



Australian Government

Department of Health and Ageing
Therapeutic Goods Administration

Regulation of Hypoxic Therapy and Altitude Training Devices in Australia

Consultation Paper



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Executive Summary

It is recommended that hypoxicators be regulated as medical devices in Australia, based on the manufacturer's claims and intended purpose of the product.

If the manufacturer's claims and intended purpose are limited to simulating air at altitude for professional training purposes; the hypoxicator would not fit the definition of a 'medical device'. Supply of these products in Australia would therefore not be regulated by the TGA.

However, if the manufacturer's claims and intended purpose extend beyond generic altitude simulation, and include statements relating to possible physiological changes or therapeutic benefits, such products supplied in Australia will be regulated by the TGA as "medical devices".

Active (electrically powered) hypoxicators are considered to be Class IIb medical devices, while non-active hypoxicators may be classed as Class IIa or Class I medical devices, depending on whether the hypoxicator connects to an active medical device.

Before a hypoxicator can be supplied in Australia as a medical device, the manufacturer must first obtain appropriate conformity assessment certification, and the Australian sponsor must then include the device in the ARTG.

Hypoxicators may be supplied in Australia during the certification process, and prior to entry in the ARTG, on the condition that only general altitude simulation and fitness claims are made by the manufacturer. Claims relating to possible physiological changes or therapeutic benefits may only be made by the manufacturer after they have obtained appropriate certification, and the Australian sponsor has obtained an ARTG entry for the device.

Persons found to be supplying a hypoxicator without a valid ARTG entry, whose manufacturer makes physiological or therapeutic claims, shall be deemed to be supplying medical devices in Australia illegally, and may be penalised accordingly under the *Therapeutic Goods Act 1989*.

Introduction

The Therapeutic Goods Administration (TGA) has recently become aware of safety concerns relating to the use of products designed to deliver reduced-oxygen (hypoxic) air to people. The TGA uses the term “hypoxicator” to describe this type of product.

Hypoxicators are a relatively new technology, most commonly used to simulate the effects of reduced atmospheric oxygen levels at various altitudes on the human body. Although the mode of action and physical representation of these products may differ substantially, each product intends to achieve a similar goal; that is, allowing the user to experience air of the same oxygen concentration found at moderate to high altitudes.

Hypoxicators have primarily been used in recent times to assist in improving performance of athletes; however there is an increasing use of these products in training of other professions (such as pilots and defence force personnel), and amongst the general public for various health and wellbeing applications.

Although the TGA has always regulated products which make therapeutic claims, it has not always been clear whether hypoxicators were within the boundaries of the Australian therapeutic goods legislation. The TGA recently determined that, in many cases, hypoxicators were being used for therapeutic purposes, and therefore should comply with the current Australian regulations for medical devices.

In recognition of the fact that the hypoxicator industry may have been unaware of the Australian therapeutic goods legislation, and the increasing proliferation of such devices on the Australian market, the TGA is initiating a consultation process with industry and other stakeholders to develop an appropriate and responsible regulatory framework for these products.

This consultation paper examines the relevant issues relating to the use of hypoxicators, and proposes a number of regulatory framework options for these devices. Industry stakeholders are invited to respond, and after comments are received, the TGA will further proceed to establish a suitable regulatory framework.

Until such time that the TGA implements the regulatory requirements for hypoxic therapy devices, care must be shown in the claims made in the labelling, advertising and promoting of these goods. Claims related to fitness, sports training and high altitude simulation are considered appropriate, as long as there are no additional therapeutic claims made either directly or indirectly.

It should be noted that where a hypoxicator product is not regulated as a medical device under the *Therapeutic Goods Act 1989*, that such products may be regulated by other federal or state bodies concerned with the safety of consumers.

Background

The hypoxicator industry is relatively small around the world compared to other medical device sectors, and particularly in Australia where there are only a handful of manufacturers and suppliers of these products.

The technologies incorporated in the hypoxicator products differ greatly in their complexity. The scope of the intended uses and target user groups are also diverse. These products are no longer exclusively used by elite athletes attempting to improve their performance, but are also used by an increasing number of professions for training purposes, and by the wider community to improve their health and well-being.

Types of Products

Hypoxicators are designed and presented in a number of forms for many different applications. However, hypoxicators generally fit into one of three different categories; non-powered personal devices, powered personal devices, and enclosures.

Non-powered personal devices

These are commonly known as “re-breathing” devices and are usually portable, worn by the user, and often fitted with a closed face mask, allowing mobility of the wearer (e.g. an athlete on a running track, or person at home). The devices incorporate a filter which usually removes carbon dioxide from exhaled air, and reduces the oxygen content of the air subsequently inhaled by the user. Carbon dioxide filters must be replaced regularly to maintain the function of the device. Non-powered devices may be used in conjunction with a separate pulse oximeter to monitor the user’s blood oxygen saturation levels.

Powered personal devices

These include electrically powered (mains or battery) devices that utilise pumps and filters to deliver air with reduced oxygen content to the user. Devices are often fitted with various controls to adjust the percentage of oxygen delivered to the user, and a user interface displaying both the gas mix delivered, and the physiological state of the user (via pulse oximetry). The user may be connected to the hypoxic air supply via a face mask strapped to their head. Although these devices are often described as “portable”, they usually require the user to stay within very close proximity to the device.

Enclosures

Consist of an enclosed space, such as a dedicated room or a tent, fitted with gas processing systems to reduce the oxygen content of the air within the enclosed space. Although generally intended for use by more than one person concurrently (such as a sporting team), they can also be presented for extended use by an individual when fitted over a bed while sleeping. Enclosed hypoxicator systems may be used in conjunction with a separate pulse oximeter to monitor the user’s blood oxygen saturation levels.

Intended Purpose & Features

Each of the devices described above may be used under the supervision of a trained health professional (such as a sports physiologist), or used by an individual in their own home without medical supervision.

Many of the powered devices incorporate some form of biofeedback where the hypoxicator changes its operation based on the user's blood oxygen saturation levels. For example, if the users SaO₂ levels, monitored by a pulse oximeter, drop below a pre-set value, the hypoxicator will cease operation and may not allow the user to operate the device again for a period of time. Manufacturers often advertise this as a valuable safety feature.

Although these devices may be supplied as a stand-alone unit, in most cases the devices are supplied as part of a system incorporating other medical devices or products such as; portable pulse oximeters, battery powered oxygen analysers, breathing bags, spare CO₂ filters, and face masks.

Product Claims

Many claims are made by manufacturers and suppliers of hypoxicators. Some advertise the general benefits gained from training at altitude, or the possible physiological effects of using their product, while others claim to treat specific medical conditions. Claims currently made by manufacturers of hypoxicators include, but are not limited to:

Generic altitude simulation and fitness claims

- “preparation for high altitude exposure”
- “exercising at simulated altitude”
- “sleeping at simulated altitude”
- “enhanced power output and speed”
- “improved strength and endurance”
- “allow athletes ... to maximise performance and gain a competitive advantage through ... altitude training technology”
- “simulate the lower oxygen levels normally experienced at altitude”
- “simulate high altitude environments regardless of the elevation at which they are used”
- “the body makes various adaptations to cope more efficiently with the reduced oxygen availability ... these physiological adaptations can increase capacity for exercise at altitude”

Physiological claims

- “stimulated production of EPO, haemoglobin and reticulocytes, enhancing the bloods oxygen carrying capacity”
- “release of VEGF (Vascular Endothelial Growth Factor) – the protein that facilitates creation of new micro capillaries and increases blood vessel diameter (vasodilation) – allowing for oxygen to be more efficiently delivered to organs and muscles”

- “new red blood cell production” or “increases blood volume”
- “new blood capillary growth”
- “decreased resting heart-rate and blood pressure”
- “increase oxygen delivery to damaged tissue”
- “increased production and release of Human Growth Hormone (HGH)”
- “heart protecting properties”, “improved heart function” or “improved circulation”
- “improve lung function”
- “boost immune system”
- “increased metabolic rate and calorie burn”
- “increase mental ability”

Therapeutic claims

- “reduced symptoms of Acute Mountain Sickness”
- “altitude simulation programs are proven to reduce the symptoms of a number of endemic health problems ... these include:
 - asthma
 - bronchial conditions
 - high blood pressure
 - high cholesterol
 - type 2 diabetes
 - chronic fatigue sufferers
 - weight loss
 - fertility”
- “improve sleep and assistance with sleep disorders”
- “improve mild to moderate asthma”
- “individuals can expect the following benefits from an IHT ... program:
 - improved sexual performance and libido
 - reduced blood pressure and hypertension
 - enhanced metabolism and increased weight-loss
 - boosted allergy resistance
 - lower cholesterol levels
 - strengthened immune system function”
- “use of hypoxic therapy as a complimentary and extremely effective method for managing and controlling diabetes”
- “Type II diabetes and in some case Type I Diabetes may be almost completely eliminated”
- “sufferers of Type II Diabetes Mellitus can expect the following benefits from the use of hypoxic therapy:
 - controlled blood glucose levels
 - decreased blood pressure
 - reduced probability of disease-related health complications (eg. Renal failure, retinopathy etc.)”

- “bronchial asthma patients can expect the following benefits:
 - reduction of asthmatic episodes and chronic bronchial inflammation
 - increased Forced Vital Capacity (FVC)
 - increased Forced Expiratory Velocity (FEV)”
- “this concept has been successfully applied to the treatment of asthma, allergies, diabetes, sleep disorders, and many other degenerative or chronic diseases”
- “can boost an adult’s defence against unavoidable oxidative stress, hopefully aiding in the following:
 - Prevention/alleviation of chronic and degenerative illnesses (Alzheimer’s, diabetes, cancer)
 - Slowing of the aging process
 - Promotion of overall health, wellness and rejuvenation”

Potential Hazards & Safety Concerns

Oxygen comprises approximately 21% of the atmosphere at sea level. Oxygen is needed by every cell in the human body, with organs such as brain and heart particularly needing an uninterrupted, steady continuous supply of oxygen to function normally. These “vital organs” are quite intolerant of acute interruptions in oxygen flow.

The term “oxygen flux” refers to the steady flow of oxygen (O₂) from the atmosphere, via the lungs and the blood stream, to every cell in the human body. A concentration gradient exists by which oxygen flows “downhill” from higher partial pressure in the air we breathe, to lower partial pressure at the cellular level within our body tissues.

There are many intermediate steps. Particularly important is the normal functioning of red blood cells (RBC) and haemoglobin (Hb), which carries molecular oxygen from the lungs, to the periphery, and also carries carbon dioxide (CO₂) from the periphery to the lungs for excretion in exhaled gases. The carbon dioxide is a by-product of metabolic processes combining nutrients and oxygen to generate “energy” to both sustain living cells, and to enable physical work to be performed by organs within our body.

The body of each person is micro-adapted to their particular “usual environment”, and particularly to the normal ambient oxygen pressure. Step reductions in this atmospheric oxygen concentration and pressure can seriously disrupt the vital normal “oxygen flux”, such that tissue hypoxia occurs¹.

Normal human responses to hypoxia can vary from acute, intermediate to long term; however there is much individual variation in response to reduced inspired oxygen conditions. Part of this variation is related to the normal variation of individuals within our population.

Some individuals, leading an apparently normal life near sea level, can unknowingly have lethal genetic susceptibility to hypoxia such that a rapid demise can follow suddenly reduced oxygen concentrations in inspired air. Furthermore individuals can unknowingly have a congenital abnormality (such as congenital absence of left pulmonary artery²).

¹ [http://en.wikipedia.org/wiki/Hypoxia_\(medical\)](http://en.wikipedia.org/wiki/Hypoxia_(medical))

² <http://www.pubmedcentral.nih.gov/picrender.fcgi?artid=1979133&blobtype=pdf>

Another major cause for variation in response to reduced inspired oxygen conditions is underlying disorders of metabolism or cardio-respiratory disorders in particular. Thus there are many variables which can alter an individual's response to hypoxia.

The effects of hypoxia on the brain include³:

- Impaired reasoning and judgement.
- Inability to speak.
- Difficulty processing visual information.
- Loss of muscle coordination.
- Abnormal movement.
- Muscular weakness.
- Hyperventilation.

As well as:

- Loss of consciousness
- Cardiac failure (and cardiac arrhythmia)
- Brain failure (and seizures)

This cluster of immediate symptoms in response to hypoxia is not directly related to classic descriptions of "altitude sickness"⁴, which describes more intermediate term responses to altitude.

Importantly, it is not possible to predict how an individual will respond to hypoxia. People can rapidly, and unexpectedly, suffer brain failure with impaired reasoning and judgement, such that they do not protect themselves by removing themselves from the hypoxic environment.

This summary outlines the risks of lower inspired oxygen levels, whether it be ascent of mountains, air travel, or exposure to devices that lower inspired oxygen levels below that of normal air.

Compared to these hazards, there are few scientifically validated reports to indicate benefits of lowering oxygen levels of inspired air, by any means. There is however ongoing studies concerning the use of these devices to train personnel who may encounter conditions of lowered inspired oxygen in extreme circumstances and for the possible enhancement of endurance in athletes.

Independent Clinical Advice

Since becoming aware of safety concerns regarding the use of hypoxicators, the TGA has sought independent advice on the use of hypoxicator products in different clinical situations and user populations.

³ <http://casa.gov.au/fsa/2005/aug/21-23.pdf>

⁴ http://en.wikipedia.org/wiki/Altitude_sickness

The Medical Device Evaluation Committee (MDEC) provides independent medical and scientific advice to the Minister and the TGA on the safety, quality and performance of medical devices supplied in Australia; including issues relating to pre-market conformity assessment and post market monitoring. More information regarding the expertise and function of MDEC can be found at <<http://www.tga.gov.au/docs/html/mdec/index.htm>>.

Hypoxicator products were discussed by the MDEC in 2007. The committee raised a number of concerns regarding the safety of such products when used without constant supervision by qualified medical professionals. These concerns were not limited to the use of hypoxicators by the frail or unwell, but also applied to users who might otherwise be considered healthy individuals.

The MDEC was of the opinion that a hypoxicator was potentially hazardous, regardless of the manufacturer's intended purpose, and that their use could result in the user experiencing adverse side effects, such as hypoxaemia.

Current Regulatory Requirements

The *Therapeutic Goods Act 1989* (the Act) and the *Therapeutic Goods (Medical Devices) Regulations 2002* (the Regulations) provide the legislative basis for uniform national control over medical devices used in the prevention, diagnosis, curing, or alleviation of a disease, ailment, defect or injury.

The Therapeutic Goods Administration (TGA), a Division of the Commonwealth Department of Health and Ageing, is responsible for administering the Act. The Office of Devices, Blood and Tissues (ODBT) is the area within the TGA responsible for regulating medical devices.

The therapeutic goods legislation and regulations incorporates accepted best practice relating to safety, quality and risk management procedures, as well as providing the flexibility and capacity to regulate new and changing technology. The regulatory framework also adopts the principles of the Global Harmonisation Task Force (GHTF) on medical devices. More information regarding the GHTF can be found at <<http://www.ghrf.org>>.

The medical device regulatory system has the following features:

- a device classification scheme based on different levels of risk for each class of device;
- essential principles for the quality, safety and performance of the medical device that must be complied with before the product can be supplied;
- options as to how compliance with the essential principles can be satisfied and assessed – manufacturer quality systems, type testing, and design evaluation;
- the use of international standards to satisfy the requirements of the essential principles;
- a comprehensive post market surveillance and adverse incident reporting program;
- appropriate regulatory controls for the manufacturing processes of medical devices; and
- the inclusion of products on the Australian Register of Therapeutic Goods (ARTG) as the central point of control for the legal supply of medical devices in Australia.

Definitions

For a product to be regulated in Australia as a medical device it must first meet the definition of a “therapeutic good”, before applying the definition of a “medical device”. If a product satisfies both of these definitions, its supply in Australia shall be regulated by the TGA via an entry on the ARTG.

What is a “Therapeutic Good”?

The formal definitions of a therapeutic good and therapeutic use, as defined in Section 3 of the Act, are as follows:

therapeutic goods means goods:

- a. *that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:*
 - i. *for therapeutic use; or*

- ii. *for use as an ingredient or component in the manufacture of therapeutic goods; or*
- iii. *for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or*
- b. *included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a) (ii) or (iii);*

and includes goods declared to be therapeutic goods under an order in force under section 7, but does not include:

- c. *goods declared not to be therapeutic goods under an order in force under section 7; or*
- d. *goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or*
- e. *foods.*

therapeutic use means use in or in connection with:

- a. *preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or*
- b. *influencing, inhibiting or modifying a physiological process in persons or animals; or*
- c. *testing the susceptibility of persons or animals to a disease or ailment; or*
- d. *influencing, controlling or preventing conception in persons; or*
- e. *testing for pregnancy in persons; or*
- f. *the replacement or modification of parts of the anatomy in persons or animals.*

What is a “Medical Device”?

Section 41BD of the Act defines a medical device as:

(1) ***A medical device is:***

- (a) ***any instrument, apparatus, appliance, material or other article (whether used alone or in combination, and including the software necessary for its proper application) intended, by the person under whose name it is or is to be supplied, to be used for human beings for the purpose of one or more of the following:***
 - (i) *diagnosis, prevention, monitoring, treatment or alleviation of disease;*
 - (ii) *diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;*
 - (iii) ***investigation, replacement or modification of the anatomy or of a physiological process;***
 - (iv) *control of conception;*

and that does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but that may be assisted in its function by such means; or

- (b) ***an accessory to such an instrument, apparatus, appliance, material or other article.***

Please note some text within the definition has been bolded for emphasis. The issue of whether a product is a medical device or not, for the purposes of regulation, is determined by the manufacturer of the device, and the decision is based on claims presented by the manufacturer in the product's supporting information (such as labelling, instructions for use, or any advertising material).

What is a "System or Procedure Pack"?

Section 41BF of the Act defines a system or procedure pack as:

- (1) *A package and therapeutic goods in the package are a system or procedure pack if:*
- (a) *the package and the therapeutic goods are for use as a unit, either in combination as a system or in a medical or surgical procedure; and*
 - (b) *the package contains at least one medical device; and*
 - (c) *the package and the therapeutic goods do not constitute a composite pack.*
- (2) *To avoid doubt, a system or procedure pack is a medical device.*

This definition refers to a group of products that are supplied together, where at least one of the products is a medical device.

Which definitions apply to hypoxicators?

The issue of whether these definitions apply to hypoxicators is heavily dependent on how each hypoxicator is presented by the manufacturer. In general however, hypoxicators currently on the market would fit the definition of a therapeutic good, because they are used (or likely to be used) for a therapeutic use.

The definition of therapeutic use is applicable to hypoxicators where the manufacturer claims they can be used in connection with either:

- preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury; or
- influencing, inhibiting or modifying a physiological process.

Once again, the manufacturer's claims must be taken into account when deciding whether a hypoxicator fits the definition of a medical device. Clearly, where a manufacturer makes a *therapeutic* claim (such as the examples given previously), the hypoxicator would be considered a medical device because it is used for the "*diagnosis, prevention, monitoring, treatment or alleviation of disease ... or compensation for an injury or handicap*".

If a manufacturer does not make any therapeutic claims, the relevance of the definition of a medical device becomes less obvious. However, where the manufacturer makes specific *physiological* claims (such as the examples given previously), the hypoxicator would still meet the definition of a medical device because it is used for the "*investigation ... or modification of ... a physiological process*".

If a manufacturer does not make therapeutic or physiological claims, but limits their intended purpose and claims to those of general altitude simulation (such as the examples given previously), the hypoxicator would not fit the definition of a medical device.

However, in such instances the definition of a therapeutic good, and therapeutic use, *may* still apply. This is because the hypoxicator could still be “*likely to be taken to be*” for “*influencing, inhibiting or modifying a physiological process*”.

This interpretation would mean that the hypoxicator would be regulated as a therapeutic good, but not as a medical device. Therapeutic goods are regulated under Chapter 3 of the Act, and require a Listing or Registration on the ARTG prior to supply in Australia.

If a hypoxicator is supplied in a package with other products, the package may fit the definition of a system or procedure pack. The following scenarios may exist:

1. The hypoxicator is a medical device and is supplied in a pack with any combination of other items. In this case the whole pack/system would be regulated in its own right as a medical device.
2. The hypoxicator is not a medical device, but is supplied in a pack with other items, including at least one medical device (such as a pulse oximeter). In this case the whole pack/system would be regulated in its own right as a medical device.
3. The hypoxicator is not a medical device, and is supplied in a pack with other items, none of which are medical devices. In this case the pack/system would not be regulated as a medical device.

Classification of Medical Devices

The risks associated with using medical devices can range from little or no risk to patients and users, to significant potential risks inherent in the type of device. The level of pre-market intervention by the TGA is proportional to the level of potential risk, and is established through a classification system based on that potential risk.

The classification risk is determined from the manufacturer’s intended purpose for the medical device, and a set of classification rules. These rules classify medical devices into one of five classes:

- Class I – for low risk medical devices (includes low risk devices that are sterile and /or have a measuring function),
- Class IIa – for low-medium risk medical devices,
- Class IIb – for medium–high risk medical devices,
- Class III – for high risk medical devices, and
- AIMD – for Active Implantable Medical Devices (treated as Class III medical devices).

Schedule 2 of the Regulations describes each of the classification rules applicable to medical devices. Before applying the classification rules the manufacturer must consider the following:

- Is the product a “medical device”?
- Do the special classification rules (Schedule 2, Part 5 of the Regulations) apply?
- Is the device intended to be non-invasive?
- Is the device intended to be invasive through a “body orifice”?
- Is the device intended to be “surgically invasive”?
- Is the device an “active medical device”?

It is important that the following points are taken into account when classifying a medical device:

- The manufacturer is responsible for determining the class of a device. However, the TGA makes the final decision on whether a medical device has been correctly classified by a manufacturer.
- The classification rules are based on the manufacturer's intended purpose, taking into account the mechanism of action, and in some cases, more than one rule can apply. If this happens, the higher classification applies with the exception of medical devices for export only (Rule 5.8) which are classified as Class I.
- The classification rules do not take into account individual design features of a device to reduce the risk of a particular hazard occurring. For example, there is no classification difference between a device which relies on AC mains power, and the same device which has been designed to operate from DC battery power to eliminate electric shock hazards. If the manufacturer's intended purpose is the same, both devices would be classified the same using the classification rules for active medical devices.
- All the relevant classification rules must be considered to determine the class of the medical device.
- The classification must be consistent with the information accompanying the medical device, including; the label, directions for use, brochures, operating manuals and websites.
- If the intended purpose is not clear in the information, the TGA will assume an intended purpose consistent with the purpose generally accepted in clinical practice.
- If the device is to be used in combination with another medical device, the classification rules must be applied separately to each device.
- Accessories are classified separately to the medical device they are used with.
- Software intended to drive or influence the use of a medical device falls under the same classification as the medical device.
- Based on the intended purpose, software may be a medical device in its own right.
- For a system or procedure pack, the component with the highest medical device classification determines the overall classification for the system or procedure pack. For example, a procedure pack containing a Class III medical device will also be Class III

A guidance document regarding the classification rules for medical devices supplied in Australia can be found at <<http://www.tga.gov.au/docs/html/devguid25.htm>>.

What class is a hypoxicator or hypoxicator system?

Before the class of a hypoxicator can be determined, a number of definitions must first be considered relating to the operation of the hypoxicator. Hypoxicators may either be electrically powered or non-powered.

Active hypoxicators & systems

The term "active medical device" applies to all devices which rely on a source of electrical energy to operate, and is defined in the Regulations as follows:

Active medical device:

- a. *Means a medical device that is intended by the manufacturer:*
 - i. *To depend for its operation on a source of electrical energy or other source of energy (other than a source of energy generated directly by a human being or gravity); and*
 - ii. *To act by converting this energy; but*
- b. *Does not include a medical device that is intended by the manufacturer to transmit energy, a substance, or any other element, between an active medical device and a human being without any significant change in the energy, substance or other element being transmitted.*

There are a number of special classification rules in Schedule 2, Part 4 of the Regulations which apply specifically to active medical devices.

Rule 4.1 states that active medical devices are classified as Class I, unless another classification rule results in a higher classification.

Rule 4.2 applies to active medical devices for therapy that administer energy to a patient. Such devices are classified as Class IIa; or Class IIb if the exchange of energy occurs in a potentially hazardous way. This rule is unlikely to apply to hypoxicators.

Rule 4.3 applies to active medical devices for diagnosis and results in a classification of Class IIa; or Class IIb if the device monitors vital physiological parameters that could result in immediate danger, or emits ionising radiation. This rule is unlikely to apply to individual hypoxicators, but may apply to *systems* incorporating a hypoxicator (and other medical devices) used for diagnosis.

Rule 4.4 applies to active medical devices intended to administer or remove medicines, etc from a patient's body. In particular this rule states that:

- (1) *Subject to subclause (2), an active medical device that is intended by the manufacturer to be used to administer medicine, body liquids or other substances to a patient, or to remove medicine, body liquids or other substances from a patient, is classified as Class IIa.*
- (2) *If the device is of a kind such that the administration or removal of the medicine, body liquids or other substances is potentially hazardous to the patient, having regard to the nature of the substances involved, the part of the patient's body concerned, and the characteristics of the device, the device is classified as Class IIb.*

In the case of hypoxicators that satisfy the definition of an active medical device, they are intended by the manufacturer to administer a substance (gas mixture with a certain oxygen concentration) to a patient (user). Therefore classification Rule 4.4 applies to hypoxicators that are considered active medical devices.

If the administration of this reduced-oxygen air to the user is considered to occur in a potentially hazardous way, the hypoxicator would be classified as Class IIb; otherwise the hypoxicator would be classified as Class IIa.

Non-active hypoxicators

For hypoxicators that do not rely on an energy source, the classification rules in Schedule 2, Part 2 for non-invasive medical devices would apply. Rule 2.1 states that a non-invasive medical device is classified as Class I, unless another classification rule results in a higher classification.

Rule 2.2 applies to non-invasive medical devices intended to channel or store blood etc. In particular this rule states:

- (1) *This clause applies to:*
 - (a) *a non invasive medical device that is intended by the manufacturer to be used to channel or store blood or body liquids that are to be infused, administered or introduced into a patient; and*
 - (b) *a non invasive medical device that is intended by the manufacturer to be used to store an organ, part of an organ or body tissue that is to be later introduced into a patient; and*
 - (c) *a non invasive medical device that:*
 - (i) *is intended by the manufacturer to be used to channel or store a liquid or gas that is to be infused, administered or introduced into a patient; and*
 - (ii) *may be connected to an active medical device classified as Class IIa or higher.*
- (2) *The device is classified as Class IIa.*

Rule 2.2(1)(c) may apply to hypoxicators, but *only* if the hypoxicator is intended to be connected to another active medical device that is Class IIa or higher (for example a separate pulse oximeter).

Rule 2.3 applies to non invasive medical devices intended to modify the biological or chemical composition of blood, etc. This rule is unlikely to apply to hypoxicators because they do not involve blood, or other liquids, being infused into the user.

Rule 2.4 applies to non invasive medical devices intended to have contact with injured skin. This rule is unlikely to apply to hypoxicators because they are usually not intended to come into contact with injured skin.

Essential Principles

The fourteen essential principles, detailed in Schedule 1 of the Regulations, list the safety and performance requirements for *all* medical devices. The underlying notion of the essential principles is that the risks of using a medical device must be outweighed by the benefits gained from the use of the medical device.

There are two main categories of essential principles; the general principles apply to all devices, and the applicability of the principles dealing with design and construction depend on the intended purpose and properties of the medical device.

The essential principles include:

- General Principles (apply to all medical devices)
 - the use of a medical device must not compromise health and safety
 - the design and construction of a medical device has to conform with safety principles
 - medical devices are to be suitable for the intended purpose
 - long term safety
 - medical devices are not adversely affected by transport or storage
 - the benefits of medical devices are to outweigh any side effects
- Principles about Design and Construction
 - chemical, physical and biological properties
 - infection and microbial contamination
 - construction and environmental properties
 - medical devices with a measuring function
 - protection against radiation
 - medical devices connected to or equipped with an energy source
 - information to be provided with medical devices (applies to all medical devices)
 - clinical evidence (applies to all medical devices)

If a hypoxicator is considered a medical device, the manufacturer must ensure that it meets all of the applicable essential principles. It should be noted that clinical evidence must exist for all medical devices, regardless of their classification.

Conformity Assessment Procedures

The classification of a medical device determines the conformity assessment procedure(s) a manufacturer can choose to ensure that the device is adequately assessed to conform to the particular requirements for the class of device. Higher class devices undergo a more stringent form of conformity assessment than lower class devices.

The responsibility for conformity assessment rests with the manufacturer of a medical device. The role of the TGA, or an overseas notified body, is to issue certification after they have confirmed that the conformity assessment procedures are appropriate and have been applied. This intervention will vary according to the class of the device.

Conformity assessment by the TGA is also required for Australian manufacturers of medical devices intended for supply in Australia.

Schedule 3 of the Regulations outlines the particular requirements of each of the conformity assessment procedures. Further information regarding the conformity assessment procedures can be found in a guidance document at <<http://www.tga.gov.au/docs/html/devguid3.htm>>.

Manufacturers of non-sterile Class IIb medical devices are required to undergo certification to one of the following conformity assessment procedures:

- Part 1 Full Quality Assurance (excluding Part 1.6 Design Examination), or
- Part 2 Type Examination **plus** Part 4 Production Quality Assurance, or
- Part 2 Type Examination **plus** Part 5 Product Quality Assurance.

Manufacturers of non-sterile Class IIa medical devices are required to undergo certification to one of the following conformity assessment procedures:

- Part 1 Full Quality Assurance, or
- Part 6 Declaration of Conformity **plus** Part 4 Production Quality Assurance, or
- Part 6 Declaration of Conformity **plus** Part 5 Product Quality Assurance.

Manufacturers of non-sterile, non-measuring Class I medical devices are only required to use the Part 6 self declaration conformity assessment procedure.

Supplying Medical Devices in Australia

All medical devices supplied in Australia must have a ‘sponsor’ for the goods, resident in Australia, who takes responsibility for the products, compliance with regulatory obligations, and any post-market action, such as regulatory reporting to the TGA, distribution, and product recalls.

Prior to the Australian sponsor supplying a medical device in Australia, the device must be included on the Australian Register of Therapeutic Goods (ARTG). This is done using an e-business account which the sponsor establishes with the TGA, using the TGA’s Devices Electronic Application Lodgement (DEAL) system. Guidance on establishing an e-business account, and lodging applications to include devices on the ARTG, can be found at <http://www.tga.gov.au/devices/dealfaq.htm>.

Before an application to include the device on the ARTG can be made, the Australian sponsor is initially required to provide evidence that the manufacturer has applied an appropriate Conformity Assessment Procedure to manufacture the device.

This is known as “Manufacturer’s Evidence”. For non-Australian manufacturers this may be in the form of a CE certificate from a European Notified Body under an appropriate Annex of the *Medical Devices Directive (MDD) 93/42/EEC*. More information regarding manufacturer’s evidence can be found at http://www.tga.gov.au/devices/fs_eccert.htm.

For Australian manufacturers the manufacturer must hold a TGA Conformity Assessment certificate under Schedule 3 of the *Therapeutic Goods (Medical Devices) Regulations 2002*. Non-Australian manufacturers may also obtain a TGA certificate if they do not hold CE certification. Further information on how to apply for a TGA Conformity Assessment certificate can be found at <http://www.tga.gov.au/docs/html/devguid26.htm>.

Entries on the ARTG are distinguished by a code which describes the ‘kind of medical device’. The ARTG utilises the list of codes maintained by the Global Medical Device Nomenclature (GMDN) Agency. They are commonly referred to as GMDN codes.

Fees are payable for most applications, and an annual fee is payable for each entry held by an Australian sponsor on the ARTG. A summary of current fees and charges can be found at <http://www.tga.gov.au/fees/fees07.htm>.

Please note:

A certificate from the US Food and Drug Administration (FDA) is not acceptable because it has been issued against a different auditing criteria to that required under the Australian legislation. Similarly, ISO 13485 or ISO 9001 compliance certificates are not acceptable as they do not provide assurance that the requirements of the Australian Regulations have been taken into consideration.

Further Information

The following links to the TGA website have been provided to assist in understanding the regulatory requirements for the supply of medical devices in Australia:

- TGA Medical Devices home page:
<<http://www.tga.gov.au/devices/devices.htm>>
- An overview of the medical device regulatory framework in Australia:
<<http://www.tga.gov.au/docs/html/devguid1.htm>>
- Roles and responsibilities of medical device sponsors and manufacturers:
<<http://www.tga.gov.au/docs/html/devguid20.htm>>

Sponsors & Manufacturers

Under the Act sponsors and manufacturers of medical devices have separate, yet inter-linked responsibilities and obligations. The differences and similarities need to be clearly understood. This is especially important for medical device manufacturers.

If someone carries out activities that would normally be carried out by a manufacturer, they would then be considered a manufacturer. This also refers to rewording or fabricating statements or declarations that should be made by manufacturers about their products, including the intended purpose of use, any instructions, labelling or advertising.

The Act makes an interesting distinction between sponsors and manufacturers. On the whole sponsors have responsibilities, while manufacturers mostly have obligations. The distinction means that penalties will be incurred by a sponsor by way of the suspension or cancellation of the sponsor's entry in the ARTG, and/or fines for the manufacturers if they do not fulfil their obligations. Additionally, if the manufacturer has been issued a conformity assessment certificate by the TGA, breaching conditions of the conformity assessment certificate may lead to the suspension or revocation of the certificate. It may also be an offence that will incur a financial penalty.

Sponsor's Responsibilities

Before someone can supply a therapeutic good in Australia, including a medical device, and assuming that the product is not an excluded good, they are required to make an application to have the product entered in the Australian Register of Therapeutic Goods (ARTG).

Sponsors Certification

When making the application to include a medical device in the ARTG the person must comply with section 41FD of the Act and certify that:

- the product applied for is a medical device;
- the device is intended for a specific purpose;
- the device is correctly classified;
- the device complies with the essential principles as well as having available and sufficient information to substantiate compliance with the essential principles;
- an appropriate conformity assessment procedure has been applied to the device as well as having available and sufficient information to substantiate the application of the conformity assessment procedures;
- the advertising for the device complies with all requirements;
- the device does not contain any prohibited imports;
- the information included in or with the application is complete and correct.

It should be noted that an offence would be committed if the person made a false or misleading statement in connection with the application or a certificate associated with the application. Severe financial penalties may be incurred.

ARTG Conditions

If an application is successful conditions will be imposed on the supply of the medical device. If the conditions are breached various penalties can be imposed, ranging from suspension or cancellation of the entry in the ARTG, to large fines.

Conditions applying automatically to entries in the ARTG under section 41FN of the Act require the sponsor to:

- allow an authorised person from the TGA to enter, at any reasonable time, any premises, including premises outside Australia, at which that person, or any other person deals with the medical devices. This is required so that the authorised person can inspect the premises and medical devices and to take samples. It should be noted that the TGA would pay for the samples. If requested by the authorised person the sponsor will also need to produce any documents relating to the medical device and to allow the documents to be copied by the authorised person.
- deliver a reasonable number of samples of the medical device within a specified period of time and according to any specified requirements from the TGA;
- have sufficient information to substantiate compliance with the essential principles;
- have sufficient information to substantiate that the conformity assessment procedures have been applied to the medical device;
- have available information relating to changes to the medical device including the product range, the quality management system of the manufacturer of the medical device;
- give this information to the TGA, if requested;
- under section 41MP, give information to the TGA about any malfunction or deterioration in the characteristics or performance of the medical device or any inadequacy in the design, production, labelling, instructions for use or advertising materials for the medical device, or any use in accordance with, or contrary to, the use intended by the manufacturer that:

- led to the death of a patient or a user of the medical device or a serious deterioration in their state of health, or another person, within 10 days after becoming aware of the event or occurrence, or
- led to a serious threat to public health, within 48 hours of becoming aware of the event, or
- that might lead to the death of a patient or a user of the medical device or a serious deterioration in their state of health, or another person, within 30 days of becoming aware of the event.
- information to the TGA:
 - that indicates that a medical device does not comply with essential principles;
 - that indicates that a certificate not issued by the TGA certifying compliance with the essential principles or the application of relevant conformity assessment procedures used to support an application for inclusion in the ARTG has been restricted, suspended, revoked or is no longer valid;
- give the manufacturer of the medical device information relevant to the manufacturer's obligations under the conformity assessment procedures, especially the requirements for post-market monitoring, and whether the medical device complies with the essential principles; and
- ensure advertising material used is consistent with the intended purpose for the medical device.

Advertising Rules

Advertisements for therapeutic goods, including medical devices, directed to consumers are required to comply with the *Therapeutic Goods Act 1989*, Part 2 of the *Therapeutic Goods Regulations 1990*, and the *Therapeutic Goods Advertising Code (TGAC)*.

Amongst other things, if specific therapeutic claims are made for a therapeutic good the advertisement must not:

- be likely to arouse unwarranted or unrealistic expectations of product effectiveness;
- be likely to lead to consumers self-diagnosing or inappropriately treating potentially serious diseases;
- abuse the trust or exploit the lack of knowledge of consumers or contain language which could bring about fear or distress;
- contain any claim, statement or implication that it is infallible, unfailing, magical, miraculous, or that it is a certain, guaranteed or sure cure;
- contain any claim, statement or implication that it is effective in all cases of a condition; or
- contain any claim, statement or implication that the goods are safe or that their use cannot cause harm or that they have no side effects.

More information regarding the regulation of advertising of therapeutic goods in Australia can be found at <<http://www.tga.gov.au/docs/html/advreg.htm>>.

A guidance document detailing specific requirements for the advertising of medical devices in Australia can be found at <<http://www.tga.gov.au/docs/html/devguid8.htm>>.

Offences & Penalties

There are serious penalties for individuals or companies found to have supplied medical devices in Australia without an appropriate entry on the ARTG. Offences include; illegal importation, exportation, manufacture or supply of medical devices not included in the ARTG, and not subject to an appropriate exemption (section 41MI of the Act), with maximum penalties for individuals of imprisonment for 12 months or A\$110 000, or both, and A\$550 000 for corporations.

More information on the various offences and penalties under the Act can be found at <http://www.tga.gov.au/devices/fs-offences.htm>.

Discussion

There is a wide variety of products currently on the market that could loosely be described as ‘hypoxicators’. Although the mode of action and physical representation of these products may differ substantially, each product intends to achieve a similar goal; that is, allowing the user to experience air of the same oxygen concentration found at high altitudes.

Hypoxicators Defined as Therapeutic Goods

Based on the current regulatory definitions all hypoxicators could be considered therapeutic goods, and any hypoxicator that makes any physiological or therapeutic claims would also be considered a medical device.

However, it has been highlighted that if a hypoxicator manufacturer only makes general claims of reducing oxygen levels to correspond to various altitudes, the product may still be considered to be a ‘therapeutic good’ because it is “*likely to be taken to be*” for “*influencing, inhibiting or modifying a physiological process*”.

If the same definition was applied to all other types of products, items such as exercise bikes, treadmills, SCUBA gear, or air conditioners, could also be interpreted to meet the definition of a therapeutic good, because they are likely to be taken to influence, inhibit, or modify a physiological process (e.g. perspiration, increase heart rate, or ability to breathe).

It is not the intention of the TGA to regulate such products as therapeutic goods. Therefore, in order to specifically exclude such products from the therapeutic goods regulatory framework, an amendment would have to be made to the current list of excluded goods, on the condition that advertising claims are limited to enhancing general fitness.

Classification of Hypoxicators

Based on the available information for hypoxicators currently on the market, there are four possible classification rules that could apply under the Regulations:

Type of Hypoxicator	Intended Use	Classification	Classification Rule
Active medical device (e.g. electrically powered)	Potentially hazardous	Class IIb	4.4(2)
	Not potentially hazardous	Class IIa	4.4(1)
Non-invasive medical device	Connects to an active device Class IIa or higher	Class IIa	2.2(1)(c)
	Not connected to an active device Class IIa or higher	Class I	2.1

Although the classification of a hypoxicator is the responsibility of each manufacturer, and is based on the manufacturer's intended purpose, the MDEC has examined the use of some electrically powered hypoxicators, and concluded that they are potentially hazardous for all their intended purposes. As such, all hypoxicators and hypoxicator systems that are active medical devices would be regulated as Class IIb medical devices.

If the TGA wished to regulate all types of hypoxicators at the same classification (for example Class IIb), regardless of the technology or manufacturer's claims, Schedule 2 of the Regulations would need to be amended to include a new special classification rule applying specifically to hypoxicator devices.

GMDN Codes for Hypoxicators

If a hypoxicator is considered to be a medical device, an Australian sponsor would be required to include the device on the ARTG prior to supply. For devices classified lower than Class III, a separate entry on the register is required for each '*kind of medical device*'; that is, the combination of manufacturer, sponsor, classification, and GMDN code.

There are currently two GMDN codes registered with the GMDN Agency that can be used to describe hypoxic therapy devices:

GMDN Code	Preferred Term	Description
46105	Hypoxicator, line-powered	A mains electricity (AC-powered), stationary device used to produce reduced-oxygen air for a therapeutic/fitness method that alternates the monitored breathing of hypoxic air and ambient air, to potentially improve the user's oxygen (O ₂) metabolism. It typically consists of a pump with controls used to compress ambient air through a membrane to filter out O ₂ and to regulate air O ₂ concentration, and a flowmeter to monitor the output to a face-mask breathing system applied to the user. This device may be used by athletes in training, to pre-acclimatize for high-altitude travel, or to treat various chronic disorders (e.g., chronic fatigue, reactive airway, allergies).
46106	Hypoxicator, non-powered	A non-powered, portable device used to produce reduced-oxygen air for a therapeutic/fitness method that alternates the monitored breathing of hypoxic air and ambient air, to potentially improve the user's oxygen (O ₂) metabolism. It typically consists of a plastic housing with a replaceable soda lime filter/carbon dioxide (CO ₂) scrubber used to decrease CO ₂ concentration in the air that is re-breathed, and ports to connect to air monitoring devices and to a face-mask breathing system applied to the user. This device may be used by athletes in training, to pre-acclimatize for high-altitude travel, or to treat various chronic disorders (e.g., chronic fatigue, reactive airway, allergies).

Claims & Advertising

There is a distinction between simply claiming that a hypoxicator allows the user to experience the oxygen content of air at simulated altitudes; and claims about physiological or therapeutic benefits based on the effects of using such a device.

Any direct or indirect therapeutic claims, such as the examples shown previously in this document, result in the hypoxicator being considered a therapeutic good and a medical device, and therefore regulated by the TGA under the Act and Regulations.

The TGA has examined the advertising claims of hypoxicator manufacturers, and found that all non-Australian manufacturers make some form of specific therapeutic or physiological claim. One Australian manufacturer currently makes claims of improved sporting performance via physiological benefits, while another Australian manufacturer currently only makes general simulated altitude and fitness claims.

Some hypoxicator manufacturers currently make claims that their product is “100% safe and effective”, or “has no adverse side effects”. In relation to therapeutic goods, these types of claims are not allowed to be made under the *Therapeutic Goods Advertising Code* (TGAC).

Some manufacturers also provide claims in the form of satisfied customer endorsements. Although the endorsements are made by a customer, the manufacturer is presenting them, and therefore the endorsements must also comply with the requirements of the TGAC.

Possible Regulatory Options

Taking all of the background information into account, the TGA considers that there are three options available to regulate the future supply of hypoxicators in Australia.

Option 1 – Regulate all hypoxicators as medical devices

The first option is to regulate **all** hypoxicator products as “medical devices”, regardless of the claims made by the manufacturer. This would capture all products that supply reduced oxygen air to an individual or group of people. Products for personal use, and altitude rooms or tents, would be regulated as medical devices.

This option would alleviate concerns over the safety and efficacy of such products, by ensuring that the manufacturer complies with the essential principles for medical devices.

However, this option would require sponsors to cease supply of all hypoxicators until they were entered on the ARTG. Given that no manufacturer of hypoxicators currently holds conformity assessment certification, no sponsor is expected to be in a position to include a hypoxicator on the ARTG as a medical device some time.

As such, a transition period would need to be considered, which would allow the supply of hypoxicators with limited claims, while the manufacturer went through the process of obtaining certification. The manufacturer would only be allowed to expand the scope of their claims once they had received certification to cover those claims, and the product was included on the ARTG.

Option 2 – Regulate based on manufacturer’s claims

The second option is to regulate hypoxicators as medical devices using the existing medical device regulatory framework, based on the manufacturer’s claims and intended purpose.

For example, where a hypoxicator manufacturer *only* claims to simulate oxygen levels at various altitudes, the hypoxicator would not fit the definition of a medical device under section 41BD of the Act. The TGA would elect not to interpret the hypoxicator to be a ‘therapeutic good’ (either informally or via amendments to the excluded goods order), and therefore not regulate its supply in Australia.

However, where a hypoxicator manufacturer makes any additional claims relating to physiological effects or therapeutic benefits, the hypoxicator would fit the definition of a ‘medical device’ under section 41BD of the Act, and the TGA would therefore regulate its supply in Australia.

Before any additional physiological or therapeutic claims could be made, the manufacturer would need to obtain certification incorporating such claims, and the hypoxicator would need to be entered on the ARTG as a medical device.

This option removes the need for a transition period to be imposed by the TGA, and allows manufacturers to continue the supply of hypoxicators where claims are limited to improved athletic performance and general altitude simulation.

This option would also allow hypoxicators to be regulated under the current medical device regulatory framework, without requiring amendments to the Act or Regulations.

Option 3 – Amend Regulations to regulate hypoxicators

The third option would be to make amendments to the medical device legislation to specifically include or exclude certain types of hypoxicators, and how to regulate their supply as medical devices. The following changes to the legislation could be considered.

Declaring hypoxicators to not be therapeutic goods

The *Therapeutic Goods (Excluded Goods) Order No. 1 of 2005* includes a list of products that are declared not to be therapeutic goods or medical devices for the purpose of the Act.

This option would amend the Excluded Goods Order to declare hypoxicator products not to be therapeutic goods, whether generally or for specific indications.

If all hypoxicators were placed generally in the Excluded Goods Order, the TGA would not regulate or monitor the supply of hypoxicators in Australia.

This option may be appropriate for hypoxicators with limited claims (e.g. simulate oxygen levels at high altitude only) to prevent them from having to be regulated as therapeutic goods rather than medical devices.

Adding a special classification rule for hypoxicators

A special classification rule could be added to the Regulations to represent the level of risk that the TGA considers appropriate for hypoxicators considered to be “medical devices”.

Special classification rules for particular kinds of medical devices are detailed in Schedule 2, Part 5 of the Regulations. A new classification rule could be added to specify that a medical device that delivers hypoxic air to a person is classified as Class IIb. This classification has been chosen because hypoxicators can be potentially hazardous to the user, regardless of the risk mitigation strategies employed by the manufacturer.

Hypoxicators to undergo a mandatory application audit

Under the current Regulations, if a hypoxicator is classified lower than Class III, it would not be subject to a mandatory pre-market application audit by the TGA. In recognition that active hypoxicators are potentially hazardous, this option would amend Regulation 5.3 to include “active hypoxicators” in the list of devices required to undergo a mandatory application audit prior to being included in the ARTG.

Section 41FH of the Act and Regulation 5.3 specify that applications to include certain medical devices in the ARTG must be selected for a pre-market “application audit” prior to being included in the register. An application audit assessment fee will be charged for these cases.

An application audit will confirm that the manufacturer of a medical device has carried out the conformity assessment procedures appropriate to the classification of that medical device.

Mandatory pre-market application audits for active hypoxicators should involve a review of the following data:

1. Manufacturer's Australian Declaration of Conformity (DoC)
2. CE certification issued by a recognised European Notified Body under the MDD/93/42/EEC
3. CE certification audit report and close-out of non-conformities
4. Labelling, instructions for use (IFU), and advertising material
5. Risk management report
6. Summary of clinical evidence used to establish conformity with Essential Principle 14
7. Checklist showing compliance with the Australian Essential Principles or European Essential Requirements

If the outcome of an application audit is satisfactory a certificate of inclusion in the ARTG will be issued to the applicant. If the application audit is unsuccessful the application will be rejected and the applicant advised in writing. Re-application should not be attempted until it can be verified that the manufacturer has completed the appropriate conformity assessment procedures.

An alternative to prescribing active hypoxicators to undergo a mandatory application audit would be to select them for a non-mandatory application audit. The same data set would be reviewed during this process, but there would be no additional assessment fee.

More information on application audits can be found at <http://www.tga.gov.au/docs/html/devguid2.htm>.

Recommendations

It is recommended that hypoxicators be regulated as medical devices in Australia, based on the manufacturer's claims and intended purpose, as described in Option 2 above.

The regulatory requirements would include the following:

1. The consideration of whether a hypoxicator is a medical device is to be determined from the manufacturer's claims and intended purpose.
 - a. If the manufacturer's claims and intended purpose are limited to simulating air at altitude for professional training purposes; the hypoxicator would not fit the definition of a 'medical device', and the TGA would not interpret the definition of 'therapeutic use' or 'therapeutic good' to apply. Supply of these products in Australia would therefore not be regulated by the TGA.
 - i. To ensure consistency when applying the definition of 'therapeutic good', the *Therapeutic Goods (Excluded Goods) Order No. 1 of 2005* should be amended to exclude hypoxicators that only make general simulated oxygen levels at altitude and fitness claims.
 - b. If the manufacturer's claims and intended purpose extend beyond generic altitude simulation, and include statements relating to possible physiological changes or therapeutic benefits, such products supplied in Australia will be regulated by the TGA as "medical devices".
2. The addition of a special classification rule for hypoxicators is not necessary. As long as another classification rule does not result in a higher classification, the following existing classification rules shall apply to hypoxicators considered to be medical devices:
 - a. Where a hypoxicator is an active medical device, the device should be classified as Class IIb using Classification Rule 4.4(2) – *Active medical devices intended to administer or remove medicines etc from a patient's body*.
 - b. Where a hypoxicator is a non-active, non-invasive medical device, the device should be classified as:
 - i. Class IIa using Classification Rule 2.2(1)(c) – *Non-invasive medical devices intended to channel or store blood etc*, or
 - ii. Class I using Classification Rule 2.1.
3. Before a hypoxicator can be supplied in Australia as a medical device, the manufacturer should first obtain appropriate conformity assessment certification, and the Australian sponsor must include the device in the ARTG.
 - a. Australian medical device manufacturers must obtain conformity assessment certification from the TGA.
 - b. Non-Australian medical device manufacturers may obtain certification under the Australia-EC Mutual Recognition Agreement, CE certification under the MDD 93/42/EEC from a recognised European Notified Body, or Conformity Assessment certification from the TGA.
 - i. Any application for inclusion on the ARTG, where a non-Australian manufacturer holds CE certification, may be selected for a non-mandatory pre-market application audit.

- c. Hypoxicators may be supplied in Australia during the certification process, and prior to entry in the ARTG, on the condition that only general altitude simulation and fitness claims are made by the manufacturer.
 - d. Claims relating to possible physiological changes or therapeutic benefits may only be made by the manufacturer after they have obtained appropriate certification, and the Australian sponsor has obtained an ARTG entry for the device.
4. Persons found to be supplying a hypoxicator without a valid ARTG entry, whose manufacturer makes physiological or therapeutic claims, shall be deemed to be supplying medical devices in Australia illegally, and may be penalised accordingly under the *Therapeutic Goods Act 1989*.

Consultation Period & Feedback

Relevant industry sectors, professional and consumer groups are invited to provide feedback on this document, prior to an official decision being made regarding the regulation of hypoxicators in Australia.

The consultation period to enable the affected parties to consider the recommendations and provide feedback will end on **Friday 5 September 2008**. Feedback received after this date will not be considered.

Once the consultation period has closed, the TGA shall collate all feedback received, incorporate any necessary changes to the proposed recommendations, and release a final position paper by **Friday 3 October 2008**.

The final position paper will set out the exact details of how hypoxicators are to be regulated in Australia by the TGA, and provide information for manufacturers and sponsors on the required steps to achieve regulatory compliance.

Please forward all consultation feedback to:

Parliamentary and Management Group
Office of Devices, Blood and Tissues
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

or Parliamentary and Management Group
Office of Devices, Blood and Tissues
Therapeutic Goods Administration
136 Narrabundah Lane
SYMONSTON ACT 2609

Or via email to: ODBTConsult@tga.gov.au

Please note:

The recommendations in this first consultation document are not yet enforceable, and should therefore not be relied upon for advice regarding the regulation of hypoxicators. Final recommendations, and the TGA's official position on how hypoxicators are to be regulated, shall be issued at a later date.

Appendix 1 – Terms & Abbreviations

Act	Therapeutic Goods Act 1989
AIMD	Active Implantable Medical Device
ARTG	Australian Register of Therapeutic Goods
CA	Conformity Assessment
DEAL	Devices Electronic Application Lodgement system
DoC	Declaration of Conformity
EC	European Community
GHTF	Global Harmonisation Task Force
GMDN	Global Medical Device Nomenclature
Hb	Haemoglobin
IFU	Instructions For Use
IRIS	Incident Report Investigation Scheme
MDD	Medical Devices Directive 93/42/EEC
MDEC	Medical Device Evaluation Committee
MRA	Mutual Recognition Agreement
ODBT	Office of Devices, Blood & Tissues
QA	Quality Assurance
QMS	Quality Management System
RBC	Red Blood Cells
Regulations	Therapeutic Goods (Medical Devices) Regulations 2002
TGA	Therapeutic Goods Administration
TGAC	Therapeutic Goods Advertising Code