The Hon Greg Hunt MP
Minister for Health

Ms Catherine King MP
Shadow Minister for Health and Medicare
Member for Ballarat

Mr Tony Zappia MP
Shadow Assistant Minister for Medicare
Member for Makin

Parliament House
CANBERRA ACT 2600

Dear Ms King and Mr Zappia

Re: Therapeutic Goods Amendment (2017 Measures No. 1) Bill 2017

I am aware that in some stakeholder submissions to the Senate Community Affairs Legislation Committee Inquiry on this Bill, concerns were raised regarding certain aspects of proposed changes to complementary medicines regulation and the future arrangements to the advertising of therapeutic goods. I also note the additional comments made by Labor Senators' to the Report of the Senate Community Affairs Legislation Committee.

The measures in the Bill derive directly from the acceptance by Government of specific recommendations from the Expert Panel Review of Medicines and Medical Devices Regulation, which was conducted over 2014-15 and involved extensive stakeholder consultation.

The Expert Panel recommended that mandatory pre-approval of advertisements be abolished in favour of a self-regulatory scheme. Their reasoning was that the current system was outdated and deficient in numerous ways and no longer fit for purpose. In its place they recommended implementation of a package of other measures (which are included in this Bill) such as a new advertising Code which more clearly specified advertising requirements in a legally-binding fashion, introduction of a mandatory list of permitted indications for complementary medicines (which forbids non-permitted claims being made), simplification of advertising complaints to a single agency with much tougher enforcement provisions and more timely complaints handling including the powers to seek injunction against highly-damaging advertising provide more than sufficient safeguards to render a requirement for mandatory pre-approvals of advertising redundant.

This would position TGA in a similar way to other regulators such as the ACCC.
Australia is the only country I know of that has mandated pre-approval of advertisements for products such as over-the-counter and complementary medicines. Other countries such as the UK and Canada have successfully implemented voluntary pre-screening programs, delivered by industry peak bodies. In Australia, one peak body ASMI, the Australian Self-Medication Industry (which represent OTC and complementary medicines companies) has proposed that they will step up and offer a similar service after the passage of the Bill.

I want consumers to be protected from misleading advertising claims, and the measures under the Bill are designed to achieve this. I am also aware that if mandatory pre-approvals were maintained there is little incentive for companies to become familiar with the requirements for producing compliant advertisements.

To underpin the development of a more compliant industry, I seek Labor's support for five non-statutory initiatives that are additional to those proposed in the Bill:

a. Installing a pre-screening service for all advertisements for 2 years.

I intend to develop a pre-screening service that was available to provide advice within a short time frame on whether the submitted advertisements are likely to have compliance issues, and provide specific advice as to how the advertisement should be amended. It would not be mandated but I expect most advertisers would avail themselves of this service, particularly if it were provided for free or at a discounted rate. This service could be operated by ASMI (with support and advice provided by the TGA), or the TGA alone (or a hybrid of both)). I will work with these parties to develop a proposal to stand up these arrangements as an alternative to mandatory pre approvals from 1 July 2018.

b. A comprehensive industry and consumer education program on the new advertising regulatory scheme

TGA would employ two "advertising education officers" who will directly provide assistance in educating sponsors and advertisers of their obligations under the advertising code. They would operate a phone advisory service to advertisers (and consumers) as well as conduct workshops with advertisers (and consumer groups) in all capital cities. Some workshops would be co-hosted with peak industry bodies and the Consumer Health Forum. 10 of these workshops could be held in the first year of the new scheme.

I believe that the tougher compliance and other measures already in the Bill together with the pre-screening service and the comprehensive industry and consumer education programs that I am now proposing will enable potential harms from inappropriate advertising to be comprehensively prevented but at the same time make it clear to industry that they have the responsibility to produce compliant advertisements in the first place. These aspects are both deficient in the therapeutic goods advertising system that is currently in place.

c. Public performance measures for advertising complaints management

I can confirm that TGA will be adequately resourced and staffed to manage complaints from July 1. Triage processes and public (time and performance) Key Performance Indicators for managing advertising complaints will be developed and published by the TGA, following public consultation on the KPIs with consumer groups and healthcare professionals as well as industry.

These measures would be reported publicly on the TGA website and to Government as part of the formal annual Regulator Performance framework report, provide confidence to stakeholders of the management of the complaints handling system. For example it is proposed that critical complaints will be actioned within 10 days and high and medium impact cases closed within 20 and 40 days. This is far faster than the current (outsourced) Complaints Resolution Panel resolutions which average over 130 days, also noting that because the current panel's decisions are not binding, 40 % of advertisers decline to comply and the matter is then referred to the TGA for the process to start again.

d. Improved stakeholder engagement on therapeutic goods advertising

To improve stakeholder engagement in the new advertising model post 1 July 2018, a new Therapeutic Goods Advertising Committee will be established. This non-statutory committee would meet three or four times a year, most likely in association with meetings of the existing TGA Consultative Committee. It is proposed to establish a more modern consultative

committee that is more inclusive of all the therapeutic goods industry (including the IVD and biotech sectors which are currently not represented) and membership that is more reflective of modern advertising platforms including internet and social media as well as the traditional TV and broadcasting membership and wider professional and consumer representation. It would also include strong representation from consumer and health care professional organisations.

It is envisaged that the committee would not have a decision making role around individual advertising complaints mainly because this would slow done the complaints-handling process. Instead, it would review compliance and non-compliance for advertisements for particular types of products and of advertisements in particular media; review and advise on compliance priorities and TGA's Key Performance Indicators in managing advertising; review and advise on the policy settings for advertising, including for products such as medical devices that were formerly not included or incompletely included in the advertising regulatory framework. They would provide advice to the Department and the Minister if changes are felt to be needed, such as shaping transparency and reporting approaches.

e. A review of the impact of the new advertising measures (as included in the Bill) and of the four initiatives listed above to be conducted within two years from implementation.

It is proposed that the review be independently conducted by a small panel which would include a consumer representative and its report made public. This would then advise on whether further changes to advertising regulation are required.

Some other proposals have been made by particular academics around permitted indications for complementary medicines and consumer protection, and I would like to correct some misinterpretations, both of the intent of the Bill and of the current medicine and consumer regulatory law in these proposals.

The measure in the Bill to enable the preparation of a legislative instrument listing permitted indications for complementary medicines is designed to protect consumers from companies making inappropriate claims for these products. There are two types of complementary medicines – those for which scientific evidence of efficacy must by law be held and those which may be listed based on documented evidence of traditional use e.g. in Australian indigenous or in Chinese medicine. This evidence must also legally be held by the sponsor and provided to TGA upon request.

In 2008, the former Government committed Australia as a signatory to the WHO Traditional Medicine strategy, which includes implementation of regulatory systems that support the availability of traditional medicine products. The Consumer Health Forum also supports there being a list of permitted indications along the lines described in the Bill.

To give consumers greater clarity about the evidence base for listed complementary medicines, there will be a new mandatory requirement for listed medicine products to identify the evidence base on the product label e.g. "Traditionally used in Chinese medicine".

It has been asserted that the measure will enable complementary medicines to be promoted as treatments for cancer. Cancer and other serious conditions are already excluded from complementary medicine listing claims and allowed advertising and the Bill will further strengthen that prohibition, along with introducing the ability to seek advertising injunctions and implement stronger penalties for non-compliance.

Finally, it has been proposed by some academics that the Bill be amended to enable the powers of Australian Consumer Law to be available. They are, and will continue to be available. The Therapeutic Goods Act and the Australian Consumer Law act in concert and both can be used for

different aspects of enforcement, as has been demonstrated recently with inappropriate promotion of Nurofen products, which was prosecuted by the ACCC.

I believe that the initiatives above, for which I seek bipartisan support, will add to the measures in what is already a very good Bill.

I believe the passage of this Bill is essential as it includes many other important measures such as:

- the introduction of a provisional approvals scheme that will enable desperately ill patients to access new medicines up to two years sooner;
- the implementation of reforms to enable wider access to new medical devices;
- the streamlining of public awareness of products that support public health, such as tests for sexually transmitted disease s and provides TGA with the compliance and enforcement powers required for a modern public health and safety regulator.

I am happy to discuss these suggestions further with you.

I also understand that my Chief of Staff and relevant advisers from my office and Minister McKenzie's office are seeking to discuss the Bill with your staff on Monday, 5 February.

Yours sincerely

Greg Hunt