Submission to the TGA on Premarket Medical Device Assessment

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“Friends of Science in Medicine”.
Executive Summary

The Therapeutic Goods Administration (TGA) is Australia's regulatory authority for therapeutic goods.

According to the TGA website:

“We carry out a range of assessment and monitoring activities to ensure therapeutic goods available in Australia are of an acceptable standard with the aim of ensuring that the Australian community has access, within a reasonable time, to therapeutic advances.”

On 30 August 2011, the Australian National Audit Office’s (ANAO) released their audit on the Therapeutic Goods Administration’s (TGA) performance as the regulator of complementary medicines (CM). While that report focused on CMs only, the same system applies to 'low risk' so-called ‘medical devices’. If they were audited, the results would undoubtedly have been the same.

In 2010 the TGA reviewed and cancelled a number of unproven 'medical devices', at the same time many more were, and continue to be, automatically accepted onto their register. In so doing Friends of Science in Medicine (FSM) believes that the TGA is failing to protect consumers by not assessing and monitoring these devices within a "reasonable time". Some of these cancelled devices have now reappeared on ARTG.

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.

In this report we document numerous ‘medical devices’ that should never have been listed. Many of these have been on the Australian Register of Therapeutic Goods (ARTG) for over seven years.

Our report highlights numerous devices that are incapable of providing the benefits claimed by there proponents and includes:

a. A range of ‘medical devices’ on the ARTG, including body contouring devices, “subluxation” diagnostic and treatment devices, ear candles, magnetic therapy devices, electro-dermal screening devices and Trans-cutaneous Electrical Nerve Stimulation (TENS) devices;

b. A range of Chiropractic devices used to diagnose and/or remove so-called “subluxations”

c. The Hemaview™ live blood analysis, which came under the jurisdiction of the TGA in July 2010

d. A selection of the 'intended purposes' submitted during application for listing on the ARTG and claims made in complaints upheld by the TGA's Complaints Resolution Panel; and

e. A selection of miscellaneous devices such as health bracelets and devices for smoking cessation.

These devices are draining many millions of dollar from our vulnerable patients, the misguided parents of children and many who suffer chronic pain and struggle with their efforts to overcome obesity. Their sponsors are selling hope without proof and causing many to waste time that might be needed for accurate diagnosis and effective treatment.

MAJOR CONCLUSION AND RECOMMENDATION

This report recommends that 'low risk' devices, particularly Class I, Class IIA, IIB, IIIC and 'other therapeutic goods' are scrutinised pre-listing to ensure satisfactory product specification, labelling, instructions, packaging, advertising and (most importantly) evidence that they can deliver the suggested benefits.
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1. Introduction

This submission is provided by Friends of Science in Medicine (FSM). Our organisation has nearly 1000 scientists, clinicians, lawyers and consumer advocates as supporters. We have no links to any industry. A key aim of our organisation is to ensure that Australians have access to therapeutic interventions based on sound clinical evidence of efficacy.

The TGA currently does not have a mechanism that would allow it to 'approve' goods/devices that are proposed for listing. This does not stop numerous providers of devices from claiming that TGA listing is tantamount to a tick of approval. However the unacceptable reality is that the TGSA will list devices that it, literally, know nothing about; all the TGA does pre-marketing is 'accept' applications.

Medical devices are automatically included on the Australian Register of Therapeutic Goods (ARTG) when an application for them is received meets their regulatory requirements. These requirements fall far short of the standard needed to protect consumers.

Class I medical devices do not need to be issued with a conformity assessment certificate before an application for inclusion on the ARTG can be submitted to the TGA.

Inclusion on the ARTG allows medical devices to be legally supplied in or exported from Australia.

The regulation of medical devices in Australia is risk based - with the level of pre-market assessment being commensurate with the level of risk of the device.

The proposals put forward by the TGA focus on conformity assessment and approval for marketing through inclusion on the Australian Register of Therapeutic Goods (ARTG).

This TGA proposal paper details the following proposals:

1. Increased scrutiny of conformity assessment as part of mandatory application audits prior to ARTG inclusion;
2. Publication of medical device regulatory decisions; and
3. Abolition of requirement for TGA conformity assessment for Australian manufacturers of lower Class medical devices (to be implemented in association with proposal 1).

The abovementioned proposals, in our opinion, unsatisfactory as they will not stop the flood of ineffective 'low risk' devices onto the ARTG and will do little to remove them once they are identified.

2. 'High Risk' Vs 'Low Risk' medical devices

For most medical devices manufactured outside Australia, TGA may accept CE Mark certification from European notified bodies as evidence of conformity assessment as part of the premarket approval process.

2.1 'High risk' medical devices

For 'high risk' medical devices, the required certification includes a conformity assessment certification which has been issued by an approved Conformity Assessment Body (CAB). The TGA will assess these goods to confirm that the medical technology is safe and efficacious in accordance with the intended use as declared by the manufacturer of that technology. This assessment is done on an “application by application” basis. No comparisons of clinical effectiveness or cost benefit comparisons within product groups or for like products are undertaken by the TGA or are required to be undertaken under the legislation.

2.2 'Low risk' medical devices

'Low risk’ include class I, class IIa, class IIb, class IIc and 'other therapeutic goods' which are classifications commonly used by the sponsors of questionable medical devices (including ear candles, magnetic therapy etc). The class I devices do not need to be issued with a conformity assessment certificate before an application for inclusion on the ARTG can be submitted to the TGA.
2.3 Problems with 'low risk' medical devices

'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.

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.

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

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

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.

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

These products are put onto the ARTG pending a review that generally never happens.

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.

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.

For imported 'low risk' medical devices, the TGA merely accepts EU Certification that means nothing more than that the device is not dangerous.

This is providing opportunities for recalcitrant manufacturers to introduce unproven or disproven devices onto the Australian market where they:
- May state one 'intended purpose' on their application, but they may promote different or additional claims in their goods marketing, product inserts or in their training courses;
- May rely on the low level of scrutiny of new goods to include pseudoscientific or inaccurate 'intended purposes' in their applications that appear on the ARTG Public Summaries;
- May not publicly advertise claims, which they know are false and misleading in order to avoid the Therapeutic Goods Administration Complaint Resolution Panel (TGACRP);
- Know that complaints sent to the TGACRP can take up to six months before resolution; and
- Know that they can ignore determinations against the claims made for their goods.

If consumers requests that the TGA remove these goods, they will be asked to submit a complaint to the TGACRP and it is unlikely that the goods will be cancelled.

3. Unproven medical devices

There are hundreds of 'low risk' medical devices that have either no proof of efficacy or are used for unapproved "intended purposes", yet many of them continue to remain on the ARTG.

These include:
- 'Bioptron' light therapy
- Ear Candles
- Electro-dermal Screening devices
Magnetic Therapy devices
- Transcutaneous Electrical Nerve Stimulator (TENS)/ Electro-acupuncture
- 'Subluxation' diagnostic/treatment gadgets
- 'Subluxation' diagnostic devices
- Live blood Analysis (Hemaview™)
- Body contouring devices
- Hyperbaric oxygen chambers

While not all of these devices are on the ARTG, they all come under the jurisdiction of the Therapeutic Goods Act. Some of these devices have been listed since 2004, but new ones continue to be added. Some of the devices cancelled in 2010 have been relisted.

Many of these devices are used by “alternative” therapists, including massage therapists and beauticians, (who, of course, have no medical training), to give false diagnostic information either to motivate their patients to purchase unproven complementary medicines for considerable profit, or to over-service them. Such tactics may put the health of individuals and families at risk by potentially missing real health problems and delaying proven treatments.

Apart from the Hemaview™ live blood analysis, this report does not include in-vitro diagnostics such as heavy metal testing, urinary incandescent tests and zinc tally tests.

3.01 'Bioptron' light therapy

This device was cancelled in 2010 and was relisted in 2012.


Sponsor & Practitioner Website Claims
The claims made about the device include the following:
- Improves microcirculation
- Harmonizes metabolic processes
- Reinforces the human defence system
- Stimulates regenerative and reparative processes of the entire organism
- Promotes wound healing
- Relieves pain and decreases its intensity

Other claims in relation to the coloured filters used include:
- Red: to treat rheumatics, arthritic pain, liver stimulant that also produces collagen by stimulating fibroblast cells thus being excellent for skin rejuvenation and stretch marks.
- Orange: to restore the spleen, sexual organs, bladder, bowel and lower intestine, bronchia, chest discomfort, kidneys, stomach, gallstones, hernias and sinuses. It increases the intake of oxygen to assist lungs.
- Yellow: to treat ulcers, gall stones, catarrh of the large intestine or diabetes. It aids lymph flow.
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- Green: to treat acne lesions, high blood pressure, burns, cuts, bruises, pigmentation, nervous conditions, hay fever, ulcers, influenza, malaria, colds, sexual disorders, heart, lungs, circulation, arms, hands, legs and feet.
- Blue: to treat thyroid, mouth, teeth, tongue, jaw, parathyroid and lungs. It also reduces inflammation and aids acne by killing P. acnes, a strain of bacteria that contributes to acne, on the surface of the skin. It also prevents or controls periodontal conditions, which can result in the loss of bone and it helps insomnia, sunburn, toothache, rashes and laryngitis.
- Indigo: to treat pituitary gland, pineal gland, skull, brain, left eye, sinus region, and nasal cavity. It raises concentration and strengthens lymphatic, eyes, ear, nose, throat, sinuses, lungs and to treat migraines.
- Violet: to treat nervous irritations, the upper spine, brain stem, somatosensory cortex (pain centre), cerebral cortex, upper brain function, central nervous system (CNS), pineal gland, the right eye acne blemishes, lymph drainage, neuralgia, muscle relaxer, rheumatic, rosacea, sciatica, acts as an anti-inflammatory and speedup natural healing and to relieve pain.

Complaints Upheld against device

There have been 8 complaints upheld by the Complaints Resolution Panel against the Bioptron since 2010iii.

3.02 Ear Candles

These devices have been banned in other countries and, according to experts, "do more harm than good"iv. There are over 20 ear candles listed on the ARTG.

ARTG Id 131710

Examples of 'intended purposes'

For "The candle flame and geometry creates a gentle vacuum, which through osmosis draws out the debris"v and "a cone shaped candle that when burnt allows the warmth of the candle to warm the ear canal and loosen the wax and other debris within the canal. The candle flame and geometry creates a gentle vacuum, which through osmosis draws out the debris."vi

Complaints Upheld against devices

There have been more than 28 complaints upheld by the Complaints Resolution Panel against the ear candles since 2009.

Claims rejected related to sinus problems, earache, glue ear, swimmers’ ear, chronic headaches, ringing in the ear, hearing difficulties, and removal of ear waxvi.

3.03 Electro-dermal screening (bio-feedback) devices

These devices are often entered for biofeedbackviii but are promoted by natural therapists for diagnosing allergies, viruses, parasites, fungi, radiation, toxins and nutritional deficiencies and for smoking cessation. While some were cancelled in 2010 (e.g. Vega & QXCI), others remain on the ARTG.
Examples of 'intended purposes''

"This electronic system provides visual and auditory signals corresponding to the patient’s physiological status. It detects changes in physiological functions that are outside of normal awareness, amplified these signals and proved this as feedback to the patient with the intention of promoting the healing process. Examples of use are pain reduction, muscle relaxation, stress reduction and reduction of allergic reaction."\(^{ix}\)

Complaints Upheld against devices

There have been a number of complaints upheld against a variety of bio-resonance devices\(^{x}\) including BICOM, Magnagraph, ESteck Bio-Impedance, Wegamed, VEGA, Avatar and AT 2000.

3.04 Magnetic Therapy devices

There are over 30 magnetic therapy devices listed with the TGA. While their Sponsors have cancelled many of these devices, some of the Sponsors have relisted their devices under different company names e.g. Biomagnetics delisted ARTG Id 127383, 131842 & 131843 but relisted as The Natural Group Pty Ltd - ARTG Id 177485, 177486, 177487, 182012, 182020, 182021, 182022, 185433 & 185436 - a net increase of 6 medical devices.

Other Sponsors who delisted, such as Australian Magnetic Therapy - ARTG Id 152050, 152431, 152432, 152433 & 154434 continue to sell their products through websites\(^{xi}\), twitter\(^{xii}\) and facebook\(^{xiii}\).

Examples of 'intended purposes'\

"A static magnetic device used to help elevate period pain for pre and post menopausal women"\(^{xiv}\) and "To provide localised temporary pain relief. For temporary relief of aches and pains via a static magnetic field produced by magnets in garments, bracelets, necklaces etc worn by the patient"\(^{xv}\).

Complaints Upheld against devices

There have been a number of complaints upheld against magnetic therapy devices including magnetic underlay's\(^{xvi}\), jewellery\(^{xvii}\), knee straps\(^{xviii}\) and back supports\(^{xix}\).
3.05 Transcutaneous Electrical Nerve Stimulator (TENS)/electro-acupuncture

With names such as "No More Pain" and "Painaway" these devices are primarily promoted for pain relief, including the pain experienced during labour & delivery. As at 2010 there were over 88 devices on the ARTG.

Examples of ‘intended purposes’

"TENS machine: Using electronic pulse to effectively alleviate the symptoms of cervical spondylosis, scapulohumeral periarthritis, arthritis, and lumbar muscle strain. It can ease peripheral nerve palsy. It can ease myalgia. It can promote blood circulation. It can remove fatigue."[xxx]

"Used on healthy people to optimize vitality, to increase well being, strengthen resistance and to assist in prevention of sickness.[xxxi]

"Can be effective for antiemetic and tissue healing effects. "May help to prevent DVT/PE through counteracting venous stasis for subjects who are immobile."[xxvii] "A treatment with broad applications for a variety of syndromes involving pain and for the management of anxiety, depression and/or insomnia. Also for the short-term relief of pain, anxiety, depression and/or insomnia. The AS Stress Control System is a treatment for a variety of anxiety disorders, or for the short-term relief of anxiety, depression and/or insomnia. The AS PPM is indicated for a variety of syndromes involving acute, chronic and post-operative pain."[xxv]

"Hand-held TENS type device used to alleviate pain and facilitate functional restoration and improvement" and "to apply pulsed electrical stimuli to acupuncture points via electrodes or acupuncture needles for relieving pain, or to promote other various therapeutic benefits associated with electro-acupuncture treatment. Can also be used to locate acupuncture points, measure & store acupuncture points.[xxvi]

Complaints Upheld against devices

There have been five complaints against TENS devices for claims of “pain treatments” and included claims relating to “a variety of disease categories” such as “circulatory”, “musculoskeletal”, “respiratory”, “ear and mastoid”, “gastrointestinal”, “eye and adnexae”, “genitor-urinary”, “mouth/jaw/salivary glands”, and “gynaecological and obstetrical”, together with references to “aid[ing] recovery from cardiac arrest, massive trauma, and coma”, burns, fractures, insect bites, allergic reactions, immune disorders, depression and other mental afflictions, dental problems, and skin conditions.[xxxvii]

3.06 “Subluxation” diagnostic/treatment gadgets

Also referred to as 'subluxations', the Vertebral Subluxation Complex (VSC) is a term made up by the founder of chiropractic in the 19th century. There is no evidence that VSC exist.

These gadgets and devices are promoted by chiropractors for diagnosing VSC and for treatments, called 'adjustments', which they claim removes them, which will prevent or cure most diseases.
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Six gadgets have been identified including the:

- Activator
- Arthrostim
- Impulse
- Integrator
- Torque Release
- Impulse Adjustment System
- Nervoscope

The Activator was accepted onto the ARTG in 2004.

Examples of ‘intended purposes’
The device identified was promoted as a "Chiropractic Adjustment device".

Complaints upheld against devices
The Activator, Arthrostim, Impulse, Integrator, Torque Release and Impulse Adjustment System are all based on the concept that a series of rapid punches to the patient's body removes VSC. The sponsors of these devices claim that they are "supported by extensive research, provide unparalleled reliability and produce superior results for patients". Expert opinion is that this is a placebo device.

"An instant lengthening" to children who have one leg shorter than the other, "has been designed as part of scientific research into the health benefits of chiropractic and for the correction of Subluxations".

Other claims include that they are effective, reliable and consistent and have been scientifically tested "Out of the largest human population research study in chiropractic history", "developed out of randomized clinical trial, blinded and with placebo control".

Sponsors claim that the devices are scientifically proven to work for a wide range of children's health conditions.

The Nervoscope is used for diagnosing VSCs.

Promoted on the basis that spinal misalignments are 'joints out of position', the sponsors of this device claim that it can detect VSCs. The sponsor also claims that VSCs 'irritate' the nerves which affects the blood supply to the skin resulting in detectable temperature variations.
Claims include that this device and help identify VSCs, spinal problems and improvements through temperature changes.

Nerve 'irritations' do not exist and there is no evidence to support the claims made that this device can diagnose any health condition.

On 27 May 2011 a complaint was upheld against the Arthostim by the Complaints Resolution Panel\textsuperscript{xl} for a range of false and misleading claims including:

- treats injured joints and tissues by delivering a rapid series of gentle taps
- the treatment is painless, and does not involve any twisting or cracking of the spine
- effective for a wide array of conditions
- particularly well suited for... people in acute pain.

The sections of the Therapeutic Goods Code\textsuperscript{xl} found to have been breached included sections 4(1)(b), 4(2)(a), 4(2)(c), 4(2)(d) and the determination required the advertiser to "withdraw advertisement; withdraw representations".

Section 42DL(1)(g) of the Act prohibits the publication of advertisements for therapeutic goods that are not included in the Register and which are represented as being for therapeutic use (such as the alleviation of acute pain, the treatment of injured joints, and the treatment of injured tissue).

This section was also found to have been breached by the Panel suggesting that the device was not on the ARTG.

3.07 Subluxation diagnostic devices

Four diagnostic machines have been marketed to diagnose a wide range of health conditions.

These include:
- Insight Subluxation Station\textsuperscript{xliii}
- Neuroinfinitex\textsuperscript{xliv}
- Myovision\textsuperscript{xlv}
- Titron

Some of these devices are on the ARTG (e.g. Insight Subluxation Station - ARTG 159476)

Examples of ‘intended purposes’

The sponsors of these devices claim they are “non invasive, multi-modality physiological monitoring device”. However it is being promoted as "a wonderful machine which provides all Chiropractors with a tool of compelling power when used to diagnose vertebral subluxation". Other claims made are that they can be used for “scoliosis rehab, ADD rehab”.

ARTG Id 159476
Complaints upheld against devices

Most of the claims are made for these devices come from overseas websites, which are outside the jurisdiction of the Complaints Resolution Panel. As yet, no complaints have been submitted against these devices in Australia. However, the FDA has issued warning letters against one such device.

3.08 Body contouring devices

These devices are promoted for permanent cellulite reduction and fat loss. Twenty contouring devices have been accepted onto the ARTG including 4 recent entries (ARTG Id 187836, 188048, 188735 & 188738).

Examples of ‘intended purposes’

Claims made for body contouring devices are that they use radio frequencies to “selectively damage the membranes of fat cells resulting in a reduction of body fat” \textsuperscript{41}, or to “stimulate trans-dermal RF energy to target fat cells to disrupt (or emulsify or induce fatty acid dissolution) of fat cells” \textsuperscript{42,43}.

Other claims include that the device work by “liquefying and melting fat, tightening skin, blasting, exploding or destroying fat cells, making fat cells vibrate, causing fat cells to collapse, stimulating blood flow and lympthatic drainage, vacuuming fat away, fat drainage, contracting collagen within the skin, inducing new collagen formation”, and many other claims of therapeutic effects”.

Also “reducing joint stiffness, mitigation of pain, erectile dysfunction & urinary incontinence.” \textsuperscript{44}

Complaints upheld against devices

Websites suggest that treatments with contouring devices can remove fat or can provide a long-term solution to wrinkles and loose skin when they state that they give “an all natural option to actively turn back the clock on aging skin”. \textsuperscript{45} These types of devices have only been approved by the FDA for “relief of minor muscle aches and pain, relief of muscle spasms, temporary improvement of local blood circulation, and temporary reduction in the appearance of cellulite”. A number of complaints have been upheld against website promoting these types of devices. Practitioners state their “claims on information provided by the manufacturers of the machine, and provided some documentary material relating to the efficacy of the product in destroying fat cells” \textsuperscript{46}. Practitioners state their “claims on information provided by the manufacturers of the machine, and provided some documentary material relating to the efficacy of the product in destroying fat cells”. \textsuperscript{47}

Other complaints have been upheld for claims relating to “skin tightening, anti-cellulite, “spot reduction”, tightening of collagen fibres, thinning of fat deposits, collagen remodelling, lifting and “slenderizing” facial contours, eliminating “double chin”, “saggy jowls”, reducing lines and wrinkles, “unsightly bulges”, immediate collagen contraction, long term collagen remodelling, reduction of fat deposits, elimination of cellulite symptoms, reduction in pore size, deep micro massage, “fibrosis breakage”, “breakage of the fat cell membrane which permanently destroys the cell”.

Other statements include “loosening of calcified deposits along the walls of fat cells”, “increase in cell membrane permeability allowing for more efficient movement of wastes out of cells”, more efficient nutrient absorption, improvement in cellular metabolism, “unwanted fat elimination”, the “non-surgical equivalent to lipo-suction”, addressing “typical problem areas [such as] tummy, thighs, bottom, love handles, fatty male breasts and more”.
increase in the flow of blood and lymph, increase in metabolic rate, "chemical breakdown of more complex fat molecules", tightening the “lose [sic] skin after fat loss”, and “demolishing deeper, even visceral fat”.

Claims also include that “the liquefied fat along with fragments of fat cell walls are eliminated from the body naturally by the lymphatic system”.

3.09 **Live Blood Analysis (Hemaview™)**

These in-vitro diagnostic devices came under the jurisdiction of the TGA on 1 July 2011. While the sponsor has another 3 years to apply for a listing on the ARTG, the TGA has been provided with evidence and expert opinion that these devices do not provide the diagnostic capabilities claimed. However, they continue to be heavily used and promoted.

![Not on ARTG](image)

Not on ARTG

*Examples of 'intended purposes'*

This device is not on the ARTG.

*Complaints Upheld against devices*

There are a number of complaints against this device from practitioners who state that “using only one or two drops of your blood, I can investigate the size, shape, and ratios of the red cells, white cells, and platelets in the sample... I can show how your blood picture is affected by poor diet and lifestyle choices”, “it can help screen for a number of risk factors that may be affecting your blood, including: high fat diets; poor nutrition; smoking, alcohol; stress”, “Hemaview is based on the medical science of Hematology”, “it provides an accurate and immediate indication of the state of your general health”, “Hemaview can help your Practitioner assess you for the following factors: high fat diets; poor nutrition; smoking, alcohol; stress; immune system health; oxidative stress and free radical damage; inflammation; liver health”, and “fast, effective, accurate, reliable, and totally amazing”.

3.10 **Hyperbaric Oxygen Therapy Chamber (On ARTG)**

There are four hyperbaric devices listed on the ARTG as "GMDN 12061 Chamber, patient, hyperbaric".

Three of these appear to be legitimate devices that are used in hospitals.

However, one of them, ARTG 147142, from Uvec Pty Ltd, is being promoted for a wide range of unproven medical treatments.

Claims made include Autism, Multiple sclerosis, Cerebral oedema, Multi-infarct dementia, Spinal cord injury, Parkinson’s disease, Cerebral palsy, Vascular diseases of the spinal cord, Brain abscess, Peripheral neuropathy, Radiation myelitis, Crohn’s disease, Osteoporosis and Rheumatoid arthritis and are listed on their brochure.

The machine was imported from DIVEX (UK) and is sponsored by Hyperbaric Worx.
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ARTG ID 147142

*Intended purpose* for device

"To provide hyperbaric oxygen to patients via a sealed mask for therapeutic purposes"

3.11 Hyperbaric Oxygen Therapy Chamber (Not on ARTG)

There are a number of other hyperbaric devices that may not be on the ARTG, that make similar claims.

These include:
- Viaetris 320
- Hypo800
- Hypermed

This is not the complete list of devices being promoted to patients.

*Vitaeris 320*

Sunshine Coast Sports Hyperbaric Therapy Pty Ltd

*Hypo800*

Sunshine Coast Sports Hyperbaric Therapy Pty Ltd

*HyperMed*

The director of HyperMed is a chiropractor who has been investigated by the Victorian Civil and Administrative Tribunal for claiming that the oxygen treatment could improve epilepsy, multiple sclerosis, Parkinson's disease, infertility and AIDS.
3.22 Clinics promoting unproven Hyperbaric Oxygen Therapy

The *Hyperbaric Worx* device, sponsored by *Uvec Pty Ltd*, is on the ARTG (Aust L 147142).

A growing number of clinics using these devices are targeting our most vulnerable patients including those with Autism, Multiple sclerosis, Spinal cord injury, Parkinson’s disease, Cerebral palsy, Crohn’s disease, Osteoporosis and Rheumatoid arthritis.

Other clinics promoting unproven treatments include:

- Glebe Healing Centre\[iii\]
- BWell Hyperbaric Therapy\[lv\]

This is not the complete list of clinics promoting this therapy.

**Complaint Upheld against device**

A complaint against the claims made by the *HypO2 hyperbaric oxygen chamber* was upheld on 3 March 2011 and the determination required the printing of a retraction\[lxv\].

3.23 Miscellaneous medical devices

The ARTG includes devices such as Shuzi (bracelet stimulator)\[lxvii\]lxviii, acupressure wristbands\[lxvii\], low level laser smoking cessation devices\[lxvii\] and Ear Microsystem seed/pellet\[lxix\].

**Examples of 'intended purposes'**

“Intended for use to stimulate and strengthen the body’s biofield by fine-tuning the body’s own natural frequency and providing healthier blood. The combination of multiple identical tuning forks that emit their own frequency create a subtle vibrational energy, effective enough that it interacts with the body’s biofield. The device emits many unique frequencies chosen to be compatible with human cells, and is effective in contact with the body’s biofield, usually within 6 inches of the skin.”\[lxx\]

The Laser Quit device intended purpose is “for the safe treatment of Pain, Wound Healing, Soft Tissue Injuries and Non Needle Acupuncture for smoking cessation and as part of a weight control programme.”

The 'Acupuncture unit' intended purpose some use “Acupressure wrist band for nausea and vomiting. Pressure exerted on the P6 acupuncture point on the forearm my relieve nausea and vomiting”.

Other claims include “for the safe treatment of Pain, Wound Healing, Soft Tissue Injuries and Non Needle Acupuncture for smoking cessation and as part of a weight control programme.”
There are a number of complaints against these types of devices, but not those on the ARTG.

4. Conclusion

This report has identified a large number of medical devices listed on the ARTG that are incapable of providing the benefits claimed. These devices fall within the jurisdiction of the TGA and their proponents are breaching in Therapeutic Goods Act. Even when the fraudulent nature of claims made for these devices are notified to the TGA very few of them have been de-listed! Similarly useless devices are continually being added to the ARTG.

These devices are targeting vulnerable patients including children, overweight people and people with chronic pain offering false hope and directly and indirectly, wasting millions of dollars.

We have structured our report to highlight the reasons why we feel it is imperative that current regulations should be strengthened to stop such devices automatically being accepted onto the ARTG. While FSM supports the proposals for ‘high risk’ devices, it remains concerned that ‘low risk’ devices will continue to be ignored. The suggested changes will do little to discourage recalcitrant sponsors or to improve consumer protection.

We understand the problems for the TGA that result from limited human resources but would emphasise that even a cursory examination by a competent clinician of claims made would instantly allow a device to be added to a list of those where the sponsor should be asked to submit proof of the claims made; preferably in the pre-marketing phase. We suggest that such clinical resources be made available to the office of the Chief Medical Adviser. It is also advisable for computer technology to be used to scan applications looking for a list of key words and phrases that should arouse suspicions. For example any submission containing reference to magnetic therapy, energy medicine, computer aided diagnostics, light therapy etc would be brought to the attention of TGA officers. The same scanning could be applied to currently listed devices to make random checks less random.

MAJOR CONCLUSION AND RECOMMENDATION

This report recommends that ‘low risk’ devices, particularly Class I, Class IIA, IIB, IIIC and ‘other therapeutic goods’ are scrutinised pre-listing to ensure satisfactory product specification, labelling, instructions, packaging, advertising and (most importantly) evidence that they can deliver the suggested benefits. Increased scrutiny of devices already listed is crucial. Loopholes that allow sponsors to re-enter the market with an identical product to one de-listed by the TGA must be closed. Additional human resources to implement these recommendations need to be made available to the office of the Chief Medical Adviser. The cost/benefit ratio from so doing is all in favour of benefit as the resort to the useless devices in question often leads to a delay in accurate diagnosis and treatment which adds unnecessary costs to our health system as well as unnecessary suffering for those with health problems.
Submission to the TGA on premarket medical device assessment
Submission to the TGA on premarket medical device assessment

References

Submission to the TGA on premarket medical device assessment

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