therapeutic claims.

On the Bioptron product popup, it quotes: "Bioptron THE MEDICAL INNOVATION WITH NATURAL HEALING POWER The BIOPTRON Light Therapy System is advanced system for simple and fast treatment at your home Pain Relief, Wound Healing, Skin Problems, Sports Injuries, Seasonal Affective Disorder (SAD)"

Since 2015, there has been 6 upheld or settled ASA complaints against Bioptron: 15/352, 15/463, 15/462, 15/370, 15/369, 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 NEW ZEALAND

We have received your letter dated 09.10.17 with details of complaint against the advertising for the Bioptron Light on the Go Green Expo Website.

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.

All Zepter New Zealand official advertising is completely in line with instructions from the Swiss manufacturer. We do not create or interpret anything locally. Bioptron AG is a reputable, award winning company that has been advertising the Bioptron Light worldwide for 29 years. All of their advertising is subject to a very high level of expert control in the European Union.

This particular complaint is a follow up to previous complaints without a proper and precise check of the exact language of this advertisement.

I would like to bring to your attention a Complaints Board decision from the 13.07.2010 regarding complaints 10/228 and 10/233. Please also see the Complaints Board decision regarding complaint 14/249 and appeal 14/017. For your reference and convenience I am sending you copies of all 3 decisions. If you check the advertising in them against the one on Go Green Expo Website you will find that their wording is almost identical word for word.

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

RESPONSE FROM MEDIA – Go Green Expo

This listing is our exhibitor listing Provided by Bioptron – if you are able to contact them please we can make the appropriate changes.

Bioptron is the advertiser not Go Green Expo