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| Complementary medicines reforms |
| Standard/coded indications project |
|  |

Version 1, August 2012



About the Therapeutic Goods Administration (TGA)

* The TGA is a division of the Australian Government Department of Health and Ageing, and is responsible for regulating medicines and medical devices.
* TGA administers the *Therapeutic Goods Act* 1989 (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety and efficacy (performance), when necessary.
* The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to consumers outweigh any risks associated with the use of medicines and medical devices.
* The TGA relies on the public, healthcare professionals and industry to report problems with medicines or medical devices. TGA investigates reports received by it to determine any necessary regulatory action.
* To report a problem with a medicine or medical device, please see the information on the TGA website <[www.tga.gov.au](http://www.tga.gov.au)>.

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Version history

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| Version | Description of change | Author | Effective date |
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## Introduction

The Therapeutic Goods Administration (TGA) is progressing with a series of reforms to the regulation of complementary medicines that seeks to improve community confidence in the safety and quality of these medicines. This will be achieved by:

* ensuring that the TGA effectively informs the community of its role in providing timely access to the therapeutic goods that Australians need, and that they meet appropriate standards of quality, safety and efficacy
* clarifying requirements for sponsors of complementary medicines
* improving the Australian community's understanding of the TGA's regulatory processes and decisions for complementary medicines
* strengthening the integrity and transparency of the regulatory framework for complementary medicines; and
* enhancing the complementary medicine regulatory framework to ensure that it remains adaptable to community and industry expectations.

The reforms are part of the [TGA reforms: A blueprint for TGA's future](http://www.tga.gov.au/newsroom/media-2011-tga-reforms-111208.htm) ("the Blueprint"), including a number of recommendations from the [Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines](http://www.anao.gov.au/Publications/Audit-Reports/2011-2012/Therapeutic-Goods-Regulation-Complementary-Medicines) ("the Auditor-General's Report"). The reforms will initially focus on the recommendations from the Auditor-General's report; the recommendations will be implemented through the following projects:

1. [Key regulatory guidance materials](http://www.tga.gov.au/industry/cm-notices-guidance-materials-120604.htm)
2. [Standard indications](http://www.tga.gov.au/industry/cm-notices-standard-indications-120604.htm)
3. [Publishing outcomes of post-market reviews](http://www.tga.gov.au/industry/cm-notice-publish-reviews-120604.htm)
4. [Using risk profiles in post-market reviews](http://www.tga.gov.au/industry/cm-notices-risk-profiles-120604.htm)
5. [Investigation processes for advertising breaches](http://www.tga.gov.au/industry/cm-notices-advertising-breaches-120604.htm)

Additional recommendations included in the [Blueprint](http://www.tga.gov.au/newsroom/media-2011-tga-reforms-111208.htm) also impact upon complementary medicines regulation and will lead to further projects in the future.

### Background

Listed medicines are included on the Australian Register of Therapeutic Goods (ARTG) by sponsors through the eBS Listing Facility (ELF). ). Listed medicines can only contain listable ingredients, must be manufactured in accordance with Good Manufacturing Practice and may only have listable indications (see Section 1 below).

Listed medicines may be selected for listing compliance review and the review may involve an assessment of product quality, safety and/or efficacy. This may be done by means of laboratory testing, review of evidence, and/or assessment of manufacturing documentation or product labels.

### Overview of the project

Recommendation 2 of the Auditor-General’s report indicated that the TGA should finalise work on the coded [standard] indications project (a TGA-industry initiative) to rationalise and update the list of indications available to sponsors so as to limit the use of inappropriate indications on the ARTG.

When listing a product, sponsors may select indications from a limited number of standard indications, or may utilise a free text field to describe indications in their own words. Standard indications have existed in ELF since 2003. However, unlimited use of the free text field has resulted in a large number of inappropriate indications and claims being included on the ARTG. Under this standard indications proposal, the TGA intends to remove the free‐text option and require sponsors to select only from the standard list. To achieve this, the TGA needs to revise the list of standard indications already in use and make it sufficiently comprehensive.

During 2009 and 2010, the TGA worked with industry representatives to work towards expanding the list of existing standard indications. The current project aims to reclassify and expand existing standard indications to enable modification or removal of the free text box in ELF. Reclassifications will utilise the existing International Classification of Diseases (ICD) ‐10 framework to maximise the capacity of the system to cater for new standard indications. The ICD is the world’s standard tool to capture mortality and morbidity data and it organises and codes health information that is used for statistics and epidemiology, health care management, allocation of resources, monitoring and evaluation, research, primary care, prevention and treatment.

### Purpose of this document

This document outlines the requirements for a standard indication that can be used for listed medicines and provides the framework for completion of the standard indications project. In order to facilitate the work on the standard indications it is proposed that a TGA-industry collaborative approach be reinstated.

A draft list of updated indications based on the one previously prepared with industry has been created for review and finalisation **(Attachment 1, Tab 1).** In addition, appropriate indications were sourced from Health Canada monographs, European Medicines Agency (EMA) monographs and the Japanese Foods with Nutrient Function Claims.

**Members of the Informal Working Group on Complementary Medicines are asked to consider the indications included in Attachment 1, Tab 1 for appropriateness and comprehensiveness. Any comments in relation to individual standard indications included in Tab 1 can be provided in column L.**

**Members are also asked to nominate appropriate additional standard indications to ensure that the list is as comprehensive as possible. Attachment 1, Tab 4 (PROPOSED RECODED STD IND IWGM) is provided for this purpose. Any proposed standard indications must be coded in accordance with ICD 10 framework.**

**In commenting on the proposed recoded standard indications, or when proposing new standard indications, members are requested to consider the following:**

1. **Acceptable parameters for listable indications**
2. **An accepted structure for listable indications**
3. **Types of listable indications**
4. **A consistent approach to coding standard indications**
5. **The relationship between standard indications included on the ARTG and statements included on the labels of products**
6. **Words in standard indications that are considered equivalent and interchangeable**
7. **The omission of standard indications that are not appropriate for listed medicines**

As the coded indications project advances and it is possible to restrict new listed products to only standard indications, an implementation plan will be developed to require the same discipline to be imposed on existing products as well as new ones. A draft implementation schedule is at Appendix 1.

## 1. Acceptable parameters for listable indications

Listed medicines are considered ‘low risk’. This means that products eligible for listing must be safe for the use for which they are indicated in the absence of health practitioner supervision. In order to minimise potential risk, restrictions are placed on the nature of the ingredients permitted for use in listed medicines, and also on the indications that may be associated with listed medicines.

An indication for a listed medicine:

* must describe a specific therapeutic use
* in general, must only refer to ailments or health states that are self-diagnosable, self-treatable, self-resolving and the consumer can recognise if the product is ineffective and make decisions to discontinue use, seek an alternate product or seek the advice of a healthcare professional, as appropriate; and
* must not refer to a disease, ailment, defect or condition generally accepted to be beyond the ability of the average consumer to diagnose, treat or manage without the intervention of an appropriately qualified healthcare practitioner (this includes obesity but does not include management of overweight as the serious health risks associated with obesity require intervention and management by an appropriately qualified healthcare professional. Medicines with indications that refer to obesity must be included in the ARTG as registered medicines).

In order to ensure that standard indications refer to a specific therapeutic use, the word ‘may’ is not considered appropriate for inclusion within standard indications.

## 2. Structure of listable indications

An indication, in relation to therapeutic goods, must describe the specific therapeutic use(s) of the goods. Indications refer to a particular health benefit and are structured to include a nominated action or effect (such as reduces, prevents, improves, maintains, stimulates, or treats) on a defined target (such as a biological factor or process, a health state or a clinical condition). Targets may be general—such as pain, fever or general well being—or specific—referring to defined conditions such as knee pain or headache, or a specific receptor, molecule or biological process. Additional qualifying terms may be included to provide information relating to the context of therapeutic use (e.g. within a particular traditional health paradigm or a particular subset of the population) or the specific qualities of the action or effect (e.g. rapid or sustained) or target (e.g. acute, severe or persistent). Indications can generally be schematically represented in the following way:

**(CONTEXT) to/for the (QA) ACTION of (QT) TARGET**

**Example indications:**

*Traditionally used in Herbal Medicine to reduce the recurrence of urinary tract infections*

*For the temporary relief of mild to moderate headache*

QT

CONTEXT

TARGET

ACTION

QT

QA

ACTION

TARGET

Where:

CONTEXT = contextual qualifier where appropriate

ACTION = action, outcome or effect

TARGET = the clinical condition, health status or biological factor

QA = action qualifier if appropriate

QT = target qualifier if appropriate.

QT

CONTEXT

ACTION

QA

ACTION

QT

TARGET

## 3. Types of listable indications

Indications are classified into ‘scientific indications’ or ‘traditional indications’ according to the type of supporting evidence. Scientific and traditional indications are fundamentally different; scientific indications are efficacy based, while traditional indications refer to a tradition of use within a particular paradigm.

Because of the nature of evidence of traditional use, traditional indications **must not** imply efficacy. Indications that are based on traditional use, **must** be true, valid, not misleading and consistent with its traditional use. Therefore, evidence of traditional use can only be used to support indications that refer to the traditional use of a medicine or ingredient for a health benefit in the context of the traditional paradigm.

Terms used in traditional listable indications must be comprehensible to consumers and consistent with those referenced in the evidence of traditional use source. In cases where the traditional terminology may be unclear to consumers, the information should be communicated using appropriate conventional terminology. Traditional listable indications must **not**:

* reference specific anatomical, physiological or pharmacological effects that are not envisaged within the paradigm and/or require scientific substantiation such as stimulation or modulation of the immune system or antioxidant functions
* reference conditions that cannot be diagnosed within the identified healing paradigm such as the maintenance of normal glucose levels, blood pressure or cholesterol
* be interpreted or extrapolated to infer benefits that were not readily recognised within the traditional paradigm such as weight loss, addiction cessation and providing specific vitamins, minerals or essential fatty acids
* contain vague or ambiguous terms that may be misinterpreted by consumers to infer use in serious forms of health disorders or conditions, such as ‘useful for chronic inflammation’ or ‘used as a healing aid for urinary disorders’

In order to reduce the possibility that traditional indications are misinterpreted by consumers to imply efficacy, traditional indications must indicate that the health benefit is based exclusively on long-term use and experience. This information should be included in the form of a traditional contextual qualifier.

**Examples: Expressing health benefit based on long term use or experience**

*Used traditionally in native American medicine for the relief of coughs and colds.*

*This traditional medicine has been used by native Americans for the relief of coughs and colds.*

*Traditional native American medicine for the relief of coughs and colds.*

*Use of this traditional medicine for the relief of coughs and colds is based upon long-standing use*.

### Types of indication according to type of health benefit

In broad terms, indications may target biological factors or processes, health states or clinical conditions. The following diagram provides a schematic representation of all states of health through health to symptomatic illness. It also includes a description of the different types of indications according to the action or effect on the indication target. Indications can be conveniently separated into three clusters – indications targeting: a generally healthy state; risk reduction/prevention; and illness.

#### Cluster 1: Health indications

Health indications target healthy individuals and assist in maintaining or improving their state of health and wellbeing. An indication that is associated with well-being, wellness or to health generally, requires supporting evidence. Well-being, wellness and health are complex states and do not just refer to the absence of illness. The multiple dimensions of these states are complex and holistic. Metrics used to quantify them would need to be valid measures and take into account both objective and subjective data such as quality of life physiological, psychological, social and demographic factors.

The health indication cluster includes the following types of indications:

* **Health maintenance**: normal physiological effects of nutrients and other substances in growth, development and normal functions of the body.
* **Health enhancement**: specific beneficial effects of nutrients and other substances on physiological and psychological activities beyond their role in normal growth, development and normal functions of the body.

#### Cluster 2: Risk Reduction and prevention indications

Risk reduction/prevention indications target individuals at risk of illness and partially or completely reduce the risk. The risk reduction/prevention indication cluster includes the following types of indications:

* **Risk Reduction**: favourablemodification of a known risk factor for a specified illness. condition, disease or disorder.
* **Prevention**: prevents the development of a named illness.

#### Cluster 3: Illness indications

Illness indications target individuals suffering an illness (condition, disease or disorder). The illness claim cluster includes the following types of claims:

* **Management**: sole agent or contributing factor in the control of an illness such that morbidity is decreased and quality of life improved without resolution of the illness.
* **Symptom relief**: reduces the frequency, duration and/or severity of a symptom or cluster of symptoms associated with a named illness.
* **Cure**: effects complete resolution of an illness and all associated morbidity**.**

**Examples of indications for each cluster**

***Cluster 1***

*Maintenance indications: (C) to/for the (QA) maintenance of (QT)T,*

*Enhancement indications: (C) to/for the (QA) enhancement of (QT)T*

***Cluster 2***

*Reduction indications: (C) to/for the (QA) reduction of (QT)T*

*Prevention indications: (C) to/for the (QA) prevention of (QT)T*

***Cluster 3***

*Management indications: (C) to/for the (QA) management of (QT)T*

*Symptomatic relief indications: (C) to/for the (QA) relief of symptoms of T*

### Nutrient Sources and Supplementation

Statements solely referring to supplementation with vitamins, minerals or other essential nutrients (eg ‘a source of calcium’) are not indications and are not required to be included on the ARTG. These statements will not be included in the list of standard indications.

## 4. Coding standard listable indications

The ICD is the standard diagnostic tool for epidemiology, health management and clinical purposes. This includes the analysis of the general health situation of population groups. It is used to monitor the incidence and prevalence of diseases and other health problems. It is used to classify diseases and other health problems recorded on many types of health and vital records including death certificates and health records.

The ICD groups conditions according to system into 22 chapters (from A-U). Each chapter then provides a number code for conditions falling within that system (from 00-99). Conditions may then be further subdivided according to aetiology.

The ICD can also be used to classify indications according to the health benefit they provide and have been adopted for the purpose of coding standard indications. The existing ICD‐10 framework will maximise the capacity of the system to cater for new standard indications.

Coding of standard indications is readily achievable if indications are aligned with the schematic representation of a standard indication provided above:

**(CONTEXT) to/for the (QA) ACTION of (QT) TARGET**

The code for a standard listable indication is of the following format:

 **\_\_\_ \_\_\_ \_\_\_ \_\_ \_\_**

 **TARGET QT ACTION QA CONTEXT**

The code for a standard listable indication is derived in the following way:

**The TARGET determines the first 3 digits**

The TARGET of a listable indication corresponds to the ICD code for a condition. There is unlikely to be a need to define clinical conditions treatable by listed medicines beyond the letter and first two digit classification provided by the ICD. Therefore an indication that refers to the common cold would receive a target code of J00. For indications that relate to the maintenance of health (health indications), an ICD code will not be available. For these indications the target is coded using the ICD system letter followed by the first two letters of the body part or function referred to in the indication. For example, an indication that refers to healthy bones would generate a target code of MBO, an indication that refers to healthy joints would generate a target code of MJO, while an indication that refers to a healthy heart would generate a target code of IHE.

Certain targets are not system or organ specific. Examples include some states of health such as ‘general well being’ and ‘general health’, and some biological factors such as free radicals. In these situations the initial letter code is replaced by a zero and the subsequent two digits take on either the first two letters (if a single word) or the first letter of the first two words (if multiple words) of the target. For example, an indication referring to general well being would receive a target code of 0GW, an indication referring to general health would receive a target code of 0GH, and an indication referring to free radicals would receive a target code of 0FR.

**The TARGET QUALIFIER determines the next 2 digits**

If a target qualifier is present as a single word the first two letter of the word are recorded. If the target qualifier consists of two words, then the first letter of each word is recorded. If no target qualifier is present, consecutive zeros are recorded.

**The ACTION determines the next 2 digits**

If an action is present as a single word the first two letter of the word are recorded. If the action consists of two words, then the first letter of each word is recorded.

**The ACTION QUALIFIER determines the next 2 digits**

If an action qualifier is present as a single word the first two letter of the word are recorded. If the action qualifier consists of two words, then the first letter of each word is recorded. If no target qualifier is present, consecutive zeros are recorded.

**The CONTEXT determines the final 3 digits**

The first of the three digits receives an S if it is a scientific indication, or a T if it’s a traditional indication. Where indications have been sourced from international regulators and the nature of the indication is unclear N has been used. The final two digits are determined by the presence of any additional contextual information. For traditional indication this will be letters representative of the traditional paradigm. For scientific indications, additional contextual information is likely to relate to restrictions on target population. If there is no additional contextual information, the last two digits will be 00.

**Eg. Used traditionally in herbal medicine to relieve symptoms of the common cold**

**Indication code: J00.SY.RE.00.THM**

**Eg. For the maintenance of a healthy cardiovascular system**

**Indication code: ICV.HE.MA.00.S00**

In some cases the action and target may be combined into a single word eg ‘anti-oxidant, or ‘vermifuge’. In these cases, the word is coded as the target.

**Eg. Acts as an antioxidant**

**Indication code: 0AO.00.AC.00.S00**

**Eg. Used traditionally in herbal medicine as a vermifuge**

**Indication code= BVE.00.US.00.THM**

There are occasions where action, target or qualifying terms contain the same first two letters and cannot be accurately coded using the above formula. The following table provides guidance regarding codes used for certain common terms.

| **Target** | **QT** | **Action** | **QA** | **Context** |
| --- | --- | --- | --- | --- |
| 0WH – wound healing | CO – conditions | AI – aid(s) | AI – aids | xPM – post menopausal women for ‘x’ context’ |
| 0SL – sleep [not disorder] | AS – astringent | PR – promote(s) | AS – assists  | xPW – pregnant women for ‘x’ context |
| 0MU – muscle – non-specific | CC – associated with common cold/ cough and cold | SP – suppress  | HE – helps |  |
| ECB – carbohydrates | DE - demulcent | RT – resets | ST – short term |  |
| 0AS – astringent | DY – associated with dyspepsia | MA – maintain(s) |  |  |
| 0HE – health | FU – function | TR – treatment; treats |  |  |
| 0EY – energy | GO – good | RE – relieves |  |  |
| 0AN – analgesic | HE – healthy | ST – stimulate  |  |  |
| DRC – red blood cells | MA – maintains | SB – stabilise  |  |  |
| DIF – immune function | MB – mood imbalance | SN – strengthen  |  |  |
| ECA – calcium | MG – management  | RS – restores |  |  |
| 0AN - antiseptic | MI – mild/minor | RD – reduces  |  |  |
| 0EN – enzyme | SY – associated symptoms | PD – production  |  |  |
| 0TI – tissue, non-specific | US – used as | SU – supports  |  |  |
| EFA – fat | TO – tonic  | RG – regulates  |  |  |
| EPR – protein |  | PV – prevents  |  |  |
| GSD – sleep disturbance |  |  |  |  |
| KDD – digestive disturbances |  |  |  |  |
| KTE – teeth [not disorder] |  |  |  |  |
| MBO – bones [ not disorder] |  |  |  |  |
| REX – expectorant |  |  |  |  |
| xIN – inflammation of ‘x’ system |  |  |  |  |
| xTO – tonic for ‘x’ system |  |  |  |  |
| IAR – artieries |  |  |  |  |
| HEY – eyes |  |  |  |  |
| HFU – eye function |  |  |  |  |
| EGM – glucose metabolism |  |  |  |  |
| 0GL – glucose levels |  |  |  |  |
| KSP – gastrointestinal spasms |  |  |  |  |
| KGC - Gastrointestinal complaints |  |  |  |  |
| JCC – Coughs and colds |  |  |  |  |
| KMM – mucous membranes |  |  |  |  |

## 5. The relationship between standard indications included on the ARTG & statements included on product labels

Indications are defined in the Act as the specific therapeutic uses of the goods and are therefore statements that specifically relate to product efficacy. In other words, indications describe the beneficial physiological or health effect of active ingredients contained within the product.

REPRESENTATIONS

INDICATIONS

Representations are statements that offer a promise to consumers, this may relate to the efficacy (indication representations) or other desirable qualities of a medicine (non-indication representations). Non-indication representations include content representations, such as ‘mercury free’ or ‘contains natural ingredients’, and other factual statements about a medicine, such as ‘rapid acting’, ‘once daily dosing’ and ‘clinically proven.’

The benefits associated with a medicine (indications) are recorded on the ARTG. The ARTG need not include other properties of the product that may underscore non-indication representations. However, such representations may be included on product labels and may be used to promote the use of a product during advertising campaigns.

The information on the label of listed medicines indicated for health benefits must provide useful information that assists consumers in making informed choices about self care.

The general labelling requirements for medicines regulated in Australia by the TGA are specified in Therapeutic Goods Order No. 69 (TGO 69) – General requirements for labels for medicines (<http://www.tga.gov.au/docs/html/tgo/tgo69.htm>) and in the document Required Advisory Statements for Medicine Labels (<http://www.tga.gov.au/meds/rasml.htm>). All representations on the label that promote the good (including indications, product performance statements, brand names, and promotional images) must comply with the Therapeutic Goods Advertising Code (<http://www.tga.gov.au/advert/tgac.htm>).

**Indication representations**

Indication representations are advertising statements. All indication representations for a listed product must be based on indications included on the ARTG. Recall that a typical indication consists of 2 mandatory components and a variable number of potential qualifiers:

|  |  |
| --- | --- |
| Mandatory components | Potential Qualifiers |
| Action | Action qualifier |
| Target | Target qualifier |
|  | Context\* |

\*Context mandatory for indications based on traditional evidence

**(C) to/for the (QA)A of (QT)T**

Where:

C= Potential context qualifier (eg traditional disclaimer for traditional indications)

A=Action, outcome or effect

QA = potential action qualifier

T =Target (clinical condition, health status or biological factor), QT is a potential target qualifier

All indications on the ARTG include (by definition) an action/effect on a target factor or condition. The remaining qualifiers are applicable to only certain circumstances.

Label representations that refer to a therapeutic use must be identical to their parent ARTG indication. New components can not be added and components in the parent indication can not be omitted. Actions, targets and qualifiers can not be replaced with related terms that imply or may be interpreted as “different”.

| **ARTG Indication** | **Examples of acceptable Representations** | **Examples of unacceptable representations** |
| --- | --- | --- |
| Contributes to a natural healthy gut microflora | Contributes to a natural healthy gut microfloraContains substance X, which contributes to a natural healthy gut microflora | Assists in the maintenance of a natural healthy gut microfloraHelps prevent disorders due to imbalance of gut microflora |
| Enhances weight loss in overweight individuals when used in conjunction with a (calorie- or kilojoule-) controlled diet and physical activity (or exercise) | Enhances weight loss in overweight individuals when used in conjunction with a (calorie- or kilojoule-) controlled diet and physical activity (or exercise)Contains substance Y which enhances weight loss in overweight individuals when used in conjunction with a (calorie- or kilojoule-) controlled diet and physical activity (or exercise) | Enhances weight loss in obese individuals when used in conjunction with a (calorie- or kilojoule-) controlled diet and physical activity (or exercise) |
| Suppresses appetite | Suppresses appetiteContains substance Z which suppresses appetite | Inhibits appetiteEnhances weight loss |
| Essential for healthy strong bones | Essential for healthy strong bones Contains substance W which is essential for healthy strong bones | Reduces bone fractures |

Representations must not be phrased in ways that may mislead consumers, and care must be taken to ensure that representations are phrased so as not to infer related health benefits that are not directly related to the parent indication.

*Terms such as weight maintenance, weight control and weight management are ambiguous and can not be used to substitute for weight loss in a parent indication.*

**Non-indication representations**

Non-indication representations include content representations. Content representations must accurately reflect the composition of the medicine. If described as a source of a particular nutrient, that nutrient must be present in the product at a biologically meaningful level. Evidence must be held to substantiate such representations; however they are not required to be included on the ARTG and will not be included in the list of standard indications.

As outlined in the table above, non-indication representations can be merged with indication representations in order to provide useful information to consumers in a concise manner.

## 6. Words in standard indications that are considered equivalent and interchangeable

As discussed above, label representations that refer to a therapeutic use must be identical to their parent ARTG indication. Therefore, it is important that standard indications include a sufficient number of equivalent terms that describe a therapeutic effect to allow for flexibility when marketing listed products.

**The informal working group is asked to consider appropriate and equivalent action, target and qualifier terms to be included in standard indications such that the overall meaning of the indication is maintained. When considering the acceptability of substitute terms, working group members should refer to an established thesaurus. Attachment 1, Tab 5 (EQUIVALENT TERMS) is provided for this purpose.**

*Example: Reduce may be considered equivalent to terms such as decrease and lower.*

## 7. The omission of standard indications that are not appropriate for listed medicines

An indication for a listed medicine must not refer to a disease, ailment, defect or condition generally accepted to be beyond the ability of the average consumer to diagnose, treat or manage without the intervention of an appropriately qualified healthcare practitioner (this includes obesity but does not include management of overweight- see section 1). Indications for listed medicines, in general, must only refer to ailments or health states that are self-diagnosable, self-treatable, self-resolving and the consumer can recognise if the product is ineffective and make decisions to discontinue use, seek an alternate product or seek the advice of a healthcare professional, as appropriate.

**Based on the above criteria, a number of currently available standard indications are considered unsuitable for use in listed medicines. These have been identified and provided in Attachment 1, Tab 2 (STD IND CONSIDERED FOR OMISSION) in the proposed list of standard indications**.

**Working group members are asked to consider the appropriateness of these indications for use on listed medicines. In doing so, members should consider the following:**

* **Whether the condition is appropriate to be diagnosed by an average consumer**
* **Whether the condition is appropriate to be managed by an average consumer**
* **Whether the condition is appropriate to be evaluated or monitored by an average consumer**
* **Whether any associated risks associated with use of the indication may be mitigated through use of a disclaimer**

**Any comments on indications considered for omission can be provided in Tab 2.**

### Appendix 1: Draft Implementation Schedule for Standard Indications Project

**(indicative dates only)**

Development of expanded list of standard indications (TGA-industry)

*July 2012 – September 2012*

Electronic Listing Facility (ELF) amendments to support rationalisation

*September 2012*

Consultation with key stakeholders: changes to ELF & expanded list of standard indications

*October 2012*

Regulatory Impact Statement developed based on public consultation

*November – December 2012*

Legislative changes to restrict to standard indications and allow for approval of new standard indication

*March 2013*

Implementation Date

*1 July 2013*

Transition period

*1 July 2013 to 1 July 2015*

### Appendix 2: Excerpt from the Therapeutic Goods Advertising Code 2007

**Appendix 6:**  **Prohibited, Restricted Representations**

**Part 1 – Prohibited Representations**

A prohibited representation is defined as:

1. Any representation regarding abortifacient action
2. Any representation regarding the treatment, cure or prevention of the following diseases:
* Neoplastic
* Sexually Transmitted Diseases (STD)
* HIV AIDS and/or HCV
* Mental illness

**Except** for the following representations which are to become restricted representations:

1. prevention of skin cancer through the use of sunscreens
2. devices used in contraception or in the prevention of transmission of disease between persons

**Part 2 – Restricted Representations**

An advertisement for therapeutic goods may refer, expressly or by implication, to a disease, condition, ailment or defect specified in Table 1, provided that prior approval is obtained forsuch a reference**.** Approval may be obtained from the TGA, upon recommendation from the TGACC and appropriate expert committee or committees.

**Table 1. Diseases, conditions, ailments and defects for which the advertising of serious forms is restricted**

|  |  |
| --- | --- |
| * Cardiovascular diseases
* Dental and periodontal diseases
* Diseases of joint, bone, collagen, and rheumatic disease
* Diseases of the eye or ear likely to lead to blindness or deafness
* Diseases of the liver, biliary system or pancreas
* Endocrine diseases and conditions including diabetes and prostatic disease
* Gastrointestinal diseases or disorder
 | * Haematological diseases
* Infectious diseases
* Immunological diseases
* Mental disturbances
* Metabolic disorders
* Musculo-skeletal diseases
* Nervous system diseases
* Poisoning, venomous bites and stings
* Renal diseases
* Respiratory diseases
* Skin diseases
* Substance dependence
* Urogenital diseases and conditions
 |

***Serious*** in the context of this table will mean forms of those diseases, conditions, ailments or defects which are:

* Generally accepted not to be appropriate to be diagnosed and/or treated without consulting a suitably qualified healthcare professional, and/or

Generally accepted to be beyond the ability of the average consumer to evaluate accurately and to treat safely without regular supervision by a qualified healthcare professional.

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| --- |
| Therapeutic Goods Administration |
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