



SUBMISSION

**TGA CONSULTATION:
OPTIONS FOR THE
FUTURE REGULATION
OF “LOW RISK”
PRODUCTS**

May 2017

NICM

The science of integrative medicine



PREAMBLE

NICM is Australia's leader in integrative medicine research and policy development. The Institute was established with bilateral support from the Commonwealth Coalition Government and the New South Wales Labour Governments in 2007. As an Excellence in Research Australia (ERA) 5 ranking institute, NICM is globally recognised for its world-class research, from preclinical studies to translation to healthcare.

NICM provided an extensive submission to the Australian Government Review of Medicines and Medical Devices Regulation in 2015.

NICM's response to the TGA Consultation Paper: Options for the future regulation of 'low risk' products released in March 2017 is outlined below.

Many of the items included in this TGA Consultation Paper fall outside of NICM's areas of research expertise (for example disinfectants, sunscreens) for which NICM defers to other more relevant and experienced agencies to provide informed comment.

For the purposes of this consultation paper NICM has limited its responses to its key areas of research expertise, including herbal and nutritional medicine and/or practices included within Chinese medicine. NICM has also not provided further response where the pathway forward is already clearly delineated within the TGA Consultation Paper.

EAR CANDLES

Do you have a view on which (if any) of the options for ear candles would be the most appropriate way forward? If so, please provide details on potential impacts to public health, access in the marketplace, business operations etc. Any alternative recommendations would also be welcome.

NICM recommends Ear Candles continue to be regulated by the TGA as “Other Therapeutic Goods” (Option 1 – Maintain the status quo regulation). However, NICM further recommends that the TGA formally review ear candles to assess if they should continue to maintain low risk status.

A brief systematic review of the scientific literature outlined below found eight papers on ear candling from twelve papers retrieved.¹⁻¹² This included only one scientific study⁸ that refutes the purported mechanism of action of ear candles and demonstrated that residue presumed by users to be ear wax (cerumen) is in fact candle wax. In addition, a clinical study reported in the same paper demonstrated that no cerumen is removed on using ear candles and that candle wax can be deposited into ears. A New Zealand case study¹ which found candle wax deposits in the ear of a four-year old girl supports these findings. A clinical survey of Ear, Nose and Throat specialists⁸ found evidence of potential harm through the use of ear candles in 20 patients.

It appears the scientific evidence suggests that ear candles do not work; that the residue left after burning which is used as evidence of effectiveness is in fact an artefact; and that the use of ear candles is associated with the potential for harm.

On this basis, Health Canada recommends to Canadians they avoid ear candling considering it dangerous and without proven medical benefits. It regulates ear candles as a medical device and has not issued any licences. They state that selling ear candles for medical reasons in Canada is illegal; and both Canada and the United States have banned the importing of ear candles.¹³

It is on this basis NICM recommends that the low risk status of ear candles be reviewed.

Brief Systematic Literature Review

A search on the term “ear candles OR ear candle” in Medline using the US National Library of Medicine National Institutes of Health PubMed.com interface undertaken on 4 May 2017 demonstrates there are 12 papers on the topic.¹⁻¹² Four papers can be excluded, as one is a paper on antimicrobial susceptibility;⁴ one on a rare bone dystrophy;⁶ one refers to candle power and not to the use of ear candles themselves;¹² and another to a biography.² The remaining eight papers pertain to ear candling.^{1, 3, 5, 7-11}

The eight papers on ear candling can be divided into types of articles: an editorial;⁹ a professional alert;¹⁰ a case study;¹ two letters to the Editor;^{7, 11} a narrative review;⁵ a mechanistic and clinical study and professional survey;⁸ and a general article on cerumen impaction.³

None of the papers recommend ear candling. The editorial recommends that due to potential harm they should not be used⁹ and introduces the professional alert¹⁰ which states the advantage in cost is outweighed by the lack of efficacy and risk in using the device.

Responding to this alert, two researchers wrote a letter to the editor⁷ concerned about the lack of data cited to support the assertions made and reference a second letter¹¹ to a different journal where they outline the key results of a mechanistic and clinical study and professional survey.

This mechanistic and clinical study and professional survey was published in *Laryngoscope* in 1996 and may be one of the only scientific studies to be undertaken on ear candles.⁸ The case study reports on a four-year-old girl who was found to have deposits covering the medial ear canal and eardrum which resulted from regular ear candling.¹ The narrative review primarily outlines the results from the mechanistic and clinical study and professional survey with the addition of two citations from non-peer reviewed sources.⁵

The general article on cerumen impaction cites the scientific study and narrative review and recommends that ear candling should be avoided.³

The only scientific study undertaken on ear candles⁸ demonstrated that ear candling does not create a negative pressure which refutes the purported mechanism of action to draw ear wax (cerumen) from the ear canal. It also analysed the residue found in the base of the ear candle after burning by gas chromatography and mass spectroscopy and determined it was composed of multiple alkanes consistent with candle wax.

The clinical component of this study was undertaken in eight participants (four with no cerumen and four with cerumen impaction). No cerumen removal was found in the ears with cerumen impaction; and wax became deposited in two of the four (50 per cent) cerumen-free ears.

A survey sent to the membership of the Northwest Academy of Otolaryngology – Head and Neck Surgery in the USA (n=163) returned 122 responses giving a 75 per cent response rate. They found that 14 physicians had treated patients with complications of ear candle use totalling 21 injuries in 20 patients which included 13 burns of the auricle and external auditory canal, seven partial or complete occlusions of the ear canal with candle wax and one tympanic membrane perforation. External otitis (external ear canal inflammation) occurred in three of these cases and temporary hearing loss in six cases.

AROMATHERAPY PRODUCTS

Do you have a view on which (if any) of the options for aromatherapy products would be the most appropriate way forward? If so, please provide details on potential impacts to public health, access in the marketplace, business operations etc. Any alternative recommendations would also be welcome.

NICM recommends aromatherapy products presented for therapeutic use in a therapeutic form continue to be regulated by the TGA under the current provisions (Option 1 - Maintain the status quo regulation).

Essential oils are volatile, natural, complex mixtures extracted from aromatic plants.¹⁴ They have a wide range of biological activity including antimicrobial, anti-inflammatory and antioxidant activity.^{14, 15}

It is important essential oils meet appropriate quality standards as changes in aromatic constituent profile of an essential oil may change the nature of their biological activity and risk safety in use.¹⁶ It is therefore important that essential oils for therapeutic use are manufactured under GMP conditions and meet pharmacopeial and other standards for composition, including limits for potentially hazardous constituents.

Essential oils are applied by indirect and direct inhalation and through massage onto the skin. As they are highly volatile and fat soluble they are easily absorbed through mucus membranes and the skin.¹⁶ They are also administered orally which should be very carefully assessed by the TGA since some essential oils have a very low therapeutic index.¹⁶

Acute, subacute and chronic toxicity has been reported following the use of essential oils¹⁶ and it is important that they remain controlled as listed or registered therapeutic goods with appropriate standards for composition, manufacture and post-market vigilance, including the assessment of adverse reaction reports.

Essential oils are packaged as therapeutic goods, make claims as therapeutic goods and have the potential for adverse reactions which may be made worse if manufactured in a sub-standard way. It would therefore be inappropriate for essential oils to be exempted from inclusion on the ARTG or not to be manufactured under GMP.

VITAMINS AND MINERALS

Do you have a view on which (if any) of the options for vitamin and mineral products would be the most appropriate way forward? If so, please provide details on potential impacts to public health, access in the marketplace, business operations etc. Any alternative recommendations would also be welcome.

NICM recommends vitamin and mineral products presented for therapeutic use in a therapeutic form continue to be regulated by the TGA under the current provisions (Option 1 - Maintain the status quo regulation).

Consistent with the quality use of medicines and their safety-in-use, vitamins and minerals require controls over manufacture, quality, posology, indications, labelling requirements, advertising and post-market vigilance. NICM does not support the exemption of certain vitamins and minerals from these standards. Such a policy has the potential to lead to consumer confusion and loss of confidence in the regulation of this class of nutrients.

While the routine use of multivitamin and mineral preparations is currently debated, there are many population subgroups, including the elderly, women of child-bearing age and the institutionalised that are predisposed to vitamin and/or mineral deficiency where supplementation may be appropriate.¹⁷⁻¹⁹ In these individuals, it is critical that any supplement be manufactured to the highest standard and delivers the nutrients in appropriate amounts. In this population, it is also appropriate to capture any adverse events and ensure that health professionals are capable of being notified when a cluster of reactions provides a strong enough signal of concern. There also needs to be an appropriate mechanism for rapidly withdrawing dangerous or non-compliant products from the market. These are characteristics of the good manufacture and appropriate monitoring of therapeutic goods which form part of the regulation of medicines under the TGA. It is essential that the status quo be maintained to continue to ensure the public safety of these products.

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nicm.edu.au

p. +61 2 4620 3284
e. nicm@westernsydney.edu.au
a. Locked Bag 1797 Penrith NSW 2751 Australia

