

Complaint to TGA: Noncompliance by Au Remedial Pain®Gone and Pain®Gone Plus (AC-KD45638R/2018)

Acknowledgment

This complaint was worked up by a Monash staff member because of non-compliance by the advertisers to a TGA regulatory obligation letter. It was checked and submitted by Assoc Prof Ken Harvey.

Summary

A complaint about [Au Remedial, Pain®Gone and Pain®Gone Plus](#) (AC-KD45638R/2018) was sent to the TGA on 15 July 2018. Despite a previous upheld complaint for this TGACRP (2015-10-004)¹ the Au Remedial complaint only received a 'low' risk classification and was closed on 02 August 2018 with a regulatory obligations letter sent to the advertiser.

The TGA appears to regard a complaint as "low priority" if the supplier differs from that in a previously upheld complaint. This is unacceptable; a new supplier or advertiser should have done due diligence on the product they are taking over and should be aware of previous upheld complaints.

Regardless, this product is still being advertised online. Given non-compliance by the advertisers to their TGA regulatory obligation letter, I ask that this latest complaint be dealt with more effectively.

The latest complaint

Pain®Gone and Pain®Gone Plus (AC-KD45638R/2018)

There are several domains currently promoting this product:

Domain Name: paingonepen.com.au Registrant: Bampa, Robert Registrant ID: ABN 94677820036 Business name: Au Remedial Place: Level 8 11 Refactory Cct Holroyd 2142 Registrant Contact Email: au.remедial@yahoo.com.au	Domain Name: supportforaustralians.com.au Registrant: Bampa, Robert Registrant ID: ABN 94677820036 Business name: Au Remedial Place: Level 8 11 Refactory Cct Holroyd 2142 Registrant Contact Email: Rb1263@yahoo.com.au
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The above differs from information on: <https://www.paingonepen.com.au/>: 2019 © Au Remedial Pty Ltd., Registered company no. 67 622 271 658. Registered office: 5/39-41 Olympic Cct, Southport, QLD 4215. See also:

Organisations & Business Names

3 results found for "Au Remedial Pty Ltd"
Click on the name to view further details.

Display 10 results ▾ ◀ Prev 1 Next ▶

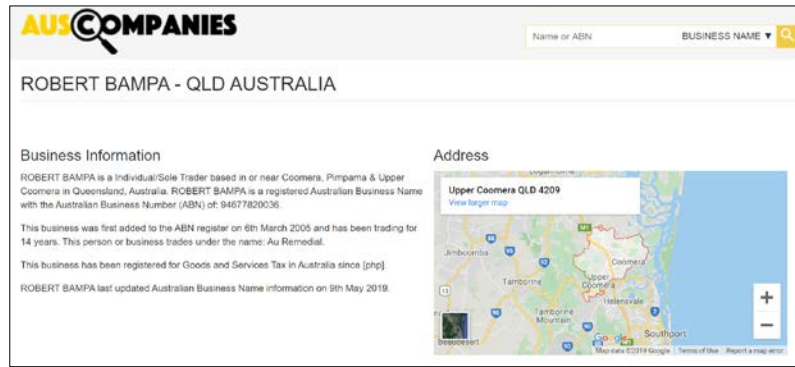
?	Name (*indicates former name)	Number	Type	Status ?	Address ?
<input type="checkbox"/>	AU REMEDIAL		Business Name	Registered	
<input type="checkbox"/>	AU REMEDIAL PTY LTD	ACN 622 271 658	Australian Propr...	Registered	PADSTOW NSW 2211
<input type="checkbox"/>	AU REMEDIALS		Business Name	Cancelled	

[View Results List \(PDF\)](#) Display 10 results ▾ ◀ Prev 1 Next ▶

https://connectonline.asic.gov.au/RegistrySearch/faces/landing/SearchRegisters.jspx?_adf.ctrl-state=14k8mcubby_38

¹ https://www.tgacrp.com.au/complaint-register/?_search=paingone&_id=2961

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Based on the company's ABN history (below), it appears that Mr Bampa has relocated to QLD from NSW.

Historical details for ABN 94 677 820 036

Current details | **Historical details** | Pdf | Print | Email

ABN details help

Entity name	From	To
BAMPA, ROBERT	06 Mar 2005	(current)
ABN Status	From	To
Active	06 Mar 2005	(current)
Entity type	Individual/Sole Trader	
Goods & Services Tax (GST)	From	To
Cancelled	30 Jun 2018	(current)
Registered	01 Jul 2013	29 Jun 2018
Main business location	From	To
QLD 4209	03 May 2019	(current)
NSW 2142	05 Nov 2018	03 May 2019
NSW 2142	18 Aug 2017	05 Nov 2018
NSW 2142	03 Aug 2016	18 Aug 2017
NSW 2142	18 Nov 2015	03 Aug 2016
NSW 2136	22 Sep 2014	18 Nov 2015
NSW 2136	16 Jan 2014	22 Sep 2014
NSW 2136	06 Mar 2005	16 Jan 2014
Business name(s)	From	To
Au Remedial	04 Jun 2015	(current)
AU REMEDIALS	08 Jun 2014	20 Jan 2016

Regardless, claims of **“Fast Effective, Drug Free Pain Relief”** continue to be made for this product at: <https://www.paingonepen.com.au/> and <https://www.supportforaustralians.com.au/product/pain-gone-pen-plus-pain-relief-erazor-paingone> (screen shots are shown in Appendix I).

It is often difficult to establish if medical devices are legally supplied by being included on the ARTG as the name of the product and sponsor on the ARTG Public Summary may bear no relation to the brand name and advertisers name. In addition, there appears to be no requirement for the ARTG number of the device to be printed on the pack or on advertisements when the product is sold on the internet.

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For example, the Pain[®]Gone devices could be a, “Stimulator, electrical, analgesic, peripheral nerve, transcutaneous” (GMDN 35372 Analgesic TENS system). There are ten of these devices included on the ARTG.² None have any identification that links them to the Pain[®]Gone devices. Alternatively, they could be a “Transcutaneous electrical stimulation probe: (GMDN 61169 Transcutaneous electrical stimulation probe). There are another ten of these devices included on the ARTG.³ The TGACRP determination (2015-10-004) identified the Pain[®]Gone device as ARTG no: 203804. I am not sure how this was done as the Public Summary for this device contains no mention of Pain[®]Gone or Au Remedial.

The studies supporting Pain[®]Gone pens were reviewed in the original complaint.⁴ They are low quality, unpublished and have a small sample size. They do not support the strong claims of “**Fast Effective, Drug Free Pain Relief**” made for these devices.

I allege the claims made breach the Therapeutic Goods Advertising Code (No.2) 2018, s.9(a), 9(b), 10(a)(ii), 10(c) & 15(2)(b).

Given the failure of the sponsor to respond to the TGA’s Regulatory Obligations letter, significant financial sanctions and a retraction order should be applied.

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Public Health and Preventive Medicine
Monash University
6 January 2020

² <http://tga-search.clients.funnelback.com/s/search.html?query=Stimulator%2C+electrical%2C+analgesic%2C+peripheral+nerve%2C+transcutaneous&collection=tga-artg&profile=record>

³ <http://tga-search.clients.funnelback.com/s/search.html?query=Transcutaneous+electrical+stimulation+probe&collection=tga-artg&profile=record>

⁴ <https://medreach.com.au/wp-content/uploads/2018/07/Complaint-to-TGA-Pain%2%aeGone-and-Pain%2%aeGone-Plus.pdf>

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Appendix I Paingone, Paingone Plus. Paingone Joint Plus



<https://www.supportforaustralians.com.au/product/pain-gone-pen-plus-pain-relief-erazor-paingone>



<https://www.supportforaustralians.com.au/product/pain-gone-pen-plus-pain-relief-erazor-paingone>

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The screenshot shows the Paingone website with a navigation menu: Overview, Clinical Trial, Watch Video, Using Paingone, Buy Now, FAQ, Locations, Contact, About Zip. Below the navigation are three product logos: 'paingone the original TENS pen', 'paingone+ the automatic TENS pen', and 'paingone JointPLUS'. A central image shows the Paingone Plus device. Surrounding it are eight feature boxes:

- The next generation of Paingone:** Delivers the same pain relief mechanism as the original Paingone, used by over 1.5 million users worldwide, but with great new benefits.
- Automatic Delivery:** Paingone Plus automatically delivers electrical impulses to the desired area. In contrast, original Paingone requires 30 to 40 manual clicks of the button per application.
- Even faster application:** Paingone Plus takes only 30 seconds to apply, letting you get back to your day even more rapidly.
- Easier to use:** No clicking means less tired fingers! Paingone Plus is ideal for those who might struggle to operate the original model, for example those with painful hands.
- Great performance:** One single AAA battery can provide more than 800 applications (based on 30 seconds per application).
- Easier to hold:** Slightly larger than the original model, Paingone Plus is easier for most users to grip and allows for easier application to hard-to-reach areas.
- Still Portable:** Although larger, Paingone Plus is still completely portable and easily fits in a bag to be taken with you, wherever you might need it.
- One battery is all you need:** No further accessories required; no gels or wires, or expensive electrode pads to be replaced. It's simple, convenient and affordable.

<https://www.paingonepen.com.au/>

The screenshot shows a TV commercial for Paingone in Australia. It features a human torso with a glowing green circle on the shoulder, and the Paingone Plus device is shown pointing at it. Text on the screen includes: 'PAINGONE TV COMMERCIAL AUSTRALIA', 'paingone', '1300 772 568 paingonepen.com.au', 'used by 1.5 million people', and a disclaimer: 'Always read the label. Use only as directed. If symptoms persist, see your healthcare professional. Paingone is a trade mark. The name doesn't imply complete pain relief. For temporary relief of pain. Results may vary.'

<https://www.paingonepen.com.au/> (<https://youtu.be/dDvp1qqKkLw>)

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Paingone Study

Paingone – Double-blind, placebo-controlled trial

Paingone has been the focus of a double-blind, placebo-controlled trial.

The study involved 86 participants suffering from a range of painful conditions.

Results support the use of paingone as a pain-management device.

“83% of individuals who used Paingone pen felt that their pain had gone from severe to moderate or none”.

Percentage of study participants reporting extreme pain before and after using Paingone for 28 days

Time Point	Percentage of Participants Reporting Extreme Pain
Before	60%
After	17%

The study suggests that Paingone may be effective for temporary relief of general, acute or chronic musculoskeletal pain

[Click here to view full clinical study](#)

<https://www.paingonepen.com.au/>

See critique at: <https://medreach.com.au/wp-content/uploads/2018/07/Complaint-to-TGA-Pain%20aeGone-and-Pain%20aeGone-Plus.pdf>.