TGA CONSULTATION: OPTIONS FOR THE FUTURE REGULATION OF "LOW RISK" PRODUCTS

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Summary

Clear, accurate and prominent labelling informing the public on lack of efficacy must be obligatory on all non-evidence based health products and diagnostic devices.

Background: The Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) made three recommendations (accepted by government) in relation to performing further reviews of the regulation of 'low risk' products (MMDR recommendations 14, 23 and 48).

In making these recommendations, the expert panel expressed the concern that "there are a range of products listed in the ARTG that are subject to a level of regulation which is not commensurate with the risk posed by these products to Australian consumers".

What is low risk? The conclusion that the products identified in this consultation posed little or no risk to consumers appeared to largely depend on the direct risk or harm these products might produce. Indirect harm, caused by misleading, unbalanced or incorrect labelling &/or claims did not appear to be considered. The latter more commonly harm consumers through delaying their access to more evidence-based products, sometimes to the detriment of their health, and by imposing unnecessary costs.

Problems with the reform options identified: Three main options for reform were identified: maintain status quo regulation; exempt from listing in the ARTG &/or GMP, or declare the product not to be a therapeutic good.

For the non-evidenced based products we have identified, we submit that maintaining the status quo fails to consider the many suggestions for improving their regulation that have arisen from previous consultations, numerous upheld complaint determinations by the Therapeutic Goods Advertising Complaint Resolution Panel and submissions to the Therapeutic Goods Advertising Code Council.

Exemption from listing provides no regulatory barrier to market entry and is likely to increase the number of inappropriate &/or substandard products making misleading claims.

Exclusion from the therapeutic goods regulatory framework means these products would be regulated as consumer goods under the auspices of the Australian Competition and Consumer Commission (ACCC) and Australian Consumer Law. Given the wide-ranging brief and enormous workload of the ACCC this would effectively mean no regulation at all, as the ACCC only has the resources to act on the most egregious cases.

In addition, the problem is broader than merely regulating the products; it also involves many non-registered, alternative health practitioners who promote and use these products, often outside their ARTG listed indications or intended purpose.

We understand that the TGA regulates products, not practitioners. However, we argue that the TGA has an educative responsibility to consumers, health practitioners and professional organisations when it becomes aware that products it regulates are causing consumer detriment by being misused &/or mispromoted.

In conclusion: We advocate that the TGA, as a specialist regulator, retains responsibility for regulating the products we have identified. However, more needs to be done to protect consumers by the application of mandatory product warnings, more stringent post-marketing surveillance, higher penalties for regulatory non-compliance and the education of the public and non-registered health practitioners who often inappropriately promote and use these products.

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Background

The Expert Panel Review of Medicines and Medical Devices Regulation (MMDR) made three recommendations (accepted by government) in relation to performing further reviews of the regulation of 'low risk' products (MMDR recommendations 14, 23 and 48).

In making these recommendations, the expert panel expressed the concern that "there are a range of products listed in the ARTG that are subject to a level of regulation which is not commensurate with the risk posed by these products to Australian consumers".

What is low risk? The Government agreed that this review focus on the range of products that poses little or no risk to the health of consumers. This raised the question of how to define 'low risk' for the purposes of these recommendations.

Six broad criteria for risk assessment for both medicines and medical devices were identified: safety; use; claims made; condition being diagnosed, treated and/or prevented; nature and size of the population using the product, and the impact of poor product quality. An additional criterion was the 'degree of regulatory familiarity' by which 'everyday' use of products by consumers with well-known regulatory risks lowers their risk when used correctly.

The conclusion that the products identified posed little or no risk to consumers appeared to largely depend on the direct risk or harm these products might produce. Indirect harm, caused by misleading, unbalanced or incorrect claims did not appear to be considered. The latter more commonly harm consumers through delaying their access to more evidence-based products, sometimes to the detriment of their health, and by imposing unnecessary costs.

Problems with the reform options identified

Three main options for reform were identified: maintain status quo regulation; exempt from listing in the ARTG &/or GMP, or declare the product not to be a therapeutic good.

For certain non-evidenced based products we have identified, the options provided failed to consider many suggestions for improving the regulation of these product that have arisen from previous consultation, numerous upheld complaint determinations by the Therapeutic Goods Advertising Complaint Resolution Panel (TGACRP) and submissions to the Therapeutic Goods Advertising Code Council (TGACC).

We illustrate our concerns by considering in detail the problems that have arisen with certain products identified in the recommendations. We do not comment on the questions raised about the remaining products.

Recommendation Fourteen: A review of the range of products currently listed in the Australian Register of Therapeutic Goods (ARTG) (not including complementary medicines) and subject to regulation under the medicines framework, with a view to ensuring that:

1. Products that might best be regulated under other regulatory frameworks, without undermining public health and safety, are removed from the auspices of the Act; and
2. Goods remaining under the auspices of the Act are subject to regulatory requirements that are commensurate with the risk posed by the regulated products.

The following low risk products, currently regulated as medicines and other therapeutic goods (other than herbal complementary medicines), were identified for the purposes of this recommendation: Ear candles; Nappy rash creams; Antiperspirants; Hard surface disinfectants; Sunscreens; Tampons and

menstrual cups, and low risk OTC products such as antiseptics for first aid treatment of minor cuts and abrasions, lozenges for relief of sore throats, antacids, etc.

Illustrative products

Ear candles: Ear candling is an alternative medical practice (often practiced by naturopaths) that involves inserting and lighting a hollow candle in the ear canal.

As with listed medicines, there is no pre-market evaluation by the TGA of Class 1 medical devices. In theory, the listing application process for ear candles should ensure that the presentation, claims and labelling for these products are appropriate and that the product is safe.

In practice, sponsors can, and do, say whatever they like in their promotion and on the ARTG public summary document subject. The only check is the complaint system and rare post-marketing reviews by the TGA.

It is often claimed that ear candles remove excess wax from the ears and promote relaxation and general wellbeing. Additional claims state that candling may assist with tinnitus (ringing in the ears), headaches, sinusitis, swimmers ear, migraines, glue ear and bacterial infections such as tonsillitis. It is also claimed that certain candles are "TGA approved".[1]

In fact, ear candles (and candling) are ineffective and dangerous. They do not remove wax from the ear and have caused injury from burns, ear canal occlusions, ear drum perforations and secondary ear canal infections with temporary hearing loss.[2,3]

Neither the current promotion of these products, nor their ARTG Public Summary documents point out these dangers.

There have been at least 20 complaints about ear candles upheld by the TGACRP on various grounds, such as claims that candling removes wax could not be substantiated, and statement that products have "TGA approval" is not allowed.[4] Given the lack of effective sanctions against upheld complaints more definitive regulatory action has been suggested.

The U.S. FDA and Health Canada have acted against manufacturers of ear candles by providing public warnings, import alerts, seizures, injunctions, and warning letters.[5]

The TGA suggests the following options:

1. Maintain the status quo: this will do nothing to address the problems described above;
2. Exempt from listing: likely to increase supply (as no listing fee) and exacerbate the problems described above;
3. Exclude from the regulatory framework (regulated solely as consumer goods under the auspices of ACCC): this handballs responsibility to the ACCC which would effectively mean no regulation given the ACCC workload and greater priorities.

[1] http://www.melbournenaturalwellness.com.au/ear-candling
[2] http://www.audiology.org/news/ear-candles-and-candling-ineffective-and-dangerous
[3] https://www.quackwatch.org/01QuackeryRelatedTopics/candling.html
[4] http://www.tgacrp.com.au/complaint-register/?_search=ear%20candles
[5] https://www.fda.gov/forconsumers/consumerupdates/ucm200277.htm

Questions

Do you have a view on which (if any) of the above 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.

We believe that none of the above options will protect consumers from the false claims and dangers associated with these products. In addition, the problem is broader than merely regulating the products; it also involves non-registered practitioners such as naturopaths who promote the application of these products.

We advocate:

1. The TGA as a specialist regulator should retain responsibility for these listed products **BUT** ensure that a prominent warning is provided on their ARTG Public Summary documents, product packaging, labelling and promotion, for example,

   Warning: these products do NOT remove wax or other impurities from the ear and have been associated with INJURY including burns, ear drum perforations and ear canal infections.

2. The TGA should conduct a targeted post-marketing review on these products to ensure that the above warning is complied with.
3. The TGA should provide a public warning about these products on their web site like that provided by the U.S. FDA.
4. The TGA should convey this warning to the organisations listed in Schedule 1. Part 2 of the Therapeutic Goods Regulations 1990[6] and ask them to pass it on to all their members.

Recommendation Twenty-Three: A review of the range of products currently classified as Class I medical devices, with a view to reclassifying products as consumer goods in circumstances where the product poses little or no risk to consumers should it not perform as specified or malfunctions.

No specific products have been singled out under this review; rather the following actions are proposed: systematically review the ARTG for potential non-therapeutic goods; engage with States and Territories; update the Excluded Goods Order, and review Class I medical device ARTG entry process.

Prior to the current medical devices regulatory framework, a range of products of **dubious evidence or non-therapeutic purpose** were declared not to be therapeutic goods. The wording of these exclusions from the 1998 Excluded Goods Order is as follows:

- Non-implantable devices, equipment or apparel intended for use in; improving comfort, enhancing relaxation, exercising or improving physiological fitness, modifying anatomical physique, improving appearance, muscle or skin tone, easing minor aches and pains, fatigue or tiredness (due to normal ageing or day to day activities), or stimulating circulation (via exercise or the application of heat or massage)

[6] https://www.tga.gov.au/schedule-1-therapeutic-goods-regulations-explained

- Devices that emit, measure or absorb, or claim to emit, measure or absorb, vibrations, waves, particles, or energy for which health benefit claims are made, the principles of which have not been scientifically validated.

These exclusions were subsequently removed with the intention that these types of products would be assessed during the application process to include them in the ARTG, which would then be an effective barrier to market for these types of products. **This intention has not been realised as the subsequent automatic inclusion process developed for most Class I medical devices does not include the level of review intended and has instead resulted in such products being included in the ARTG.**

There are many devices in the above category (also Medical Device Included Class IIa) making diagnostic and therapeutic claims that lack substantiation and used by sponsors and alternative health practitioners to prey on consumers.

Illustrative products

- **DeTox Foot Pads** (e.g. ARTG entry 201148, Medical Device Included Class 1, Detox Foot Patches Australia). Intended purpose: To Absorb (To Draw into Itself) Undesired Toxins from the Body.[7] Users are instructed to apply the products to the soles of the feet and leave them on overnight. In the morning, proponents claim, the pads will absorb toxins and turn muddy brown or black. At least 20 complaints about these products have been upheld by the TGACRP.[8]
- **BIOCOM machine** (ARTG entry 138918, Medical Device Included Class IIa, BICOM Australia Pty Ltd - Biofeedback system). A bio-resonance machine which is said to pick up specific frequency patterns from a patient (or from substances that harm or stress the organism) via input electrodes. Inside the device these frequency patterns are modulated, depending on the program selected by the therapist, and applied to the patient via output electrodes promoting the healing process.[9] Said to test and treat conditions such as food allergy, hay fever, skin rashes and respiratory problems, Chemical Toxicity or Sensitivity, Digestive Complaints and Irritable Bowel Syndrome (IBS), Viral, Bacterial and Parasitic Infections, Chronic Fatigue, etc.[10] At least 4 complaints about these machines have been upheld by the TGACRP.[11]
- **BIOPTRON machine:** (cancelled from the ARTG in 2010, relisted in 2012, ARTG entry 197700, Medical Device Included Class IIa, Zepter International Pty Ltd - Light therapy unit, photo). Intended purpose: light therapy unit that to be used in combination with other medical treatments for wound healing and pain relief. Promoted as, "A breakthrough in light healing! Clinically tested, proven & certified. No known side-effects. What it treats: Anti-Ageing, Pain, Wounds, Skin Problems, Sports Injuries, Children".[12] Also Claims to be able to treat patients based on the colours of their Chakras.[13] At least 20 complaints about this product have been upheld by the TGACRP.[14].
- **Vega (electro-diagnostic) machines** which claim to detect disease by measuring changes in body electrical currents. An allergen (such as food extract) or a homoeopathic substance may be placed a sealed glass container and brought into the electrical circuit. An alteration in

[7] http://www.detoxfootpatches.net.au/
[8] http://www.tgacrp.com.au/complaint-register/?_search=detox%20foot
[9] https://www.bicomaustralia.com.au/about
[10] http://www.sydneybicom.com/
[11] http://www.tgacrp.com.au/complaint-register/?_search=BICOM
[12] http://www.bioptron.com.au/What-it-Treats/Medical-Health.aspx
[13] http://www.heavenlyenergies.com.au/bioptron-light-therapy.php
[14] http://www.tgacrp.com.au/complaint-register/?_search=Bioptron

current is interpreted as meaning the person is "sensitive" to that substance.[15] At least one complaint about this machine has been upheld by the TGACRP.

- **VoiceBio machine:** said to be based on the concept that internal organs communicate with each other via sound waves, with each organ vibrating at certain frequencies, and with organ dysfunction being detectable by analysis of such frequencies using a computer assisted analysis of the patient's voice.[16] No complaints yet.
- **Magnet Therapy** (e.g. ARTG entry 222810 Medical Device Included Class 1 The Natural Group Pty Ltd - Static magnetic bedding). *"My own experiences had convinced me of the vital role magnetic energy plays in health and rejuvenation. My research uncovered hard science to back it up; the revelation that every living thing, even the smallest of atoms, is affected by a magnetic field."*[17] At least 20 complaints about this product have been upheld by the TGACRP.[18]
- **Hemaview diagnostic machine (not on ARTG)** 'Hemaview' Live blood analysis can identify the instances of: nutritional deficiencies, organ system dysfunctions, gut permeability & digestive health, chronic infections such as candida, allergic reactions, antioxidant levels and free radical damage, your immune system activity, etc.[19] At least one complaint about this product have been upheld by the TGACRP.[20] See also Quackwatch.[21]

It is proposed to systematically review the ARTG for potential non-therapeutic goods; engage with States and Territories; update the Excluded Goods Order and review Class I medical device ARTG entry process.

Questions

Do you have a view on any (or all) of the above actions for **Class I medical devices?** If so, please provide details on potential impacts to public health, access in the marketplace, business operations etc.

Do you have a view on any specific product types currently included in the ARTG that should specifically be considered during the review Class I medical devices in the ARTG? If yes, please provide reasoning.

Any alternative recommendations would also be welcome.

We suggest extending this review to other Medical Device classes, e.g. Class IIa BICOM machine above. In addition, we do not believe that exclusion of these devices from the ARTG will solve the problem of their extensive use by alternative health practitioners. As with ear candles above, we advocate:

1. The TGA as a specialist regulator should retain responsibility for devices that make therapeutic claims (or are used by practitioners to do so) **BUT** if the sponsor cannot substantiate the claims made then a prominent warning must be placed on their ARTG Public Summary documents, product packaging, labelling and promotion, for example,

[15] http://www.naturopathaustralia.com/services/the-vega-method
[16] http://www.helpingnatureheal.com.au/modalities/voicebio-voice-analysis
[17] https://www.thenaturalgroup.com.au/pages/magnetic-therapy
[18] http://www.tgacrp.com.au/complaint-register/?_search=magnetic
[19] http://stepintohealth.com.au/services/hemaview/
[20] http://www.tgacrp.com.au/complaint-register/?_search=hemaview
[21] https://www.quackwatch.org/01QuackeryRelatedTopics/Tests/livecell.html

Warning: there is no scientific evidence that supports the use of this device for diagnosis &/or treatment.

2. The TGA should conduct a targeted post-marketing review on these products to ensure that the above warning is complied with.
3. The TGA should provide a public warning about these products on their web site.
4. The TGA should convey this warning to the organisations listed in Schedule 1. Part 2 of the Therapeutic Goods Regulations 1990[22] and ask them to pass it on to all their members.

Recommendation Forty-eight: A review of the range of complementary medicinal products, currently listed in the ARTG and subject to regulation under the medicines framework, with a view to ensuring that products that might best be regulated under other regulatory frameworks, without undermining public health and safety, are removed from the auspices of the Act The following product categories were identified: aromatherapy products; rehydration formulas; certain vitamins and minerals (particularly water soluble ones at low-doses), and homoeopathic products.

Illustrative products

Vitamins, minerals, fish oil, etc.

These products currently demonstrate problems of unsubstantiated claims, failure to identify key ingredients such as sugar, and different rules depending on whether the products are classified as complementary medicines or foods.

For example, Nature's Way Kids Smart Vita-Gummies Multi-Vitamin for Fussy Eaters (ARTG entry: 287639) says, "specially formulated with essential vitamins, minerals and vegies to help fill nutritional gaps and zinc to help boost appetite".[23] Yet, zinc is readily available in foods such as meat, fish and poultry while cereals, grains and dairy foods also contribute substantial amounts. We are unaware of any evidence that zinc boosts the appetite of "fussy eaters". Better strategies are available for "fussy eaters".[24]

In addition, the ingredient list of this product merely says, "contains sugars". For complementary medicines, we understand there is a requirement to declare the presence, but not the quantity, of sugars on the label. For food, there is a requirement to disclose the total content of sugars on the nutrition information panel on the product label. Thus, gummies that are not ARTG listed such as, Bioglan Kids Gummies Omega 3 – Nemo, (presumably regarded as a food), state formulation: sugars 2.0g per serve (2 gummies).[25]

Choice (the Australian Consumers' Association) is currently campaigning for Food and Health Ministers to act on added sugar labelling so that consumers can limit their consumption, as advised by the WHO and other authorities, for both dental and other health reasons.[26] We suggest that the TGA and FSANZ should resolve these anomalies.

There have been more than 36 complaints about products containing vitamins, minerals, vegetable powders and fish oil upheld by the TGACRP.

[22] https://www.tga.gov.au/schedule-1-therapeutic-goods-regulations-explained
[23] http://health365.com.au/shop/natures-way-kids-smart-vita-gummies-multi-fussy-60s
[24] https://www.betterhealth.vic.gov.au/health/healthyliving/toddlers-and-fussy-eating
[25] http://www.bioglan.com.au/products/kids-health/kids-gummies-omega-3-nemo/
[26] https://www.choice.com.au/food-and-drink/nutrition/sugar/articles/added-sugar

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The TGA suggested three options for reform: maintain the status quo regulation; exempt from listing in the ARTG and/or GMP or declare vitamins and mineral not to be therapeutic goods.

Questions

Do you have a view on which (if any) of the above 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.

None of these options will fix the problems listed above. We advocate:

1. That vitamin, mineral and similar products (including omega-3 supplements) be regulated as listed therapeutic goods and only allowed to make low-level claims (unless they qualify for the proposed new complementary medicine regulatory pathway);
2. That the sugar content of complementary medicine "gummies" and similar products be specified, as for foods, on public health grounds.
3. That the specific labelling requirement for vitamins (s.4(7)(2) of the Therapeutic Goods Advertising Code 2015) be extended to apply to all products containing vitamins, mineral, food powders and omega-3 fatty acids, changed to read:

   Warning: Supplements containing vitamins, mineral, food powders and fish oil are no substitute for a healthy balanced diet".

Homeopathic products

There have been long-standing concerns by consumers and health professionals about the regulation of these products and the claims they make. A 2008 consultation produced many recommendations but, typically, no action by the TGA.[27]

There have been more than 11 complaints about these products upheld by the TGACRP.[28]

There have been concern that the claims made for certain homeopathic products, such as homeopathic melatonin[29] do not fit the homeopathic tradition and continue to be promoted, despite upheld TGACRP complaints. There is concern that the promotion of homeopathic Baby & Child Cold & Flu remedies can cause unsuspecting parents to forego more evidence based medicines, such as ibuprofen, that could better address their child's symptoms.

In addition, most consumers do not understand homeopathic principles, are not aware that these principles lack scientific validity, and are confused by Latin terminology, such as Natrum Muriaticum (instead of salt), which obscure the names of the ingredients and exploits the lack of knowledge of consumer, as does the use of decimal (X) and centesimal (C) dilutions.

The TGA suggested four options for reform: maintain the status quo regulation; serious therapeutic claims must be supported by scientific evidence, exempt from listing in the ARTG and/or GMP or declare homeopathic products not to be therapeutic goods.

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[27] https://www.tga.gov.au/regulation-homoeopathic-and-anthroposophic-medicines-australia
[28] http://www.tgacrp.com.au/complaint-register/?_search=homeopath
[29] http://www.pretoriusvitamins.com.au/supplements/melatonin-90s

Questions

Do you have a view on which (if any) of the above options for **homoeopathic 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.

Comments on the potential development of a new definition for what a 'homoeopathic' product represents are also sought.

Any alternative recommendations would also be welcome

Our comments follow:

1. **Maintain the status quo regulation of homoeopathic products:** this continues the risk of implying government endorsement of non-evidence-based products and fails to address the problems outline above.
2. **Serious therapeutic claims must be supported by scientific evidence:** this is absurd because there is no evidence supporting homeopathic products making serious therapeutic claims (despite a recent TGA decision about one such product, Restless Legs Relief).[30] It also allows minor claims to be made in relation to self-limiting conditions by invoking the using the "traditional paradigm" which, without a disclaimer about the lack of scientific evidence underpinning homeopathic products, will continue to mislead consumers.
3. **Exemption from listing in the ARTG and/or GMP:** it was suggested this could result in a greater range of products for consumers - hardly a desired public health outcome! It also runs a greater risk of sub-standard products, e.g. Hyland's Homeopathic teething tablets recall and inappropriate therapeutic representations &/or claims. Such problems would only be identified a long time after they occurred by consumer complaints, adverse event reports or targeted compliance reviews.
4. **Declare homeopathic products not to be therapeutic goods** (this would mean products being regulated solely as consumer goods under the auspices of ACCC, not a specialist regulator. Given the workload of the ACCC this would effectively mean no regulation at all as the ACCC only has the resources to act in the most egregious cases).[31]

In short, the consultation document fails to document many long-standing concerns about the supply and promotion of homeopathic products and, in our opinion, it fails to provide a viable solution to the problems outlined.

We advocate that all products making therapeutic claims by invoking the homeopathic tradition be regulated as listed products with the addition of a mandatory disclaimer / warning on their ARTG Public Summary documents, product packaging, labelling and promotion like that recently suggested by the U.S. FTC,[32] for example,

> **Warning: This product's traditional claims are based only on theories of homeopathy from the 1700s that are not accepted by most modern medical experts. There is no scientific evidence that this product works.**

[30] https://www.tga.gov.au/advert-exempt/advertising-exemption-martin-and-pleasance-restless-legs-relief
[31] https://www.accc.gov.au/media-release/court-imposes-penalty-for-false-or-misleading-claims-by-homeopathy-plus-and-ms-frances-sheffield
[32] https://www.ftc.gov/news-events/press-releases/2016/11/ftc-issues-enforcement-policy-statement-regarding-marketing

Public and non-registered health professional education by the TGA is also required.

In conclusion: We doubt that the regulatory options suggested by the TGA will protect consumers from the false claims and dangers associated with products we have identified.

We do advocate that the TGA, as a specialist regulator, retains responsibility for regulating these products.

However, more needs to be done to protect consumers by the application of mandatory product warnings, more stringent post-marketing surveillance, higher penalties for regulatory non-compliance and the education of the public and non-registered health practitioners who often inappropriately promote and use these products.