

TODS | therapeutic advertising pre-vetting service

GUIDELINE 4 General	Guide for Advertisers when promoting products such as amber teething necklaces
Last Updated	November 2013
What kind of product is this guideline for?	Amber beads / necklace / jewellery
What is the purpose of this guideline?	To provide background and guidance on advertising these products in New Zealand.

BACKGROUND

Amber has been worn for centuries as a traditional folk remedy for naturally supporting good health. Wearing amber in the form of a necklace is a traditional European practice for teething babies. In this form they are sold as items of folk jewellery¹.

When therapeutic claims are made for the amber bead necklaces or bracelets, the products then become classified as either Medicines or Medical Devices. This requires that the product be either approved as a Medicine or notified as a Medical Device with Medsafe. The sort of claims made for the products determine which category may be applicable.

This Guideline has been prepared in consultation with Medsafe and the Advertising Standards Authority, along with the Therapeutic Advertising Pre-vetting Service Adjudicators. Also refer to the Consumer Protection website.

Medicines

Claims that the beads have a therapeutic effect by releasing chemicals which are absorbed through the skin, would classify the beads as a medicine.

Medical Devices

Claims that the beads have a therapeutic effect through the wearing only would classify the beads as Medical Devices.

In either case, the therapeutic claims and the method of their effect would need to be substantiated in Clinical Trials that demonstrated efficacy. Such trials would be double blinded

against a placebo and show a statistically significant and measurable effect. With these traditional Folk products, this is fairly often not realistic, and the effect may in itself be a placebo effect, or be due to historical anecdotal reports.

Therapeutic Claims

The type of claims that would classify these products as Medicines or Medical Devices are as follows:-

- a remedy
- having pain relieving properties
- assists in pain relief
- a great pain reliever for babies when first teeth are growing
- a reduction in pain and inflammation associated with teething, ear aches, fevers, upset tummies and a lack of appetite
- when warmed against the skin, releases its therapeutic properties safely and naturally to ease teething pain in babies
- reduces body temperature
- drops the body temperature and calms the baby down
- support soothing of your baby's teething troubles,
- support soothing of teething trouble
- fight infections and improve the body's immunity
- contains a natural analgesic that will keep baby calm without resorting to drugs
- assists in reducing teething symptoms
- good for breathing

Acceptable Claims

The type of claims that could be used for the amber bead products that are not approved as medicines or notified medical devices are as follows:

- Traditionally used when baby is teething
- Traditional European use for babies who are teething
- A traditional necklace for teething babies

Warnings to be included

Because there is a risk of strangulation or choking it is recommended that warning statements be displayed in advertising to alert parents to the dangers. Some points to consider are below:

Amber necklaces are made for wearing, not for chewing.

- Babies should be supervised when wearing amber necklaces as there is a risk of strangulation and choking if the beads become loose.
- Some amber necklaces have knots between individual beads to help lower this risk.
- Amber necklaces should be removed from a baby when the baby is unattended even if
 this is likely to be for a very short period of time. Babies should not be left wearing
 necklaces while sleeping whether that is during the day or overnight.

Unacceptable Claims

Examples of the type of claims that cannot be used for the amber bead products that are not approved as medicines or notified as medical devices include but are not limited to the following:

Amber Teething Necklaces

- Do they really work? Yes they do
- Baltic Amber contains Succinic Acid which is a natural component of plant tissues. It is known to have a positive effect on our cellular metabolism
- When amber is warmed on the skin, the skin's warmth causes the amber to release trace amounts of healing oils
- The amazing quality of amber is ionization which helps protecting [sic] human body from various magnetic fields (amber absorbs some waves, including radioactive ones)
- Sometimes amber is counterfeited using a plastic resin (ambroid) which does not contain
 the active ingredient succinic acid. This could explain why some amber teething necklaces
 are less effective.
- If the beads are worn during the day, this will be enough for the oils to work during the night.
- They help in relaxing, calming the body down, but only when there is a contact with the
- When warmed against the skin, [amber] releases its therapeutic properties safely and naturally
- In contact with your baby's skin, the amber warms and the beads release healing oils to help
- How does Baltic Amber work? No one knows exactly how or why Baltic amber works
- Because Baltic amber teething necklaces have not been scientifically proven we cannot make any claims as to their effectiveness
- Baltic amber teething necklaces have been a traditional remedy for teething babies in the Balticregions for centuries
- Relieve or assist with teething pain in babies.
- Calm babies
- Baltic amber will help calm a baby without resorting to drugs
- If the child is having a bad day with teething, the necklace can be placed under the sunlight. This will make the oil to be released quicker

Mothers

- For pregnant and breastfeeding moms... It's soothing effect can lead to have more restful sleeps and reduced anxiety
- May assist in post-partum recovery
- Wearing Baltic Amber near the breast during feeding may help reduce inflammation, tenderness and mastitis

General

- Have immune-boosting properties
- Fight allergies
- Reduce body temperature
- Assist with breathing
- Are a natural analgesic
- Have anti-inflammatory properties or reduce inflammation
- Are a non-invasive remedy for the side effects associated with teething, such as ear ache, fevers, upset tummies and lack of appetite.
- Have therapeutic qualities
- Pain relief from head and back aches
- Amber has immune booting properties and helps with many other ailments including eczema, growing pains and even arthritis
- Release healing oils
- All resin colours have the same therapeutic qualities
- There is no mystic in Baltic amber, just huge amount of succinic acid which has anaesthetic and anti-allergic characteristics