Submission to the
TGA
on
Premarket Medical Device
Assessment
(Exposure Draft)
2nd Submission

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Executive Summary

This is the second submission written by Friends of Science and Medicine (FSM) on premarket medical device assessment and is a response to the May 2010 Regulation Impact Statement Changes to premarket assessment requirements for medical devices, EXPOSURE DRAFT.

While FSM appreciates that the primary objective was to provide "greater assurance that higher risk medical devices approved do not compromise public health and safety", FSM remains concerned that issues relating to the explosion in numbers and increased use by thousands of alternative therapists of 'low risk' devices, are being completely ignored by the TGA.

FSMs initial submission recommended that 'low risk' devices, particularly Class I, Class IIA, IIB, IIIC and 'other therapeutic goods', should be scrutinised for the actual product specification, label, instructions, packaging, advertising and the evidence. It also recommended adequate fines and other deterrents to discourage sponsors/manufacturers from reoffending.

It detailed our concerns at the growing number of alternative health practitioners who are wasting precious health and consumer dollars while potentially putting patient health at risk.

As we mentioned in our first report, every day thousands of Australians are being diagnosed and treated by alternative health practitioners with 'low risk' medical devices.

There are estimated to be up to 10,000 naturopaths and thousands of other alternative therapists, many of whom are using several of these unproven or disproven devices on their patients.

These practitioners are making false and misleading statements which puts patients health at risk at sometimes considerable cost. Under the guise of a 'Consultation', these interventions may be attracting a private health insurance rebate or, in some instances, Medicare Chronic Disease Management rebates and are thus wasting our precious health dollars.

Our previous report gave detailed information on a wide range of these devices, their intended purposes and the claims sponsors and practitioners make for them.

To demonstrate further our concerns, this submission uses three examples, including and two practitioner websites, to highlight the way recalcitrant sponsors promote their 'low risk' devices, encouraging alternative practitioners to exploit their patients.

FSM is concerned that your recommendation of Option 2 as the appropriate response, fails to consider any of our concerns and therefore rejects this recommendation.
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1. Introduction

This is the second submission written by Friends of Science and Medicine (FSM) on premarket medical device assessment and is a response to the May 2010 Regulation Impact Statement Changes to premarket assessment requirements for medical devices, EXPOSURE DRAFT.

Our initial submission recommended that 'low risk' devices, particularly Class I, Class IIA, IIB, IIIC and 'other therapeutic goods', should be scrutinised for the actual product specification, label, instructions, packaging, advertising and the evidence. It also recommended adequate fines and other deterrents to discourage sponsors/manufacturers from reoffending.

In our conclusion we stated the following:

"These devices are targeting our most vulnerable patients including children, overweight people and people with chronic pain offering hope without proof and both directly and indirectly, wasting billions of dollars.

These regulations should be strengthened to stop these devices automatically being accepted onto the ARTG. Existing devices should be investigated and removed from the ARTG until such time as evidence is provided to support the claims made by the sponsors. While FSM supports the proposals for 'high risk' devices, it remains concerned that 'low risk' devices continue to be ignored and the intended proposals will do nothing to discourage recalcitrant sponsors or to improve consumer protection."

This report recommends that 'low risk' devices, particularly Class I, Class IIA, IIB, IIIC and 'other therapeutic goods' are scrutinised for the actual product specification, label, instructions, packaging, advertising and the evidence. It also recommends adequate fines and other deterrents to discourage sponsors/manufacturers from reoffending.

Reform of pre-market medical assessment should not be limited to one category ('high risk') medical devices. Amendments also need to be put in place for an effective system that stops the flood of ineffective 'low risk' devices onto the ARTG and to both remove them and keep them off the ARTG and out of our communities once they are identified.

2. 'Low Risk' Medical Devices - Problems Identified

We appreciate that the primary objective was to provide "greater assurance that higher risk medical devices approved do not compromise public health and safety", however, FSM feels that the recommendation has completely ignored the thousands of 'low risk' devices used by alternative practitioners that are potentially putting patients health at risk, while undermining patient/doctor relationships at sometimes considerable expense to the patient while wasting health funding dollars.

As mentioned in our first submission:

"These devices are draining billions of dollars, primarily from our most vulnerable patients, the parents of children, and those of us in pain or who are overweight. Their sponsors are selling hope without proof, while wasting time which might be needed for accurate diagnosis and effective treatment."

Our report highlighted problems with these devices:

1. 'Low risk' I medical devices, (eg class I), do not need to be issued with a conformity assessment certificate before an application for inclusion on the Australian Register of Therapeutic Goods (ARTG) can be submitted to the TGA and these 'medical devices' are therefore automatically included on the Goods ARTG when an application for them is received meets their regulatory requirements.

2. 'Low risk' devices get virtually no pre-market scrutiny of the actual product specification, label, instructions, packaging, advertising or evidence. Apart from a few yes/no questions aimed at classification there is only a very small list of 'prohibited words' that will stop an online device application going through, and a small 'restricted word' list that will trigger a review. These hurdles are well known and easily circumvented.
3. The claims made on their Public Summaries do not reflect the evidence-based information now available and there is no effective mechanism for consumers to challenge them.

4. Once accepted onto the ARTG, less than 10% of new 'low risk' entries onto the ARTG (Class I-IIa devices) are randomly selected for post market review.

5. If the device is cancelled on safety and performance grounds, supplied devices are not subject to mandate recall and so the device can still be widely promoted even though it is no longer on the ARTG.

6. An 'effective' application has nothing whatsoever to do with the device itself. It is an application for including an entry on the ARTG that complies with all the requirements of the TG Act for inclusion of that kind and class of device. If an application is 'effective' the TG Act requires them to 'accept' the entry on the ARTG and there is no discretion to do otherwise.

7. Apart from the brief details submitted in the ‘intended purpose’ and GMDN code (which may be false and misleading), the TGA have no way of knowing what the device actually is or whether it is safe and effective.

8. There is no mechanism to prosecute for illegal supply and/or rejection of applications. These products are put onto the ARTG pending a review that generally never happens.

9. There is no deterrent to discourage sponsors/manufacturers from reoffending, as they have never been threatened with prosecution for providing false and/or misleading information in an application; and

10. By changing the name of their goods, there is no limit to the number of times a sponsor can submit a new application for what is the same product. With the current random review system, they know that they have a 90% probability of avoiding scrutiny. This will effectively guarantee them an ARTG number.

11. For imported 'low risk' medical devices, the TGA merely accepts EU Certification which means that the device may not be dangerous.

3. Alternative therapists

There are now up to 10,000 naturopaths and over 5000 chiropractors, osteopaths and other alternative therapists who are making false and misleading claims for a range of 'low risk' medical devices, many of which are on the ARTG, that they use to diagnose and treat vulnerable Australians including children, seniors, cancer patients and people with chronic pain. Alternative therapists often use more than one of these devices.

They are often encouraged to purchase these devices by offers of easy financing and promises of considerable profits. This is leading to over-servicing, false and misleading diagnostics and treatments, and the potential to miss real diagnosis of serious health conditions, such as cancer, which may lead to delays in proven treatments.

In many cases, these devices are used as part of ‘Consultations' which attract private health fund rebates, and in some instances, Medicare Chronic Disease Management rebates.

4. Example 1

An example of a device listed with the TGA is the Electro-dermal Screening Device that is promoted as being
This device, promoted as being "TGA Approved", is offered to alternative therapists with financing options (Appendix A) and with suggestions on how these practitioners can make upward of $100,000 per year (Appendix B).

Complaints have been upheld against the and several reports have been written to the TGA that included so the TGA is familiar with this device.

5. Example 2

An example of a practitioner website where the alternative therapist promotes a range of treatments using devices, that may not be on the ARTG, is. This practitioner uses a number of devices including

The website asks "Are You Unwell, In Constant Pain, Extremely Stressed, Or Simply Have An Unexplained Ailment? Are You Searching For Answers?" and claims:

we have high-tech complementary health devices that assist us to find energetic imbalances and health issues, stresses and pain management."

5.1 Device 1
Therapies included:

- Electro Acupuncture
- Biofeedback
- Detoxification
- Spinal, Dental and TMJ
- NLP
- Nutritional Balancing
- Beauty/Anti aging
- Stress Reduction
- Homeopathic
- Back Flower Remedies
- Colour & Crystal Therapy
- Iridology
- Chakra Balancing & Biorhythms
- Hormones

5.2 Device 2 -

The website claims:

- Fast
- Safe,
- Non-Invasive;
- Clinically Proven and
- World renowned

especially good at treating nerve and muscle pain, inflammation and scar tissue.

- Relieves pain
- Reduce muscle spasms
- Reduce muscle loss
- Increased blood circulation to injured areas
- Maintain and/or increase range of motion to injured areas

5.3 Device 3 -

The website claims:

- Electro Acupuncture
- Biofeedback
- Allergy Desensitization
• Detoxification
• Spinal, Dental and TMJ
• NLP
• Nutritional Balancing
• Beauty/Anti aging
• Stress Reduction
• Homeopathic
• Back Flower Remedies
• Colour & Crystal Therapy
• Iridology
• Chakra Balancing & Biorythms
• Hormones

6. Example 3

While consumers can complain against the false and misleading claims on practitioner website, and these complaints may be upheld by the TGA's Complaints Resolution Panel, there is no effective mechanism to ensure that the practitioner removes claims or publishes retractions and no way of stopping them from continuing to use these devices on their patients. Practitioners may just ignore the determination, shut down their website and set up a new one.

Seven complaints were upheld against [redacted], a clinic that uses multiple 'low risk' medical devices, including a range of electro-dermal devices. At least nine 'low risk' devices have been identified as being used by this clinic to diagnose and treat patients including:

- Magnetic Therapy devices;
- Ear Candles;
- Electro-dermal Screening devices;

Some of these devices have been cancelled and relisted, some remain on the ARTG, and others are not on the ARTG.

7. Other 'low risk' medical devices

Some 'low risk' medical devices have been listed since 2004, but new ones continue to be added. Some of the devices cancelled in 2010 have been relisted.

Devices listed in our first submission include the following:

- Magnetic Therapy devices;
- Ear Candles;
- Electro-dermal Screening devices;
- 'Bioptron' light therapy;
- Transcutaneous Electrical Nerve Stimulator (TENS)/ Electro-acupuncture;
- 'Subluxation' diagnostic/treatment gadgets (eg Activator);
- 'Subluxation' diagnostic devices (eg Insight Subluxation Station);
- Live blood Analysis (eg Hemaview\textsuperscript{TM});
- Body contouring devices;
- Hyperbaric oxygen chambers;
- Shuzi (bracelet stimulator);
- Acupressure wrist bands;
- Low level laser smoking cessation devices, and
- Ear Microsystem seed/pellets.

While not all of these devices are on the ARTG, they all come under the jurisdiction of the Therapeutic Goods Act.

8. Conclusion

Our initial report identified hundreds of unproven medical devices, all of which come under the jurisdiction of the TGA and which are breaching the Therapeutic Goods Act. The TGA is aware of these devices and have cancelled only a few of them, some of which have since been relisted, while permitting more to be accepted onto their ARTG.

Every day thousands of Australians are being diagnosed and treated by alternative practitioners with unproven or disproven 'low risk' medical devices, many of which are on the ARTG. These practitioners are making false and misleading statements about the devices, putting patient health at risk at sometimes considerable cost.

Under the guise of a 'Consultation', these interventions attract a private health insurance rebate and in some instances, Medicare Chronic Disease Management rebates and are thus wasting our precious health dollars.

Option 2 ignores any references to 'low risk' medical devices.

FSM is concerned that your recommendation of Option 2 as the appropriate response, fails to consider any of our concerns and therefore rejects this option.
Appendix B

[Redacted text]

[Redacted text]
References