COMPLAINT NUMBER	17/378
COMPLAINANT	M Honeychurch
ADVERTISER	Brand Developers Ltd
ADVERTISEMENT	Brand Developers Ltd, Pain Erazor, Digital Marketing
DATE OF MEETING	28 November 2017
OUTCOME	Not Upheld

SUMMARY

The Brand Developers website advertisement for the Pain Erazor (www.branddeevelopers.co.nz/shop/pain-erazor) made various claims about the device in treating pain or discomfort. The advertisement stated, in part:

> "With just a press of a button, you can get the relief you've been looking for… An effective way to soothe and relieve pain without using medication… Delivering fast and effective pain relief anywhere and anytime… Up to 10 years of Pain Relief. A single Pain Erazor Pen lasts up to 10 years or 100,000 clicks. Natural relief with no undesired side effects."

The Complainant was concerned the therapeutic claims made on the Brand Developers website about the Pain Erazor device were misleading. The Complainant said the statements about "drug free pain relief were misleading and was concerned the advertisement claimed there were no side effects and the testimonials were not genuine or typical.

The Complaints Board ruled the therapeutic claims made in the advertisement about the Pain Erazor device was supported by the substantiation provided by the Advertiser and consistent with the notification of the device's intended purpose on the WAND database. The Complaints Board also said the testimonials were genuine and typical and were unlikely to mislead and ruled the advertisement had been prepared with a high standard of social responsibility and was not in breach of Principle 1 and Principle 2 and Rules 2(a) and 2(f) of the Therapeutic and Health Advertising Code.

The Complaints Board ruled the complaint made about the claim "no undesired side effects" was Settled against Rule 1(b) of the Therapeutic and Health Advertising Code as the Advertiser had amended the claim.

The Complaints Board ruled the complaint was Not Upheld, in part and Settled, in part.

[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 complaint with reference to Principle 1 and Rule 1(b) and Principle 2 and Rules 2(a) and 2(f) of the Therapeutic and Health Advertising Code.

Rule 1(b) required the Complaints Board to consider whether the advertisement contained any claim, statement or implication that device advertised was safe or that their use cannot cause harm or that they have no side effects or risks; are effective in all cases; are infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure; are likely to lead persons to believe that they are suffering from a serious ailment, or harmful consequences may result from the device or service not being used.

The Complaints Board noted Principle 2 and Rule 2(a) required advertisements were truthful, balanced and not misleading, 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. Statements and claims shall be valid and shall be able to be substantiated. Substantiation should exist prior to a claim being made. For medical devices, therapeutic claims must be consistent with the listed intended purpose (for medical devices).

Rule 2(f) required the Complaints Board to consider whether the testimonials in the advertisement, where not prohibited by law, are authenticated, genuine, current, and typical and acknowledge any valuable consideration. Exceptional cases should be represented as such.

Principle 1 of the Therapeutic and Health Advertising Code required advertisements observe 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 therapeutic claims made on the Brand Developers website about the Pain Erazor device were misleading. The Complainant said the statements about "drug free pain relief were misleading and was concerned the advertisement claimed there were no side effects and the testimonials were not genuine or typical.

The Advertiser's Response

Misleading Claims

The Advertiser acknowledged the claims in the advertisement were therapeutic in nature stating, in part "*Pain Erazor* is a **Class IIa Medical Device** and as per the legislation in New Zealand, it is listed on the MedSafe WAND database. No claims are in breach of the code."
The Advertiser said the claims made about the device were in line with its listed intended purpose on the WAND database which is: "A device to provide electrical stimuli through the body surface to stimulate nerves and muscles, and stimulate the production of endorphins, in order to provide relief of chronic and acute pain."

The Advertiser said, in part: "*Pain Erazor* has received its *CE* rating in **Europe**, and qualifies as a **Class IIa Medical Device** as of **2015**. To achieve this, the *European Commission of Enterprise and Industry Directorate General* requested factual clinical information on the Pain Erazor unit. Information provided was required to substantiate effectiveness, intended

therapeutic indications and claims. This was to take the form of a *Clinical Evaluation Report* (*CER*) compiled by a recognised independent medical research facility. *Ontario Research Medical Group (Canada)* compiled the report, researched by Clinical Director **Dr Michel Rice**, **Dr Dyan Dupaya MD**, and **Dr Eric Dupaya MD**.

We have attached this report. The highlights indicate that *Pain Erazor* is a TENS device (it uses the classic TENS waveform), that high quality studies (referenced) have confirmed the ability of a TENS device to manage acute and chronic pain, and that the *Pain Erazor* is substantiated in making claims of acute and chronic pain relief, and endorphin stimulation.

For further reference, we have attached this recent high-quality double-blind placebo-controlled clinical study on the effectiveness of 'a handheld TENS pen device for pain relief'…"

The Advertiser also addressed the Complainant's concern the claim "Up to 10 Years of Pain Relief" was misleading, stating that it "refers to the 10-year/10,000 click guarantee for the device."

Side Effects
The Advertiser said the statement "no undesired side effects" referred to the "common undesired side effects of pain-killing drugs (nausea and drowsiness). Rule 1(b) prevents claims of "no side effects". We have made no claim that this medical device carries "no side effects" (a blanket statement). The claim refers only to *none of the undesired side effects [found with drugs]".*

To avoid further misinterpretation, we have expanded the claim to say, 'None of the undesired side effects of drugs.'

Testimonials
The Advertiser said "as per all testimonials featured in our advertising, Testimonial Release Forms are obtained and provided to relevant regulatory authorities. This is a requirement before any advertisements can be aired. Individuals attest that all remarks are a true an honest opinion, and represent an accurate assessment of their personal experience in using the product. We can confirm that all testimonials featured in our website advertisement are excerpts from the television commercials we are currently airing in Australia and New Zealand. These testimonials can be 'changed out' on the website as we update our television commercials, but individuals featured will already have provided signed TRFs for television.

The clear disclaimer 'individual results may vary' appears on the website. No testimonials are exceptional. All testimonials only make claims consistent with the intended purpose."

Complaints Board Discussion
The Complaints Board noted the Complainant's concerns that the advertisement made claims about the efficacy of the Pain Erazor device in treating pain without side effects and included testimonials which were not genuine or typical.

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

The Complaints Board considered the substantiation provided by the Advertiser, including the Pain Erazor Clinical Evaluation, the ARTG Certificate and the TENS Pen Clinical Study 2017. The Complaints Board said the notification of the intended purpose of the device required on the Medsafe WAND listing in New Zealand was consistent with evidence

provided 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 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 took into account the Advertiser had amended the claim "no undesired side effects" to "None of the undesired side effects of drugs" for clarity. Noting the self-regulatory actions of the Advertiser to amend this part of the advertisement, the Complaints Board ruled the aspect of the complaint was Settled against Rule 1(b) of the Therapeutic and Health Advertising Code.

The Complaints Board considered the information provided by the Advertiser that the testimonials on the website for the Pain Erazor were genuine as they were taken directly from television commercials which, the Advertiser explained, require Testimonial Release Forms prior to being approved for broadcast. As such, the Complaints Board accepted the testimonials were genuine and consistent with the notified intended purpose. The Complaints Board said the testimonials were unlikely to mislead consumers and were not in breach of Rule 2(f) of the Therapeutic Health and Advertising Code.

Summary

The Complaints Board ruled the therapeutic claims made in the advertisement about the Pain Erazor device were supported by the substantiation provided by the Advertiser and consistent with the notification of the devices intended purpose on the WAND database. The Complaints Board also said the testimonials were genuine and typical and were unlikely to mislead and ruled the advertisement had been prepared with a high standard of social responsibility and was not in breach of Principle 1 and Principle 2 and Rules 2(a) and 2(f) of the Therapeutic and Health Advertising Code.

The Complaints Board ruled the complaint made about the claim "no undesired side effects" was Settled against Rule 1(b) of the Therapeutic and Health Advertising Code as the Advertiser amended the claim.

Accordingly, the Complaints Board ruled the complaint was Not Upheld in part and Settled in part.

Decision: Complaint **Not Upheld in part and Settled in part**

DESCRIPTION OF ADVERTISEMENT

The Brand Developers website advertisement for the Pain Erazor (www.branddeevelopers.co.nz/shop/pain-erazor) made various claims about the device in treating pain or discomfort. The advertisement stated, in part:

> "With just a press of a button, you can get the relief you've been looking for… An effective way to sooth and relieve pain without using medication… Delivering fast and effective pain relief anywhere and anytime… Up to 10 years of Pain Relief. A single Pain Erazor Pen lasts up to 10 years or 100,000 clicks. Natural relief with no undesired side effects."

COMPLAINT FROM M HONEYCHURCH

Definite therapeutic claims have been made about the Pain Erazor:

"the incredible innovation in drug free pain relief. With just a press of a button, you can get the relief you've been looking for."
"Utilises your body's own natural pain response system to relieve the effects of all types of pain."
"The Pain Erazor naturally stimulates your body's endorphin's - nature's own painkillers - to send real pain relief, right where you need it."
"Up to 10 Years of Pain Relief"
"Natural relief"
"utilises your body's own natural pain response system to relieve the effects of all types of pain"
"Natural pain relief - no undesired side effects"
"Pain relief right where you need it – without drugs, messy creams or expensive treatments."
"DISCOVER THE POWER OF DRUG FREE PAIN RELIEF"
"Each click sends tiny electric impulses along the nerve paths to your brain, which releases endorphins (your body's natural defences against pain) and "interrupts" other pain and irritation signals." "For the temporary relief of pain"

These claims breach the ASA's Therapeutic and Health Advertising Code Rule 2(a), as they have not been proven to be true. It would be good to see the results of high quality studies showing that this device works, however there appears to be a lack of evidence for pain relief from piezoelectric devices in general, and I could find nothing specific to the Pain Erazor device.

Rule 1(b) is also breached by the claim of "no undesired side effects".

Rule 2(f) is breached by the video and written testimonials at the bottom of the page - the testimonials have not been shown to be genuine or typical.

THERAPEUTIC AND ADVERTISING CODES

> **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.
>
> **Rule (b):** Advertisements shall not contain any claim, statement or implication that the products, devices or services advertised;
>
> - are safe or that their use cannot cause harm or that they have no side effects or risks.
> - are effective in all cases
> - are infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure
> - are likely to lead persons to believe that;
> - they are suffering from a serious ailment, or
> - harmful consequences may result from the therapeutic or health product, device or service not being used
>
> **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).

Rule: (f): Patient testimonials and healthcare professional endorsements in advertisements, where not prohibited by law, shall comply with the Code, be authenticated, genuine, current, and typical and acknowledge any valuable consideration. Exceptional cases shall be represented as such.

RESPONSE FROM ADVERTISER – BRAND DEVELOPERS LTD

Complaint 17/378 re: Pain Erazor website

We are writing in response to the complaint about this advertisement, received from M Honeychurch of the *Society for Science Based Healthcare* on 5 OCT 2017. The website in question, *www.branddevelopers.co.nz/shop/pain-erazor*, advertises the *Pain Erazor* medical device.

The main points of the complaint are as follows…

1 Definite therapeutic claims have been made about the Pain Erazor

These claims breach the ASA's Therapeutic and Health Advertising Code Rule 2(a), as they have not been proven to be true. It would be good to see the results of high quality studies showing that this device works, however there appears to be a lack of evidence for pain relief from piezoelectric devices in general, and I could find nothing specific to the Pain Erazor device.

We acknowledge the claims are therapeutic in nature – *Pain Erazor* is a **Class IIa Medical Device** and as per the legislation in New Zealand, it is listed on the MedSafe WAND database. No claims are in breach of the code.

Therapeutic and Health Advertising Code 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).

This is the listed intended purpose for *Pain Erazor…*

Intended Purpose	A device to provide electrical stimuli through the body surface to stimulate nerves and muscles, and stimulate the production of endorphins, in order to provide relief of chronic and acute pain.

Ref: WAND Notice, ARTG Certificate

All claims made are consistent with both the WAND and ARTG listed intended purpose for this device. The claims in question…

"The incredible innovation in drug free pain relief. With just a press of a button, you can get the relief you've been looking for."

This claim refers to pain relief, and is consistent with the intended purpose.

"Utilises your body's own natural pain response system to relieve the effects of all types of pain."

This claim refers to endorphin stimulation, and is consistent with the intended purpose.
"The Pain Erazor naturally stimulates your body's endorphin's - nature's own painkillers - to send real pain relief, right where you need it."

This claim refers to endorphin stimulation, and is consistent with the intended purpose.

"Up to 10 Years of Pain Relief"

This claim refers to the 10-year/10,000 click guarantee for the device.

"Natural relief"

This claim refers to endorphins being natural painkillers, and is consistent with the intended purpose.

"Utilises your body's own natural pain response system to relieve the effects of all types of pain"

This claim refers to endorphin stimulation, and is consistent with the intended purpose.

"Natural pain relief - no undesired side effects"

This claim refers to endorphin stimulation, and is consistent with the intended purpose. In context, "no undesired side effects" is referring specifically to the common undesired side effects of pain-killing drugs (nausea and drowsiness).

"Pain relief right where you need it – without drugs, messy creams or expensive treatments."

This device uses no drugs, messy creams or expensive treatments.

"DISCOVER THE POWER OF DRUG FREE PAIN RELIEF"

This is the title of a book from *Know It All Press*, offered as a gift. It is not a claim.

"Each click sends tiny electric impulses along the nerve paths to your brain, which releases endorphins (your body's natural defences against pain) and "interrupts" other pain and irritation signals."

This claim refers to endorphin stimulation, and is consistent with the intended purpose.

"For the temporary relief of pain"

This is not a claim – it is a legally required disclaimer.

The complainant's assertion that these claims are unproven is only his opinion – and he has admitted that this conclusion is based solely on his own inability to find supporting research.

All claims are accurate, valid and substantiated. As such, these claims are **not in breach** of the ASA's Therapeutic and Health Advertising Code Rule 2(a). Part of the requirements to list a medical device in New Zealand is that the NZ sponsor (Brand Developers) is expected

to hold suitable substantiation to support the *'Evidence of Conformity Assessment'* for the safety and efficacy of the device. For the *Pain Erazor* device, Brand Developers hold the following substantiation to support the 'Evidence of Conformity Assessment' and therefore the listed intended purpose for this device…

Ref: Pain Erazor Clinical Evaluation HIGHLIGHTED.pdf

Pain Erazor has received its *CE* rating in **Europe**, and qualifies as a **Class IIa Medical Device** as of **2015**. To achieve this, the *European Commission of Enterprise and Industry Directorate General* requested factual clinical information on the Pain Erazor unit. Information provided was required to substantiate effectiveness, intended therapeutic indications and claims. This was to take the form of a *Clinical Evaluation Report* (*CER*) compiled by a recognised independent medical research facility. *Ontario Research Medical Group (Canada)* compiled the report, researched by Clinical Director **Dr Michel Rice**, **Dr Dyan Dupaya MD**, and **Dr Eric Dupaya MD**.

We have attached this report. The highlights indicate that *Pain Erazor* is a TENS device (it uses the classic TENS waveform), that high quality studies (referenced) have confirmed the ability of a TENS device to manage acute and chronic pain, and that the *Pain Erazor* is substantiated in making claims of acute and chronic pain relief, and endorphin stimulation.

The use of modulated TENS, and in particular the use of the Pain Erazor Unit is an effective pain relief therapy unit.

The clinical evaluation on the Pain Erazor can be used to support the marketing claims made by the manufacturer.

This clinical report was **evaluated and accepted** by the *European Commission of Enterprise*, and the *CE* mark was issued.

Ref: ARTG Certificate

Subsequently, substantiations in the form of this accepted *Clinical Evaluation Report* (along with other clinical studies) resulted in the **Australian Government** accepting *Pain Erazor* as a **Class IIa Medical Device** as of **2016.** An **ARTG Certificate** was granted with the following intended purpose…

Intended Purpose	A device to provide electrical stimuli through the body surface to stimulate nerves and muscles, and stimulate the production of endorphins, in order to provide relief of chronic and acute pain.

Pain Erazor has been advertised and promoted as an effective medical device for pain relief across all Australian media for more than a year.

NOTE: A WAND notice in New Zealand only requires substantiations for claims to be kept "on hand". However, the TGA in Australia, along with CAD, require all substantiations to be fully evaluated *before* an ARTG certificate can be issued, and *before* therapeutic claims can be made in advertising. The supporting materials supplied for *Pain Erazor* satisfied all relevant Australian regulatory authorities.

Ref: WAND Notice

We have attached the MedSafe WAND notice, which clearly shows the classification of *Pain Erazor* (**Class IIa Medical Device**) and intended purpose are consistent with the approved Australian and European classifications…

Intended Purpose	A device to provide electrical stimuli through the body surface to stimulate nerves and muscles, and stimulate the production of endorphins, in order to provide relief of chronic and acute pain.

Ref: TENS Pen Clinical Study 2017 Final Report 4-01-2017.pdf
For further reference, we have attached this recent high-quality double-blind placebo-controlled clinical study on the effectiveness of "a handheld TENS pen device for pain relief"…

The following conclusions were drawn from the data evaluation and analysis of this study:

1. The handheld TENS pen is effective in relieving general musculoskeletal pain

2. The handheld TENS pen is effective in relieving acute musculoskeletal pain

3. The handheld TENS pen is effective in relieving chronic musculoskeletal pain

2

Rule 1(b) is also breached by the claim of "no undesired side effects".

In the context of our advertising, "no undesired side effects" is referring specifically to the common undesired side effects of pain-killing drugs (nausea and drowsiness). Rule 1(b) prevents claims of "no side effects". We have made no claim that this medical device carries "no side effects" (a blanket statement). The claim refers only to *none of the undesired side effects [found with drugs]".*

To avoid further misinterpretation, we have expanded the claim to say, "**None of the undesired side effects of drugs**".

3

Rule 2(f) is breached by the video and written testimonials at the bottom of the page - the testimonials have not been shown to be genuine or typical.

Therapeutic and Health Advertising Code Rule 2(f)
Patient testimonials and healthcare professional endorsements in advertisements, where not prohibited by law, shall comply with the Code, be authenticated, genuine, current, and typical and acknowledge any valuable consideration. Exceptional cases shall be represented as such.

This is another incorrect assumption made by the claimant. As per all testimonials featured in our advertising, Testimonial Release Forms are obtained and provided to relevant regulatory authorities. This is a requirement before any advertisements can be aired. Individuals attest that all remarks are their true an honest opinion, and represent an accurate assessment of their personal experience in using the product. We can confirm that all testimonials featured in our website advertisement are excerpts from the television commercials we are currently airing in Australia and New Zealand. These testimonials can be "changed out" on the website as we update our television commercials, but individuals featured will already have provided signed TRFs for television.

The clear disclaimer “individual results may vary” appears on the website. No testimonials are exceptional. All testimonials only make claims consistent with the intended purpose. There is no breach of Rule 2(f).

In summary…

- The complainant alleges we cannot make therapeutic claims – he is wrong. Medical devices are permitted to make therapeutic claims congruent with the stated Intended Purpose.
- The complainant has stated our claims are not substantiated – he is wrong. All claims have been substantiated.

The complaint is therefore without merit. We are a responsible advertiser, and have insured that this advertisement for a medical device makes no unwarranted, unproven or irresponsible claims, and that it complies with all current relevant advertising codes.