

# TAPS | therapeutic advertising pre-vetting service

<b>GUIDELINE 6</b> <b>General</b>	<b>Guide for Advertisers when promoting Ear Candling</b>
Last Updated	February 2016
What kind of product / service is this guideline for?	Ear Candles and the Ear Candling procedure
What is the purpose of this guideline?	To provide background and guidance on advertising Ear Candling in New Zealand.

## BACKGROUND

Ear Candling is an alternative therapy that dates back to the year 2500 B.C. There is historical evidence showing that people used, and were familiar with, the practice of ear candling in ancient times. Today, as in times past, high-quality ear candles are handmade from beeswax and unbleached cotton cloths. These specially fabricated candles are typically nine (9) to twelve (12) inches long and will burn for approximately ten minutes.

Ear Candling has been used as alternative therapy for the ears, nose and throat.

Ear Candling is thought to act through a process called "*convection*" allowing the soft wax to oxidize debris in the ear canal and turn the debris into vapours during the procedure.

When therapeutic claims such as relief of pain, treatment of swimmers ear and reduction in sinus issues or ear infections are made in advertisements for Ear Candles and the Ear Candling procedure, these advertisements are subject to compliance with the Medicines Act. This means that the Ear Candling procedure using these Ear Candles must be recognised as being appropriate for these claims and robust substantiation must exist to support these claims before they can appear in advertisements.

Any other claims made in advertisements for Ear Candling (such as removal of wax and debris) must also be able to be substantiated. This means there must be in existence prior to advertising, robust evidence that the practice of Ear Candling does what it claims to do.

This Guideline has been prepared in consultation with the Advertising Standards Authority, along with the Therapeutic Advertising Pre-vetting Service Adjudicators.

### Medicines, Medical Devices and Methods of Treatment

Claims that the Ear Candles have a therapeutic effect (relieving e.g. swimmers ear, sinus pain, and ear ache) by removing ear wax, moisture and debris, would classify the Ear Candles as either a Medicine or a Medical Device depending on the way they work. Medicines exert effect by pharmacological, immunological or metabolic means. Medical Devices do not have an effect in this way, rather the effect is through mechanical means. The Ear Candles should either be listed on the Medsafe WAND database or have consent to distribute as a medicine if such claims have robust substantiation.

The Ear Candling procedure which claims to remove ear wax, moisture and debris to relieve symptoms of swimmers ear etc would make this a 'method of treatment' as described in the Medicines Act. The Medicines Act definition of a 'method of treatment' means *any method of treatment for reward undertaken, or represented to be undertaken, for a therapeutic purpose.*

### Important Note

**Although the Medicines Act defines method of treatment, it does not go so far as to give approval to any method of treatment, except to regulate how a method of treatment is advertised. It is the responsibility of the particular professionals to be able to justify what conditions their methods of treatment are reasonably expected to be able to treat. Some have more robust evidence than others, so the individual professionals are expected to have robust evidence base that can be verified.**

Only Medical Devices, Medicines and Methods of Treatment (as defined above) are able to make therapeutic purpose claims in advertisements. The therapeutic claims (to e.g. relieve swimmers ear, sinus pain and ear ache) and the mechanism of their effect (e.g. by removing wax, debris and moisturize from the ear canal through the process of convection) would need to be substantiated with evidence of this mechanism and with clinical trials that demonstrate the therapeutic effect. A Medical Device would be listed on the Medsafe WAND data base and a Medicine would have consent to distribute in NZ. The trials necessary to provide evidence would show a statistically significant and measurable effect. With this type of alternative therapy, it is usually not realistic to have this evidence, and the effect from any supporting information may in itself be a placebo effect, or be due to historical anecdotal reports.

### Therapeutic Claims

The type of claims that would classify Ear Candles as a Medicine or Medical Device and Ear Candling as a Method of Treatment are as follows:-

*Removal of ear wax and debris as a remedy to;*

- *relieve ear or nose of throat pain*
- *assist in the relief of pain*
- *assist / help reduce pain and inflammation associated with ear infections, sinus and throat pain*
- *assist with poor lymphatic circulation*

### **Acceptable Claims**

The type of claims that could be used for Ear Candles that are not notified as a medicine or medical device or Ear Candling that is not a method of treatment are as follows:-

*Ear Candling is used to;*

- *soothe and comfort the ear canal*

### **Unacceptable Claims**

Examples of the type of claims that cannot be used for Ear Candles or Ear Candling because they are not a medicine or a notified medical device or a method of treatment as defined in the Medicines Act, respectively, or because there is a lack of robust substantiation to support the claim, include but are not limited to the following:

#### **Ear Candling using Ear Candles**

- a remedy for removing excess ear wax
- removes debris from ear
- having pain relieving properties
- relives Swimmer's Ear
- relieves ear ache
- treats or relieves sinus problems
- assists in pain relief in ear aches or sinus issues
- reduces pain and inflammation associated with ear aches
- assists poor lymphatic circulation.
- the vast majority of people feel it is a gentle enough for use on children and those with painful ear infections
- removes moisture in the ear
- excellent in the treatment of nose and throat congestion, sinusitis, headaches, J.M.J pain, tinnitus, and otitis external/tropical ear. Ideal relaxation treatment for stress or anxiety related symptoms. Softens earwax for easy removal
- safe and a helpful treatment to assist for ear, nose and throat problems
- removes toxic residue from medication

### **Warnings to be included**

Because there is a risk of hot wax burning, scalding or causing pain it is recommended that warning statements be displayed in advertising to alert consumers to the dangers. For example:

- It is recommended that advertisements contain the following statements;
  - *Ear Candling has risks. Ask your Ear Candle provider or Ear Candling service provider to explain these to you. Check with your healthcare professional to be sure this procedure is suitable for you.*

