Gavin Mutton

20 August 2010

Dear Sir

When a therapeutic good is accepted onto the ARTG, this good may be purchased by 100 practitioners, who may use them on 100 patients per year. In a one year period this equates to 10,000 consultations that have been paid for by patients which give them false and misleading, potentially harmful, health information. At a cost of $100 per consultation this means that consumers have not only wasted $1,000,000 but have been given advice that may put their health at risk.

These patients include some of our most vulnerable Australians.

This is $1,000,000 wasted by consumers per annum in relation to just **ONE** therapeutic good.

The TGA have hundreds of such products.

These practitioners also continue to claim their good is "TGA approved". With hundreds of complaints submitted to the Complaints Resolution Panel, the TGA is aware of these goods.

The TGA has consistently resisted any attempts by the public to provide the consumer protection it was set up to do.

In my opinion this is TGA legitimized health fraud.

I have a number of questions that I feel need to be addressed in relation to the promotion/regulation of low risk goods.

1. Why does it take so long to get a listing cancelled - it's years sometime (eg Aust L 133644, Mr R Jenkins Pty Ltd took 3 years to cancel). Why does it take that amount of time? This makes no sense (the Complaints Resolution Panel asks the sponsor for the evidence that they claimed that they had at the time of application). What is the procedure? Can it be accomplished more quickly?

2. Who is responsible for cleaning up the websites when goods are cancelled (by either Dr Kelly or the Sponsor) - the states (eg HCCC, HQCC etc) or the TGA?

3. I understand that the TGA tested some devices and they have failed (eg ear candles). Why did not this automatically translate into a change in 'intended purposes' (or the carte-blanche cancellation of Ear Candles when the good is either banned overseas or is considered unsafe?)

4. Is 'relaxation' and 'improved wellbeing' acceptable 'intended purposes' (if so, why can't you put a teddy bear on the ARTG?)

5. Why is the cost so low for 'low risk' goods when this only encourages unscrupulous sponsors? Increasing the cost can fund additional pre-market investigations.

6. Why are there no fines when sponsors deliberately fill in false applications for goods?

7. At this time the system is complaints driven. Why does the TGA ignore the body of evidence now available (eg the NPS recommended databases?)

8. Why can consumers have advertising complaints upheld, but this does not flow onto labels?

9. Why are 'practitioner only' websites and practitioner journals (eg ATMS Journal) exempt from the Complaints Resolution Panel (CRP) jurisdiction? This means that consumers cannot complain about them.

10. Why can advertising continue when a complaint has been upheld by the CRP (eg biomagnetics).

11. There are hundreds of entries on the ARTG that the sponsors would not be able to provide the evidence for (55 magnetic products, Ear Candles, electro-dermal testing devices. Why does the TGA put the industry over consumer protection?

12. When a good is investigated, the Sponsor cancels in the majority of cases. Why is the public not told about all cancellations and the reasons for them?

13. When a therapeutic good is cancelled (even by Dr Kelly), why does that therapeutic good maintain currency (which means practitioners can continue to use them.)

14. Why haven't recalcitrant sponsors been fined?

15. Why are sponsors who make claims and practitioners who use the device who make the same claims treated differently? Could not the CRP accept claims for both of these groups? Could the CRP be expanded to includes advertising by therapies (eg Chiropractors claiming to treat Cancer, MS, Asthma, Depression)

15. Less than 1 in 10 new applications for low risk goods are checked. This means that if an application is flagged, the sponsor can cancel it and resubmit a new application which guarantees that their good will be accepted. What financial disincentive is there to stop sponsors from submitting fraudulent applications?

16. Are all goods that are flagged for review actually reviewed? If so what is the time frame for these reviews.

17. Why can't the CRP do ALL advertising for therapeutic goods (eg labels, brochures etc)?

18. Why is there no transparency with complaints to the TGA about therapeutic goods?

19. Why are there two systems ('low risk' & 'high risk') when both can cause harm to patients?

20. The current system for 'low risk' goods is honesty based and is clearly not working, to protect consumers should it be scrapped and be absorbed by the 'high risk' system?