TGA CONSULTATION: DRAFT LIST OF PERMITTED INDICATIONS

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Summary

1. **The proposed list of permitted indications should be drastically shortened and only contain modest low-level indications such as, "may be helpful...", "may assist…", etc. If sponsors have evidence that would justify a higher-level claim then they should use the proposed new pathway whereby the TGA assesses the evidence before approving the claim.**
2. **The TGA should add an appropriate disclaimer on all products (and their promotion) making traditional claims via amending Therapeutic Goods Order No. 69 – General Requirements for Labels for Medicines 2017.1**

Concerns

Given the lack of pre-market evaluation of listed products, and the high levels of non-compliance with the requirement that sponsors must hold evidence to support their claims,[2] we believe this long draft list of permitted indications will have little impact on the current unacceptable level of misleading and deceptive claims by the complementary medicine industry. In addition, not requiring sponsors to use permitted indications "word-for-word" will provide additional opportunities for creative interpretation.

This problem will be exacerbated by the removal of advertisement pre-approval in media such as print, radio and television. Currently, the pre-approval process reviews over 2000 advertisements per year with an average turnaround time of 7 days.[3] Most advertisements reviewed require changes to avoid Code breaches; sometimes wholesale revisions. Pre-approval is the only defence against seriously misleading advertisements on prime-time television or in national newspapers, for example promoting a treatment for cancer.[4]

We understand that the reform package also contains increased post-marketing surveillance, a more effective complaint system, increased penalties and sanctions for regulatory violations and an industry education program. However, complaints and post-marketing reviews take a long time to remove bad advertisements. Prevention is better than cure. In addition, prevention is more economically efficient given that fraudulent therapeutic claims create unnecessary health expenditure.

We submit that the proposed list of permitted indications should be drastically shortened and only contain modest low-level indications such as, "may be helpful...", "may assist…", etc. If sponsors have evidence that would justify a higher-level claim then they should use the proposed new pathway whereby the TGA assesses the evidence before approving the claim.

The TGA's draft list also contains around 1000 indications for "traditional medicines" such as Homeopathic products, Traditional Chinese Medicines, etc. Australia is a multicultural society, and it is appropriate we respect and have some knowledge of alternative medical traditions. Some observations made in these traditions have led to valuable, efficacious medicines. A recent example is Artemisinin derivatives, used for treating resistant strains of malaria, isolated from a herb used in traditional Chinese medicine. However, scientific investigation has not substantiated many other aspects of these traditions, such as traditional Chinese medicine concepts of meridians through which

[1] https://theconversation.com/new-complementary-medicine-health-claims-lack-evidence-so-why-are-they-even-on-the-table-80896
[2] https://www.tga.gov.au/book/export/html/731370
[3] https://www.doctorportal.com.au/mjainsight/2016/38/advertising-reform-watering-down-consumer-protection/
[4] https://www.tga.gov.au/alert/black-and-red-salves-treating-cancer

the life-energy known as "qi" flows and the homeopathic principles of "like cures like". The NHMRC statement on homeopathy says:

> "Based on the assessment of the evidence of effectiveness of homeopathy, NHMRC concludes that there are no health conditions for which there is reliable evidence that homeopathy is effective".[5]

In addition, we cannot assume all traditional medicines are safe, as emerging data highlights that adverse reactions and drug interactions are not uncommon.[6] For example, In China, out of the 1.33 million case reports of adverse drug event reports received by the National Adverse Drug Reaction Monitoring Center in 2014, Traditional Chinese Medicine represented around 17.3% (equivalent to around 230,000 cases).[7]

The TGA "Guidelines on the evidence required to support indications for listed complementary medicines" states:

> "If you are aware that there is conflicting evidence between the history of traditional use and contemporary scientific evidence for your medicine, then it is advisable to include a statement to this effect in any labelling and advertising associated with the medicine, for example: 'this traditional use is not supported by scientific evidence'. This will ensure that the advertised information relating to your medicine is truthful, valid and not misleading".[8]

Given the above, for consumers to make informed choices about "traditional medicines", we submit it is essential that all such medicines contain a prominent disclaimer along the lines of what the US Federal Trade Commission uses for homeopathic products.[9] For example,

> "This product's traditional claims are based on alternative health practices that are not accepted by most modern medical experts. There is no good scientific evidence that this product works. In addition, a tradition of use does not guarantee safety".

Recommendation 44 of the Review advocated that a prominent disclaimer should be applied to the advertising material of all Listed complementary medicines, noting that efficacy claims for these products have not been independently assessed (my emphasis). This was opposed by industry and rejected by the current government, presumably because of industry lobbying and acquiesce by the TGA.

It is our impression that there is currently a move towards greater use of "traditional indications" by sponsors of complementary medicines as this eliminates their requirement to hold (and produce) scientific evidence for the claims made about these products. The large number of "traditional indications" placed by industry on the TGA draft list supports our impression.

We are concerned that the draft list of permitted indications, without disclaimers for traditional medicines, will accelerate this trend. It also provides government and TGA endorsement of pseudoscience. Worse, it will encourage consumers to purchase often ineffective and sometimes dangerous products. For example, the TGA advice on permitted indications states that the following TCM indication is acceptable:

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[5] https://www.nhmrc.gov.au/_files_nhmrc/publications/attachments/cam02_nhmrc_statement_homeopathy.pdf
[6] https://www.ncbi.nlm.nih.gov/pubmed/22374080
[7] http://www.sda.gov.cn/WS01/CL0078/124407.html
[8] https://www.tga.gov.au/publication/evidence-guidelines
[9] https://www.ftc.gov/system/files/documents/federal_register_notices/2016/12/homeopathic_drugs_frn_12-13-2016.pdf

> 'Dispel Wind Heat' (TCM indication) to 'help relieve mild migraine symptoms' (General indication).[10]

We are unaware of scientific evidence that TCM products can relieve migraine symptoms. We submit that encouraging patients with mild migraine to use an unproven TCM product when there are proven efficacious conventional medicines goes against the Objects of the Therapeutic Goods Act 1989 (s.4(1)(a)):

> "provide for the establishment and maintenance of a national system of controls relating to the quality, safety, **efficacy** and timely availability of therapeutic goods…" (my emphasis).[11]

The TGA should add an appropriate disclaimer on all products (and their promotion) making traditional claims via amending Therapeutic Goods Order No. 69 – General Requirements for Labels for Medicines 2017.[12]

[10] https://www.tga.gov.au/draft-list-permitted-indications-frequently-asked-questions#
[11] http://www.austlii.edu.au/cgi-bin/viewdoc/au/legis/cth/consol_act/tga1989191/s4.html
[12] https://www.legislation.gov.au/Details/F2017L00865/Html/