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**Objectives for our meeting with Minister Butler regarding the TGA on Wednesday 19th July:**

***1. Enabling informed health choices by consumers through appropriate labelling***

Consumers are generally unaware that TGA listed products are not tested by the TGA and are not required to provide the TGA with evidence of safety and efficacy.

We suggest mandatory labelling (similar to that used by the USA's FDA) to inform consumers – for example "*This product has not been evaluated by the TGA for safety or efficacy and may not be effective or beneficial*." or for devices "*This device has not been evaluated by the TGA. This device is not intended to diagnose, treat, cure, or prevent any disease*."

***2. Deterring misleading advertising and other breaches through stronger regulatory powers***

The performance of the TGA is significantly weaker than that of the Australian Competition & Consumer Commission (ACCC), a relevant benchmark. A regulator must be prepared to take real action with respect to the regulations it is tasked to enforce.

A new **compliance unit** could be formed to actively detect, pursue, and prosecute the manufacturers or distributors of products with misleading or deceptive advertising to the extent that it will discourage poor practice. Not to detract key resources from the TGA's role of evaluating potential new medicines and vaccines, this unit could be funded by directly raising revenue by increasing listing fees and/or by the TGA retaining the penalties of their enforcement actions (if it can be assured that this does not introduce a COI).

We suggest some approaches the compliance unit could take. These could be implemented independently, or together.

1. A series of actions escalating from small, medium to larger fines through prosecution of directors for deliberate non-compliance should be implemented. The current fines are low and considered by offenders as "cost of doing business" and do not deter businesses from misleading the public or gain media attention that influences patient and policy maker decision-making.

2. Implementation of a reporting hotline where concerned consumers or healthcare professionals could alert this unit to examples of misleading or deceptive advertising.

3. Active surveillance of TGA listed products. Organisations such as FSM could assist. For example, one FSM medical academic ran very successful student projects over years, where students would identify potentially misleading advertising of TGA listed products and then assemble the scientific literature to assess such claims.

4. A stronger commitment from Government that health claims made to consumers regarding medicines and medical treatments are to be fair, balanced, and accurate and that adequate disincentives apply for organisations which breach these principles.

5. Harmonising the Therapeutic Goods Act and the Australian Consumer Law (ACL).

**The main problems we see.**

***1. Misleading and deceptive product promotion***

A medicine can be listed on the ARTG without needing to provide the national regulator, the TGA, with evidence of safety or efficacy. The responsibility is put upon the applicant to hold such information to be supplied on request. FSM have accumulated extensive evidence of inaccurate, misleading, and deceptive therapeutic claims allegedly supported by evidence, which is usually absent or fictitious.

***2. Public mis-perception of TGA endorsement***

The public believes that the TGA actually independently tests the TGA listed products for safety and efficacy,[MJA 2006, 184:27-31] and this is often exploited by product owners or distributers by stating "TGA listed".

***3. Substantially inadequate enforcement of compliance***

It is within the TGA's remit to enforce the legislation that misleading or deceptive claims should be withdrawn and there is the provision for the regulator to issue fines for non-compliance. However, the usual action by the TGA has been to write to the manufacturer or distributor of the product advising them of the appropriate practice but leaving it entirely to the recipient to take action. There is usually no follow-up or enforcement, and prosecution is rare.

***4. Phoenixing***

Another frequent tactic is to "phoenix" the offending product into an essentially similar product. For example, *Fat Blaster* was replaced with *Fat Blaster Plus* using the same website, advertising, unfounded claims, materials, and website, to avoid regulatory action.

***5. Not upholding the principles of the National Medicines Policy***

The TGA regulation of Australian Register of Therapeutic Goods (ARTG) listed products is not in line with the principles of the National Medicines Policy, namely: *"To ensure that Medicines are used safely, optimally and judiciously, with a focus on* ***informed choice*** *and well coordinated person-centred care." (Our emphasis, NMP 2022)*

**Does this matter?**

The TGA is currently permitting the unhindered use of extensive promotional material, which is often misleading or inaccurate. This absence of fair and balanced information can prevent consumers from making an informed choice about their health.

In addition, the annual spend by Australian consumers on complementary health products is larger than the total co-payments by patients to medicines on the PBS.[AFP 46 (5) 2017] There is a huge opportunity cost to the economy of these sums being spent on these products, which are often at best expensive placebos and at worst toxic products.

**Who are Friends of Science in Medicine (FSM)?**

FSM is an informal association of medical academics and consumers who are concerned about the misleading promotion of non approved medical therapies to Australian consumers. FSM is a not for profit organisation and has no links with, nor receives funding, from any pharmaceutical organisation. Our website is ***https://www.scienceinmedicine.org.au/***