Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Permitted (coded) indications for listed medicines

Consultation paper

January 2013

TGA Health Safety Regulation

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part 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>.

Confidentiality
All submissions received will be placed on the TGA's Internet site, unless marked confidential. Any confidential material contained within your submission should be provided under a separate cover and clearly marked "IN CONFIDENCE". Reasons for a claim to confidentiality must be included in the space provided on the TGA submission coversheet. For submission made by individuals, all personal details, other than your name, will be removed from your submission before it is published on the TGA's Internet site. In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission you must specifically request this in the space provided on the submission coversheet.

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Summary

Indications for listed medicines

The TGA regulates complementary medicines to ensure quality, safety and that indications and claims on product labels are evidence-based. Indications are defined in the *Therapeutic Goods Act 1989* (the Act) as the specific therapeutic uses of therapeutic goods.

Currently, listed complementary medicines can be included on the Australian Register of Therapeutic Goods (ARTG) *via* an electronic application and validation process, with no premarket regulatory oversight by the TGA, provided that certain conditions are met including certification by the applicant that the medicine complies with regulatory requirements. As part of the listing process, the sponsor is required to specify the indications (specific therapeutic uses) applicable to the medicine by:

- selecting one or more indications from a list of coded indications; or
- recording specific indications in a free text field.

The 'Blueprint' was released by the Government in December 2011 and an implementation plan was published in July 2012. It details a package of reforms in response to recent reviews, including those that examined the regulation of complementary medicines. The Australian National Audit Office (ANAO) released a report (No. 3 2011-12) in August 2011 on the Department of Health and Ageing (DoHA)'s regulation of complementary medicines, which called for the TGA to improve the integrity of the certifications process for listing complementary medicines on the ARTG by finalising the coded indications project to limit the use of inappropriate claims and indications on the ARTG.

The TGA is opening a consultation seeking submissions on a range of options for permitted indications for listed medicines and to inform the Regulatory Impact Statement required before policy and legislative changes can be made.

The TGA initially worked with representatives of industry, health professionals and consumers to develop the proposals. This consultation seeks comment on:

- expansion of the number of permitted indications available to sponsors
- removal of the free text field
- coding of permitted indications in the way that is broadly consistent with the World Health Organization's International Classification of Diseases system (ICD10 or ICD11)
- development of a process for sponsors to request new permitted indications; and
- options for implementation and transition for listed medicines on the ARTG as at the date on which the new rules come into operation.

Advertising claims that do not refer to therapeutic use (and are therefore not indications) do not need to be included on the ARTG in order to be used on product labels and during advertising campaigns. It should be noted that these advertising claims must comply with the requirements of the Therapeutic Goods Advertising Code.

Removing the free-text option will limit indications to those that are appropriate for listed medicine thus providing clarity and consistency to consumers about the health benefits of listed

medicines. An inappropriate indication implying efficacy for a serious condition (or a condition that can evolve into a serious condition) can lead consumers to delay seeking medical attention. This may have serious consequences and this scheme of permitted indications is designed to reduce that risk.

Legislative amendments are required to implement the permitted (coded) indications project such as requiring sponsors to only use the available permitted indications, to allow applications to be made for a new permitted indication and for the TGA to remove the "free text" field in electronic listing facility (ELF).

Implementation is proposed for January 2014 with transitional arrangements over two years allowing for sponsors to meet the requirements.

The closing date for submissions to the consultation is 5pm 15 March 2013.

At the close of the consultation period, the TGA will collate and analyse submissions on matters that are within the scope of this consultation. An update on the progress of the review and expected timeframes for the TGA response to the comments received will be provided on the TGA website after the close of the consultation period.

Introduction

Regulation of listed medicines in Australia

The Therapeutic Goods Administration (TGA) is responsible for administering the provisions of the *Therapeutic Goods Act 1989 (*the Act). The overall objective of the Act is to provide a framework and systems of controls relating to the safety, quality, efficacy and timely availability of therapeutic goods, including medicines, medical devices and biologicals that are supplied in or exported from Australia.

Medicines supplied in Australia may be either registered or listed on the Australian Register of Therapeutic Goods (ARTG).

The process of registration is for medicines that carry higher risks to consumers because, for example, they are required to be sterile, or they are for the treatment of medical conditions that cannot be accurately diagnosed or safely managed by aconsumer without the assistance of an appropriately qualified medical practitioner. Registration involves the TGA evaluating the medicine in relation to its quality, safety and efficacy. Prescription medicines and 'over-the-counter' medicines go through the registration process before they can be included on the ARTG.

The process of listing is for medicines that, in general, do not carry the kinds of risks described above in relation to registration of medicines. A listed medicine:

- may only contain ingredients that have been evaluated by the TGA to be low risk to consumers
- must be manufactured by a licensed or certified manufacturer in accordance with the principles of Good Manufacturing Practice (GMP); and
- must not carry indications that are inappropriate for listed medicines (see section 'Permitted indications for listed medicines').

Listed medicines are not individually assessed by the TGA prior to listing on the ARTG. Instead sponsors are required to certify that the medicine complies with a range of regulatory requirements including that the medicine only contains permitted ingredients, does not have impermitted indications, that the applicant holds evidence to support any indications and claims made about the medicine and that the presentation of the medicine is not unacceptable.

Listing a medicine on the ARTG is done *via* an electronic application and validation process. For sponsors, the cost of listing a medicine is substantially less than the cost of registration because there is no evaluation for the listing of the medicine by the TGA.

Listed medicines may, however, be selected for compliance review at any time after listing on the ARTG. The review may involve a check on whether the certifications made by the applicant when listing the medicine were correct and whether advertising requirements are being complied with in relation to the medicine. Depending on the circumstances the assessment can extend to product quality and/or safety. This may be done by means of laboratory testing of the product and the review of evidence, and/or assessment of manufacturing documentation or product labels/advertisements that the sponsor will be required to provide for that purpose (see Listed complementary medicine compliance reviews). The medicine may be cancelled from the ARTG for instance, if the TGA finds that any of the certifications made at the time of listing were incorrect.

Indications

Indications are the specific therapeutic uses of therapeutic goods. The terms 'indication', 'therapeutic goods' and 'therapeutic use' are defined in section 3 (interpretation) of the Act.

To be eligible for listing a medicine cannot have indications that are for the treatment of certain diseases and conditions set out in Appendix 6 of the Therapeutic Goods Advertising Code (the Advertising code)[1]. In addition, sponsors cannot advertise an indication (including by putting it on the label of a medicine) that contains a prohibited representation[2] or a restricted representation[3] unless it has been approved or permitted by the TGA[4]. This is to align with the principle that medicines may only be listed (rather than registered) if they pose low risks to consumers.

[1] These are Neoplastic Sexually Transmitted Diseases (STD), HIV AIDS and/or HCV Mental illness, 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 disorders, 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.

[2] 'Prohibited representations' are set out in Part 1 of Schedule 2 of the Therapeutic Goods Regulations 1990, a copy of which is at Appendix 1.

[3] 'Restricted representations' are set out in Part 2 of Appendix 6 of the Advertising Code, a copy of which is at Appendix 2.

[4] See sections 42DF and 42DK of the Act.

Generally speaking a restricted representation is a reference, expressly or by implication, to serious forms of diseases, conditions, ailments or defects. 'Serious' means forms of diseases, conditions, ailments or defects that 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.

Thus indications that do not involve the treatment of the diseases and conditions set out in Appendix 6 but do contain a restricted or prohibited representation cannot lawfully be advertised for listed medicines without express TGA approval for their advertising.

An indication itself can pose a risk to consumers if, for example, when included in advertising, it may lead a consumer to attempt to self-treat a condition that cannot be diagnosed accurately or treated safely without the assistance of an appropriately qualified healthcare practitioner.

It is an offence for a sponsor to advertise a listed medicine for an indication other than the indication accepted for the listing of the medicine on the ARTG.

It is also a condition of listing that the sponsor of a listed medicine will not, by any means, advertise the goods for an indication other than those accepted for the listing of the medicine on the ARTG.

Legislative basis for listing a medicine on the ARTG for supply in Australia

Listable medicines for supply in Australia are listed on the ARTG under section 26A of the Act. Export only medicines are listed under section 26. **This consultation paper addresses indications in relation to medicines listed under section 26A only.**

Only medicines that are 'eligible for listing' i.e. satisfy the criteria set out in Part 1 (Listable goods) of Schedule 4 to the Therapeutic Goods Regulations 1990 (the Regulations) can be included in the ARTG as listed medicines. These include that the medicine's indications are not for the treatment of a disease, condition, ailment or defect referred to in footnote 1.

When applying for listing of a medicine under section 26A of the Act the applicant must certify, among other things, that the medicine is eligible for listing. The medicine can be cancelled from the ARTG if that certification is not correct.

Reforming the regulation of listed medicines

The reforms proposed in this paper are part of reforms the TGA is progressing to improve community knowledge about listed medicines and confidence in their safety and quality. The reforms are intended to:

- ensure 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 and safety
- clarify requirements for sponsors of listed medicines, including that they hold evidence to support claims made in relation to those medicines
- improve the Australian community's understanding of the TGA's regulatory processes and decisions in relation to medicines; and
- enhance the integrity and transparency of the regulatory framework for listed medicines 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 ("the Blueprint"). They include a number of recommendations from the Auditor-General's Report on Therapeutic Goods Regulation: Complementary Medicines ("the Auditor-General's Report") and the 'Informal Working Group Examining Complementary Medicines Regulation' (the Complementary Medicines Working Group).

The reforms will initially focus on the recommendations from the Auditor-General's report and the recommendations will be implemented through projects on the following themes:

1. Key regulatory guidance materials
2. Permitted (coded) indications (the subject of this consultation paper)
3. Publishing outcomes of post-market reviews
4. Using risk profiles in post-market reviews
5. Investigation processes for advertising breaches

Additional recommendations included in the Blueprint also impact upon complementary medicines regulation and will lead to further projects in the future.

This paper is concerned with the permitted (coded) indications project.

Permitted (coded) indications project

The permitted (coded) indications project began as a joint initiative of the TGA and industry to expand the list of permitted indications for listed medicines. The Auditor-General's report recommended that the TGA should finalise work on the project in order to limit the entry of inappropriate indications in the ARTG.

When listing a medicine on the ARTG *via* the electronic listing facility (ELF), sponsors may either select indications from a list or use a "free text" field to describe indications in their own words. The Auditor-General found that unlimited use of the free text field permits the inclusion of inappropriate or misleading claims and indications being entered on the ARTG[5].

In order to ensure that only those indications that are appropriate for use in listed medicines can be used, the TGA proposes to remove the free-text option in ELF. Applicants for listing will be required to select from a list of what is proposed to be called 'permitted' indications. This list

[5] See paragraphs 14, 26, 3.44, 3.50, 3.56, 3.58 and 3.61, of ANAO report

is expanded to ensure that it is comprehensive and only includes indications that are consistent with the low risk profile intended for listed medicines.

Removing the free-text option will limit indications to those that are appropriate for listed medicine thus providing clarity and consistency to consumers about the health benefits of listed medicines. An inappropriate indication implying efficacy for a serious condition (or a condition that can evolve into a serious condition) can lead consumers to delay seeking medical attention. This may have serious consequences and this scheme of permitted indications is designed to reduce that risk.

The list at Attachment 1 is a consolidation of indications currently available for use in ELF, industry input received via the Office of Complementary Medicines Industry Consultation Group (OICG) and appropriate indications sourced from Health Canada monographs, European Medicines Agency monographs and Japanese Foods with Nutrient Function Claims.

About this consultation

What are the objectives of the consultation?

The primary objective of this consultation is to seek stakeholders views on the proposed changes by the TGA to improve the integrity of the listing process for complementary medicines. The TGA recognises that the proposed changes described in this consultation paper will affect sponsors of listed complementary medicines and sunscreens by limiting their current ability to describe their own 'indications' for inclusion in the ARTG. Any such change to descriptions will affect consumers who use listed medicines.

Feedback received from stakeholder groups as part of this consultation will be used to determine an appropriate strategy to implement the changes in a way that achieves the outcome with the least possible inconvenience.

In order to do this, the TGA needs to understand the possible impacts of the proposed changes for consumers and sponsors. Through this consultation the TGA would like to:

- identify issues that might be faced by these different stakeholder groups as a result of the change; and
- use feedback received to make decisions on the final scope and content of the proposed changes and to help devise appropriate mechanisms to implement the changes.

What is outside the scope of the consultation?

The following matters are outside the scope of the proposed changes outlined in this consultation paper:

- evidence required to be held by sponsors to support indications of listed medicines and claims made in relation to listed medicines
- current processes used to conduct compliance reviews of listed complementary medicines
- medicines listed on the ARTG under section 26 of the Act (e.g. export only medicine)

- exempt medicines; and
- any other matter that is NOT directly related to the changes proposed in this document.

Any submissions received that are not directly related to the changes proposed in this document will not be considered as part of the consultation. They may be noted for future reference.

Have your say

The TGA is seeking feedback on the proposed changes to the method in which indications are included on the ARTG for listed medicines. Interested stakeholders are encouraged to provide a response to the general questions relating to the proposed regulatory changes. Stakeholders may respond to as many or as few of the questions as they wish and may provide additional information on issues not covered by the questions.

In addition to responses to the general questions for the proposed changes, the TGA is seeking industry specific information on the key issues of this consultation. In particular for each of the issues, industry and other interested stakeholders are invited to review and comment on the relevant recommendations. Responses should include:

- Whether or not you support the proposed changes. If you do not support a change, you may make suggestions for an alternative acceptable to you and provide a rationale for the commentary.
- An assessment of how the proposed change will impact on you or your business. That is, what are the likely benefits or costs to you or your business (these may be financial or non-financial). If possible, please attempt to quantify these costs and benefits.

Submissions to the general questions and industry specific information should be lodged electronically to ocm@tga.gov.au. The closing date for submissions is 5pm 15 March 2013.

What will the TGA do with your comments?

Submissions will be acknowledged as they are received. All submissions received will be placed on the TGA's internet site, unless marked confidential following the consultation process. Any confidential material contained within your submission should be provided under a separate cover and clearly marked ‘for official use only’. Reasons for a claim to confidentiality must be included in the space provided on the TGA submission coversheet.

For submissions made by individuals, all personal details other than your name will be removed from your submission before it is published on the TGA's Internet site.

In addition, a list of parties making submissions will be published. If you do not wish to be identified with your submission, you must specifically request this in the space provided on the submission coversheet.

At the close of the consultation period, the TGA will collate and analyse submissions on matters that are within the scope of this consultation. An update on the progress of the review and expected timeframes for the TGA response to the comments received will be provided on the TGA website after the close of the consultation period.

The TGA will make any refinements or amendments to the proposed changes as appropriate. The outcomes of these considerations will be published on the TGA website.

Proposed changes

The reforms described in this consultation paper include:

- clarify the regulatory parameters for indications that will be permitted for medicines listed under section 26A of the Act
- removal of the ability for sponsors to use free text in ELF to describe indications for medicines listed under section 26A of the Act
- development a list of standardised, structured, coded indications that is:
  - consistent with the regulatory parameters for permitted indications
  - sufficiently comprehensive to allow sponsors to select appropriate indications for their products; and
- allow for new indications to be added to the permitted indications list from time to time.

Permitted indications for listed medicines

In order for an indication to be included in the list of indications that will be permitted for medicines listed under section 26A of the Act an indication:

- will need to describe a specific therapeutic use
- may refer to health maintenance and/or health enhancement
- may refer to the prevention of a dietary deficiency
- may refer to a disease, ailment, defect, injury or health state provided it is self-diagnosable and self-manageable; and
- may refer to a disease or ailment that is not self diagnosable, but has been previously diagnosed by a suitably qualified healthcare professional provided that the "medically diagnosed" condition is able to be continuously evaluated accurately and managed safely by an average consumer without the assistance from, and supervision by, a suitably qualified healthcare professional.

Statements about a medicine that do not convey a therapeutic use are not indications. 'Therapeutic use' is defined in section 3(1) of the Act as use in or in connection with:

- (a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons; or
- (b) influencing, inhibiting or modifying a physiological process in persons; or
- (c) testing the susceptibility of persons 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.

Thus the following kinds of statements or claims are not likely to be 'indications':

- statements referring to supplementation with vitamins, minerals or other essential nutrients
- statements referring to 'practitioner dispensing only' – note the statement 'for practitioner dispensing only' may continue to be included in the ARTG entry of a listed medicine as a 'label disclaimer'
- statements that just describe the mechanism of action of a substance/nutrient; and
- statements that describe a physiological function but do not 'influence, modify or inhibit' a physiological process.

Statements that are not indications are not required to be included on the ARTG in order to be used on product labels and during advertising campaigns.

Indications that relate to a disease, ailment, defect or condition generally accepted to be beyond the ability of a consumer to diagnose or evaluate accurately and/or manage safely without the intervention and/or supervision of a suitably qualified healthcare practitioner will not be included in the list of permitted indications.

The diagram included at Appendix 3 provides guidance for determining whether an indication is appropriate for use in listed medicines. Examples are provided in Table 1 below.

Table 1 – Parameters for Permitted Indications

Statement	Is this an 'indication'?
Fast action formula. Tested for heavy metals.	No: Not for therapeutic use. Statements relate to the properties of the product. Not required to be included in the ARTG entry. Can be included on product labels and advertising if sponsor holds evidence to support such statements.
(Substance x) is a natural component of (a cell, tissue or organ)	No: Structure/function statement that does not 'inhibit, modify or influence' a physiological process. Not required to be included in the ARTG entry. Can be included on product labels or advertising if sponsor holds evidence to support such statement.
Promotes the absorption of phosphorus	No: The statement may imply 'modifying a physiological processes'. However it is not evident that it is linked to a meaningful health benefit.
For practitioner dispensing only	No: Not for therapeutic use therefore not an indication. This statement refers to how a listed medicine may be made available to consumers. This statement may be included in the ARTG entry of a listed medicine as a 'label disclaimer'.

Indication	Is this indication suitable for use in relation to listed medicines?
Relieves the symptoms of or manages/treats cardiovascular disease	No: Cardiovascular disease is not appropriate to be diagnosed and treated without the supervision of a suitably qualified healthcare professional. Not suitable for use in listed medicines. Cannot be associated with listed medicines.
Relieves the symptoms of cold	Yes

Structure, type and coding of permitted indications

Structure of permitted indications

As described in section 'Permitted indications for listed medicine' an indication, in relation to therapeutic goods, must describe the specific therapeutic use(s) of the goods.

Permitted indications proposed for listed medicines will generally be structured to have two elements:

1. a nominated action or effect (such as reduces, prevents, improves, maintains, or stimulates); and
2. a defined target (such as a biological factor or process, a health state or a clinical condition).

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, mild or persistent). Indications can generally be schematically represented in the following way:

(CONTEXT) to/for the (Q_A) ACTION of (Q_T) TARGET

Where:

CONTEXT = contextual qualifier where appropriate

ACTION = action, outcome or effect

TARGET = the clinical condition, health status or biological factor

Q_A = action qualifier if appropriate

Q_T = target qualifier if appropriate.

Example Indications

'**Traditionally used in Herbal Medicines**' (*context*) to **reduce** (*action*) the **duration** (*target qualifier*) of **cough** (*target*)

For the **temporary** (*action qualifier*) **relief** (*action*) of **mild to moderate** (*target qualifier*) **headache** (*target*)

Several indications (eg antioxidant) that are not in the form of structure described above have been widely used for listed medicines and are well understood by consumers. These indications are retained and have been included in the list of permitted indications for consultation (Attachment 1).

Type of permitted indications

Types of permitted indications according to types of health benefit

In broad terms, indications may target biological factors or processes, health states or clinical conditions. Indications can be conveniently separated into three clusters 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. Well-being, wellness and health are complex states and do not just refer to the absence of illness.

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**: favourable modification of a known risk factor for a specified illness, condition, disease or disorder.
- **Prevention**: prevents the development of a named condition.

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.

Table 2: Example of indications for clusters 1, 2 and 3

Example of indications for clusters 1, 2 and 3	
Cluster 1	
Maintenance indications:	(Context) to/for the (Q_A) maintenance of (Q_T)T
Enhancement indications:	(Context) to/for the (Q_A) enhancement of (Q_T)T
Cluster 2	
Reduction indications:	(Context) to/for the (Q_A) reduction of (Q_T)T
Prevention indications:	(Context) to/for the (Q_A) prevention of (Q_T)T
Cluster3	
Management indications:	(Context) to/for the (Q_A) management of (Q_T)T
Symptomatic relief indications	(Context) to/for the (Q_A) relief of symptoms of T

Types of permitted indications according to types of evidence

Indications are classified into 'scientific indications' or 'traditional indications' according to the type of supporting evidence that may exist in relation to the relevant therapeutic use. 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.

Traditional indications must state that the health benefit is based exclusively on long-term use and experience. This information should be included in the form of a contextual qualifier.

Terms used in traditional permitted indications must be true, valid, not misleading, 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.

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

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

'Used traditionally in Chinese Medicine to relieve pain'.

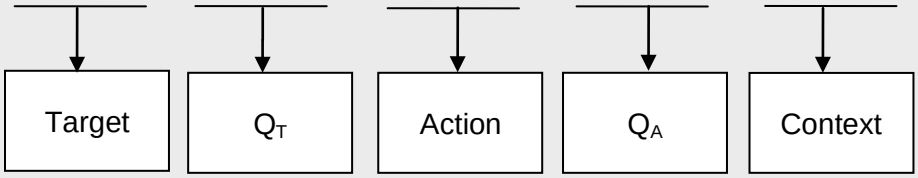
'Traditionally used in Herbal Medicine as an expectorant to relieve coughs'.

Coding permitted indications

All permitted indications for use in ELF need to have a 'computer code'. Coding of permitted indications is readily achievable if indications are aligned with the schematic representation of a permitted indication provided above:

(CONTEXT) to/for the (Q_A) ACTION of (Q_T) TARGET

The code for a permitted indication is of the following format:



The TGA proposes to code all permitted indications in a manner that is broadly consistent with the World Health Organization's International Classification of Diseases system (ICD) 10 to maximise the capacity of the ELF system to cater for new permitted indications and to make it easier for a sponsor to search the available list.

The ICD is the world's 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.

Details in relation to coding a permitted indication are included in Appendix 4.

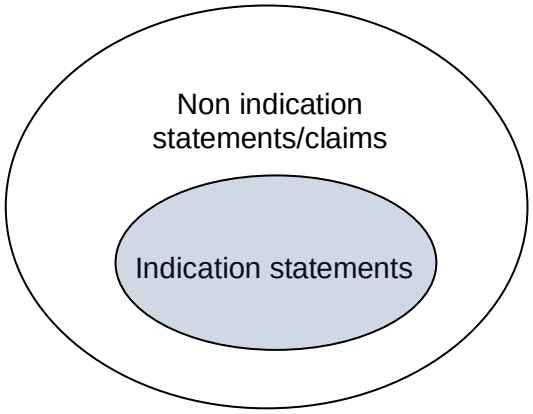
Consultation: General questions on structure, type and coding of permitted indications:

1. Please comment on any specific issues or benefit in relation to the structure, type and coding of permitted indications.

The relationship between indications included on the ARTG and statements on product labels and other advertisements

Under section 3(1) of the Act an advertisement, in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended, whether directly or indirectly, to promote the use or supply of the goods.

Indications for a listed medicine are likely to be included on the product label (indication statements) along with other statements or other claims (non-indication statements/claims). It is common for a product label and advertisements to include non-indication statements/claims that are intended to promote the use or supply of the medicine.



At the time that a medicine is listed in the ARTG under section 26A of the Act, the sponsor must certify that it holds information or evidence to support any claim (including indications) made in relation to the medicine[6]. It is also a condition of listing that the sponsor holds that information or evidence at all times that the medicine remains listed on the ARTG and can provide it to the TGA if requested to do so[7].

Both the label and other advertisements that promote the product directly to consumers (including indications, product performance statements, brand names, and promotional images) must comply with advertising requirements set out in Part 5-1 of the Act and the Advertising Code).

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 and in the document Required Advisory Statements for Medicine Labels (RASML).

Indication Statements

An essential component of the Blueprint reforms is to improve access to information that assists consumers in their healthcare decision making. Information on the label or in advertisements of listed medicines must not be misleading and must provide useful information that assists consumers in making informed choices about self-care.

It is an offence under the Act to advertise therapeutic goods for an indication that has not been accepted in the ARTG in relation to the medicine. It is also a condition of listing that the sponsor of a listed medicine must not, by any means, advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine on the ARTG.

[6] See paragraph 26(2)(j) of the Act
[7] See subsection 28(6) of the Act.

Section 22(5) of the Act provides that a person commits an office if:

- (a) the person, by any means, advertises therapeutic goods for an indication; and
- (b) the therapeutic goods are included in the ARTG; and
- (c) the indication is not an indication accepted in relation to that inclusion.

Listing of a good in the ARTG under section 26A of the Act is subject to a condition that the sponsor must not, by any means, advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the ARTG.

Section 30 of the Act provides grounds for cancelling a medicine from the ARTG if the sponsor has refused or failed to comply with a condition to which the inclusion of the goods is subject.

Sponsors therefore need to be aware that they risk committing an offence or having their product cancelled from the ARTG for breaching a condition of listing if a label or other advertising contains a statement or claim or the overall presentation of the product can be interpreted as a statement about the specific therapeutic uses of the medicine and it is not an indication that is included in ARTG in relation to the medicine

Non-indication statements/claims

Non-indication statements/claims are advertising or marketing statements that are not related to the therapeutic use of the product. Non-indication statements 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.' Non indication statements may also include structure/function statements or a mechanism of action of a nutrient/substance that are not directly related to the therapeutic use of the product.

Non-indication statements are not required to be included on the ARTG in order to be used on product labels and during advertising campaigns.

However, the applicant for a medicine listed under section 26A of the Act must certify that it holds information or evidence to support any such statement/claim. In addition, the Advertising code says that such statements must be meaningful, not misleading and accurately reflect the properties of the product and any such statement/claim made in an advertisement directed to consumers must be correct and balanced and have been verified by the sponsor.

Administratively this means that only the indications selected by the applicant will be accepted in the ARTG. Non-indications will not be accepted. Non-indication statements and claims used in advertising will not be included in the ARTG but all statements and claims (whether indication or non-indication) must be supported by information or evidence. Examples of non-indication statements are included in Table 3 below.

Table 3: Examples of non-indication statements

Non indication statements cluster	Additional information
Fast action formula. Tested for heavy metals. Contains ingredients of plant origin	These statements relate to the properties of the product. They are not related to the therapeutic uses of the product therefore would not be included on the ARTG. Evidence or information must be held by the sponsor to support such statements as required by the Act and the Advertising code.
(Substance x) is a natural component of (a cell, tissue or organ).	This is a structure/function statement that does not relate to 'inhibiting, modifying or influencing' a physiological process therefore is not for therapeutic use. It would not be included on the ARTG. This type of statements must not be misleading and must be verifiable as required by the Advertising code and supported by evidence or information as required by the Act.

Consultation: General questions on the relationship between an indication on the ARTG and a statement on the product label and other advertisements

2. Please provide comment on the description of the relationship between an indication on the ARTG and a statement on the product label and other advertisements. Do you feel sufficient clarity has been provided? If not please include a detailed explanation in your submission.
3. Do you have other comments regarding this topic?

List of permitted indications for consultation

Expanded list of indications

The TGA recognises that in order to limit the use of inappropriate indications and claims on the ARTG and require applicants of listed medicines to select indications only from the list of permitted indications approved by the TGA, the list needs to be comprehensive.

To develop a comprehensive list, indications from the following sources have been considered

- existing coded indications available for use in ELF
- previous industry input received via the OCM Industry Consultation Group
- indications from Health Canada (HC) monographs
- indications from European Medicines Agency (EMA) monographs
- indications from Japanese Foods with Nutrient Function Claims (FNFC); and

- additional input from the members of the Informal Working Group on Complementary Medicines as a result of the September 2012 consultation.

Indications from the above sources are assessed for appropriateness in accordance with the acceptable parameters for listable indications (see 'Permitted indications for listed medicines' above) and amended, where necessary, to ensure they are within the parameters of permitted indications.

Indications that are considered appropriate are then restructured and reworded, if necessary, to be consistent with the structure of permitted indications (see 'Structure, type and coding of permitted indications' above) and coded in the manner broadly consistent with the WHO's ICD 10 System (see 'Coding permitted indications' above).

The review has resulted in the proposed list of permitted indications. These indications are included in Attachment 1. Information included in each column of Attachment 1 is briefly described in table 4 below.

Table 4: Information provided in each column of Attachment 1 (proposed list of permitted indications)

Name of column	Description
No. (number)	The number assigned to the proposed indication in the document. This is a sequential number
Proposed Indication	This column includes proposed permitted indications
Label Warning	Includes the codes of label warnings that must be included on the ARTG with the corresponding permitted indications. The label warnings must also be included on the product labels with the corresponding indications. The descriptions of these warnings are included in Appendix 5.
Other requirements– route of administration	Other requirements associated with the use of proposed permitted indications (eg topical only) are included in this column.
Codes	This column includes the ICD 10 codes for the proposed permitted indications in the form of Target - Target Qualifier (QT) - Action - Action Qualifier (AT) - Contextual Qualifier (Context).

Name of column	Description
Next two columns - Source Indication and Source	The column 'Source Indication' includes indications, in their original words, obtained from a source described in the 'Source' column. Abbreviation of sources: HC: Health Canada FNFC: Japanese Foods with Nutrient Function Claims EMA: European Medicines Agency IWG: Complementary Medicines Working Group Other 'codes' included in the 'Source' column are from ELF or previous industry input received via the OCM Industry Consultation Group.

The TGA uses a number of mechanisms to ensure label disclaimers and warning statements are imposed including the Therapeutic Goods Order No. 69 - General requirements for labels for medicines (the Labelling Order).

Note: In commenting on the proposed expanded list of permitted indications, or when proposing a new permitted indication for consideration by the TGA, stakeholders are requested to consider the following:

- Indications must be for "therapeutic use" as defined in section 3(1) of the Act.
- Parameters for permitted indications.
- An accepted structure for permitted indications.
- Types of permitted indications.
- A consistent approach to coding permitted indications.
- The relationship between indications included on the ARTG and statements included on the product label/advertisements.

Consultation: General questions on the expanded list of permitted indications

4. Looking at the expanded list of proposed permitted indications included in Attachment 1, do you feel these indications are appropriate for listed medicines? If you would like to provide comments for a specific indication please quote the number of that indication.
5. Is the list sufficiently comprehensive? If not please suggest additional indications. In doing so please consider the following, noting the rules in the legislation that only indications that are included in the ARTG for a medicine can be used on the label or in advertising:
   a. the parameters for permitted indications for listed medicines
   b. accepted structure

c. type of permitted indications; and

d. the relationship between indications on the ARTG and statements included on the product label/advertisements.

6. Please provide any further comments regarding the expanded list of permitted indications.

List of existing coded indications for omission

The review of coded indications currently available in ELF against the acceptable parameters for listed medicines has indentified a small number of indications that are not appropriate for use in listed medicines. These indications are listed in Attachment 2. The TGA does not propose to include these in any list of permitted indications for use in medicines listed under section 26A of the Act.

Note: the indications included in Attachment 2 have not been re-worded or restructured.

Consultation: General questions on the list of existing coded indications for omission:

7. Please provide comment on the list of indications for omission (Attachment 2) against the parameters for permitted indications for listed medicines.

8. Do you foresee any specific concerns or benefit as a result of the proposed change? Where possible please attempt to quantify these concerns and benefits.

Removal of the free text field from ELF and introduction of a mechanism for applicants to apply for new permitted indications

Removal of the free text field from ELF

At present when listing a medicine on the ARTG via ELF, applicants may select indications from a list, or utilise a free text field to describe indications in their own words.

Effective implementation of the recommendations made by the Auditor General to ensure that inappropriate indications and claims cannot be included in the ARTG will require amendment of the Act. If agreed by the Government and passed by Parliament, the amendments would have the effect that applicants for listing of a medicine under section 26A could only select indications from a list of indications appearing in a legislative instrument made under the Act by a delegate of the Minister. This legislative instrument could be amended from time to time. As a consequence, the TGA would need to remove the free text field from ELF.

New process for applying and approving a new permitted indication

To allow for new indications to be made available for listed medicines the Act would allow anyone to apply for additional indications to be added to the list. The TGA would modify the current TGA on-line system to provide a portal for such applications to be made.

Applications for additional indications would be assessed by the TGA in accordance with the acceptable parameters for listable indications (see the section 'Permitted indications for listed medicines'). If the proposed indication were considered appropriate for listed medicines, it would be added to the list in the legislative instrument and made available for use through ELF. The proposed process is illustrated in the diagram included in Appendix 6.

The TGA is required by Government to fully recover its operating costs for all activities that fall within the scope of the Act. An application fee and assessment fee would be payable which would be based on the cost of providing the service.

The TGA recognises that it is important to make additional permitted indications available for use by the sponsor in a timely manner. It may not be possible nor practical to update the legislative instrument as soon as an additional indication is considered. For clarity and transparency, and to balance the interest of all parties involved, the TGA may update the legislative instrument at a defined interval.

Consultation: General questions on the proposed process of adding new indications:

9. Do you foresee any specific concerns or benefit as a result of the proposed changes? Please provide detailed explanation and proposal if you have concerns.
10. Do you have other comments regarding this topic?

Proposed implementation of permitted indications

Implementation date

In recognition of the likely impact on sponsors of listed medicines, and subject to Government and parliamentary approval and amendment of the Act, it is proposed to implement the following changes by **1 January 2014:**

- include the expanded list of permitted indications in a legislative instrument and ELF
- remove the ability to utilise the free text field in ELF, and
- allow for additional indications to be added to the permitted indications list from time to time.

Listing a new medicine under section 26A of the Act after 1 January 2014

All applications to list new medicines submitted to the TGA after 1 January 2014 (after the removal of the free text field in ELF) can only include indications from the list of permitted indications appearing in the legislative instrument. Subsequent changes could be made to these medicines as per the appropriate process.

Transitional arrangements for medicines listed on the ARTG as at 31 December 2013

Transitional period

The TGA proposes a two year transitional period to allow products listed on the ARTG as at 31 December 2013 to comply with the new requirements.

By 1 January 2016, all products listed on the ARTG must comply with the new requirement in relation to indications. This means that by that date all products listed on the ARTG under section 26A of the Act:

- cannot include indications in the 'specific indications field' (free text field); and
- can only include indications from the list of permitted indications approved by the TGA and appearing in the legislative instrument.

After the end of the transitional period (31 December 2015), medicines that do not comply with the above requirement will be cancelled from the ARTG. Once the medicine is cancelled from the ARTG the sponsor will not be able to supply the medicine on the Australian market.

It is an offence under section 19B(4) of the Act for a sponsor to supply a therapeutic good in Australia unless the product is listed or registered on the ARTG or is exempt from registration or listing, or is subject of an approval or authority under the Act (for instance under sections 18A, 19 or 19A).

It may also be an offence under State law to supply therapeutic goods that are not included in the ARTG.

Section 16(1A) of the Act and regulation 11 of the Therapeutic Goods Regulations 1990 provide that medicines listed under section 26A of the Act are taken to be 'separate and distinct' from other therapeutic goods if the medicines have:

- (a) different active ingredients; or
- (b) different quantities of active ingredients; or
- (c) a different dosage form; or
- (d) a different name; or
- (e) different indications; or
- (f) a different excipient; or
- (g) for medicines that contain any restricted ingredients:
  - i) a different quantity of a restricted ingredient that is an excipient; or
  - ii) if the restriction on a restricted ingredient relates to tis concentration in a relevant medicine – a different concentration of the restricted ingredient; or
  - iii) if the restriction on the restricted ingredient relates to its quantity in

the recommended single or daily dose in a relevant medicine – different directions for use setting out a different recommended single or daily dose.

Changes to medicines listed before 1 January 2014 during the transitional period

During the transitional period (between 1 January 2014 and 31 December 2015), if a change to a listed medicine is requested by the sponsor and the medicine was first listed on the ARTG before 1 January 2014, irrespective of whether the change will result in a separate or distinct good or not, it will trigger the new arrangements and the medicine must comply with the new rules. The sponsor must remove any indications that are not in the list of permitted indications in order to make the change.

Action by the TGA during the transition period

It should be noted that during the transition period the TGA will continue to review listed medicines that were on the ARTG as at 31 December 2013 to ensure that they are compliant with the rules that are applicable to them. This would include where appropriate, asking the sponsor to provide information or evidence that supports any claims or indications in relation to the medicine; checking whether the certifications made at the time the medicine was included in the ARTG (including whether the medicine is 'eligible for listing') are correct and whether the medicine complies with the advertising requirements.

Action would be taken to cancel the medicine from the ARTG in appropriate cases, where for instance the sponsor was not able to provide evidence or information to support the indications, the medicine was not eligible for listing or the presentation of the medicine (including the label) was unacceptable.

The TGA would also conduct compliance reviews of medicines listed on or after 1 January 2014 to check whether they comply with the new rules.

Consultation: General questions on transitional arrangements

11. Views of sponsors and stakeholders are sought on whether the 2 year transitional period is appropriate or should be longer or shorter.
12. Please comment on the proposed transitional arrangements. What are the likely benefit or cost to you or your business (financial or non financial). If possible please attempt to quantify these costs and benefits.

Glossary of terms

Definitions of key terms used in this consultation paper are provided in this section to facilitate a common understanding of the key issues and proposed regulatory options.

Australian Register of Therapeutic Goods (ARTG): ARTG is the publicly accessible reference database of the therapeutic goods available in Australia. The ARTG is available online. It provides information on therapeutic goods that can be supplied in Australia and includes product and sponsor name and other basic information about the goods. It is not intended to provide guidance, advice or recommendations on those goods.

Advertisement: Advertisement, in relation to therapeutic goods, includes any statement, pictorial representation or design, however made, that is intended, wether directly or indirectly, to promote the use or supply of the goods.

Complementary medicines: Complementary medicines include vitamin, mineral, herbal, aromatherapy and homoeopathic products. Complementary medicines may be either listed or registered, depending on their ingredients and the therapeutic indications made.

Label: A product label is a display of printed information upon, or securely affixed to, the container, any intermediate packaging and primary packaging of a medicine.

Presentation: Presentation, in relation to therapeutic goods, means the way in which the goods are presented for supply, and includes matters relating to the name of the goods, the labelling and packaging of the goods and any advertising or other informational material associated with the goods.

Appendix 1: 'Prohibited representations' (Part 1 of Schedule 2 of the Regulations)

Excerpt for the Therapeutic Goods Regulations 1990

Schedule 2: Prohibited and required representations (regulation 6B) Part 1: Prohibited representations

Column 1 Item No.	Column 2 Representation	Column 3 Therapeutic goods
1	a representation that is a prohibited representation under Part 1 of Appendix 6 to the Therapeutic Goods Advertising Code	all therapeutic goods
3	a representation with respect to the use of goods in which it is stated or implied that those goods: (a) are, or contain, a vitamin - unless those goods are composed of, or contain, a substance specified in column 2 of an item in Part 3 of this Schedule or a salt or derivative of a substance and that substance is described either by the name referred to in Column 2 of that item, or by the name of its salt or derivative, or by the name specified in Column 3 of that item and not otherwise; or (b) are, or contain, a substance described as a vitamin otherwise than by a description specified in Column 2 or 3 of Part 3 of this Schedule	all therapeutic goods
4	a representation referred to in subparagraph 7 (1) (e) (i) or (ii) of the Therapeutic Goods Advertising Code	analgesics
5	a representation containing a reference to bacteriostatic activity, except where it is made in conjunction with a reference to bactericidal activity	disinfectants

Column 1 Item No.	Column 2 Representation	Column 3 Therapeutic goods
6	a representation: (a) containing reference to the Rideal-Walker test or the Phenol Coefficient; or (b) on any label, containing a reference to the results of laboratory tests on micro-organisms, other than a representation provided by leaflet or on a label enclosed with the goods in their package; or (c) containing a reference to the achievement of sterility except where the representation is approved in writing by the Secretary; or (d) contradicting or conflicting with the common name; or (e) that is not more specific than the common name as a description or measure of activity against micro organisms; or (f) containing a reference to an effect against viruses, except a representation that is approved in writing by the Secretary; or (g) containing a reference to an effect against Mycobacterium tuberculosis and related acid fast bacteria, except a representation that is approved in writing by the Secretary; or (h) containing a reference to the disinfection of inaccessible parts of drains	disinfectants and antiseptics
7	a representation that antiseptics promote healing	antiseptics
8	a representation referred to in paragraph 7 (2) (a) or (b) of the Therapeutic Goods Advertising Code	vitamins
9	a representation that: (a) purports to show the recommended daily or dietary intake or allowance of a vitamin or a mineral unless the amount shown is that recommended by the National Health and Medical Research Council; or (b) expresses the quantity of a vitamin or a mineral contained in a preparation as a percentage or proportion of the recommended daily or dietary intake or allowance	vitamins and minerals

Appendix 2: 'Restricted representations' (Part 2 of Appendix 6 of the Advertising code)

Excerpt from the Therapeutic Goods Advertising Code 2007

Appendix 6 Prohibited, Restricted and Permitted Representations

Part 1 – Prohibited Representations

A prohibited representation is defined as:

- (i)Any representation regarding abortifacient action
- (ii) 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:

- (i) prevention of skin cancer through the use of sunscreens
- (ii) 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 for such 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 disorders
- 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

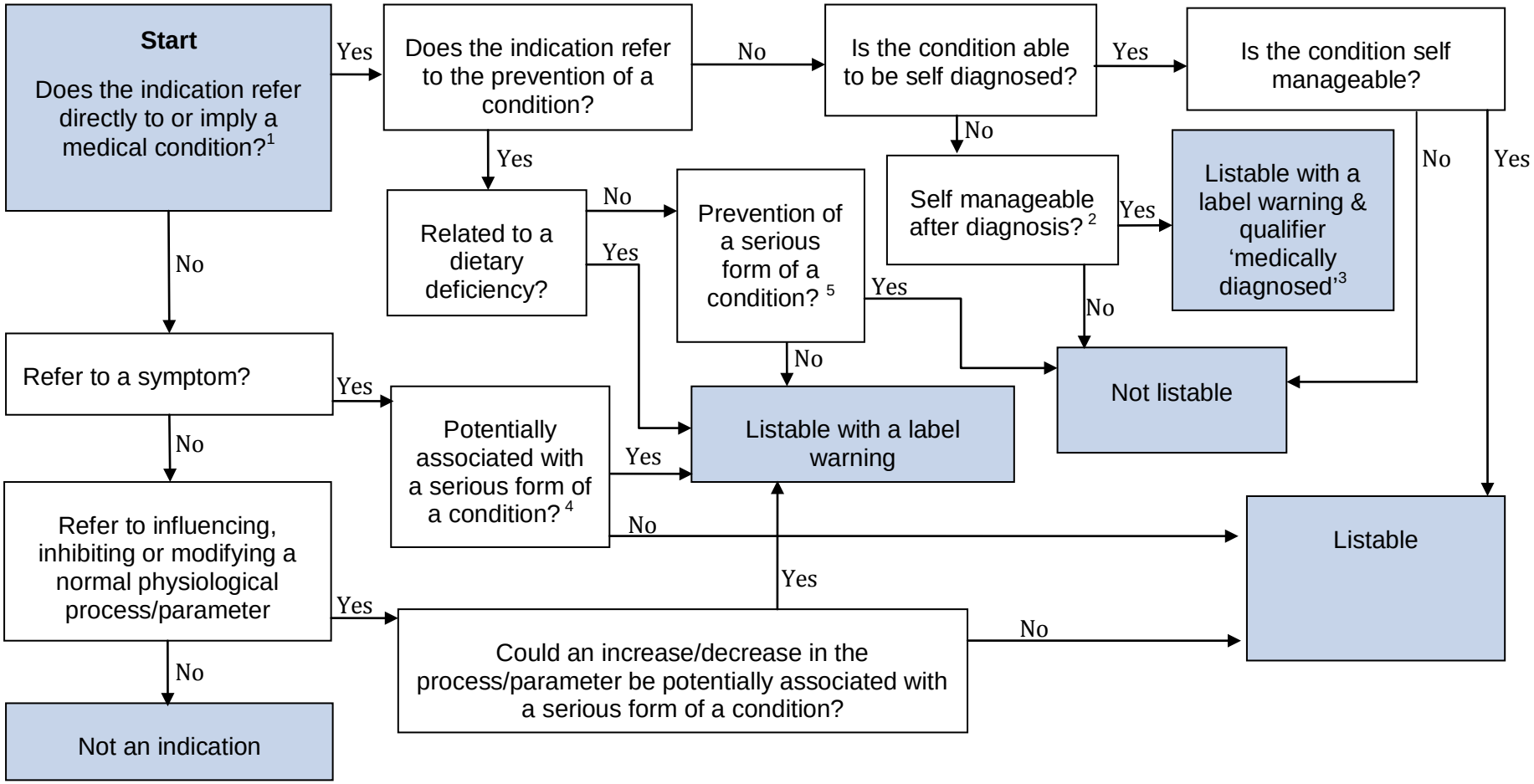
Serious in the context of this table will mean forms of those diseases, conditions, ailments or defects which are:

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.

Appendix 3: Flowchart providing guidance on determining a 'permitted indication'

Flowchart providing guidance on determining a 'permitted indication'



Notes:

1. **Condition:**The word condition covers disease, ailment, defect or injury.
2. **Self manageable after diagnosis?:** This question refers to whether the diagnosed condition is beyond the ability of the average consumer to evaluate accurately and manage safely without the supervision by and assistance from a suitably qualified health care professional.
3. **Permitted with label warning and qualifier 'medically diagnosed':** A 'medically diagnosed condition' would only be permitted for use in listed medicines in exceptional circumstances. It is only permitted when the diagnosed condition is able to be continuously evaluated accurately and managed safely by an average consumer without the supervision by and assistance from a suitably qualified healthcare professional.
4. **Serious form of a condition:** Serious form of a condition is defined in the Regulations as:

serious, in relation to a form of a disease, condition, ailment or defect, means a form of the disease, condition, ailment or defect that is:

   a. generally accepted as not being appropriate to be diagnosed or treated without consulting a suitably qualified healthcare professional; or

   b. generally accepted to be beyond the ability of the average person to evaluate accurately, or treat safely, without regular supervision by a suitably qualified healthcare professional.

5. **Prevention of a serious form of a condition:** Prevention of a serious form a condition is generally not permitted for use in listed medicines. Indications that refer to the prevention of a serious form of a condition would only be permitted for use in listed medicines under exceptional circumstance and when the following criteria are met:

   a. there is credible evidence supporting the indication

   b. it is recommended by the relevant Advisory Committee; and

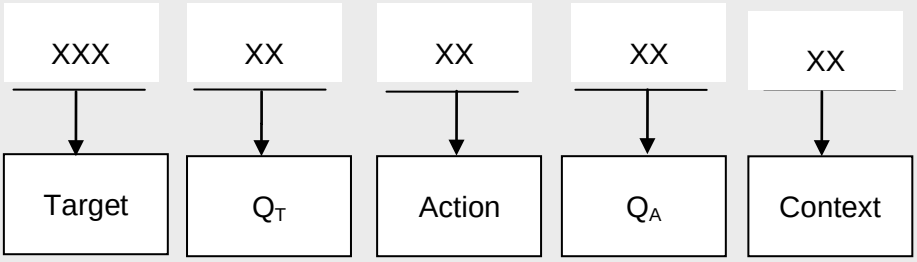
   c. not permitting such indication to be used for listed medicines will create a significant negative impact on the health and interest of the Australian population.

Appendix 4: Coding a permitted indication using ICD-10 System

TPermitted indications can generally be schematically represented in the following way:

(CONTEXT) to/for the (Q_A) ACTION of (Q_T) TARGET

The code for a permitted indication is of the following format:



The TARGET determines the first 3 digits

The TARGET of a permitted 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 letters 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 letters 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.

E.g. Used traditionally in herbal medicine to relieve symptoms of the common cold

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

E.g. 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.

E.g. 'Acts as an antioxidant'

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

E.g. '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.

Table 1: Guidance on codes for common terms

Target	Q_T	Action	Q_A	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		
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		

Target	Q_T	Action	Q_A	Context
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				
REX – expectorant				
xIN – inflammation of 'x' system				
xTO – tonic for 'x' system				

Target	Q_T	Action	Q_A	Context
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				

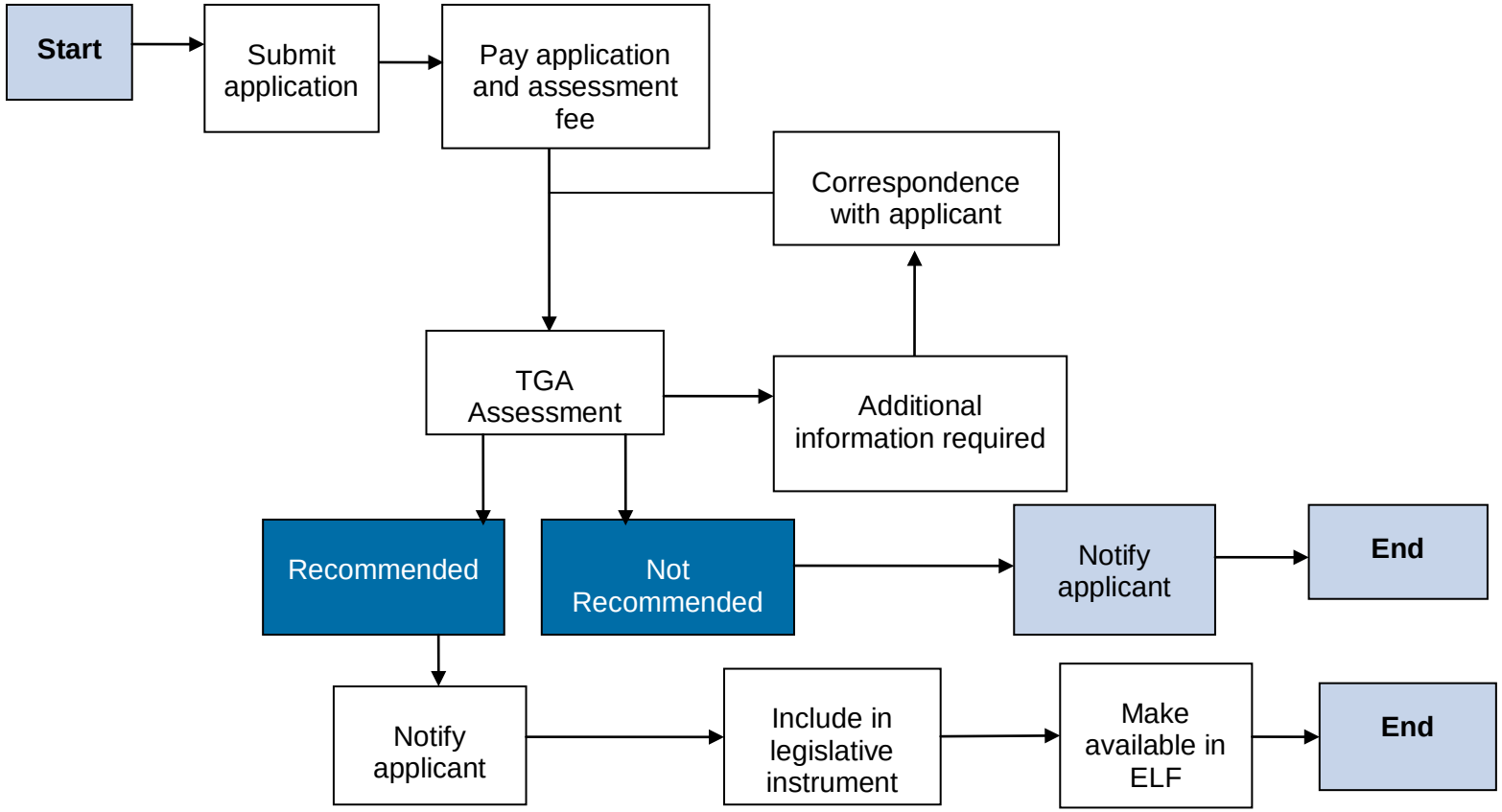
Appendix 5: Label warnings

Code	Label warning description
COLD	Adults only. **OR** Not to be used in children under two years of age
COU1	Adults only. **OR** Not to be used in children under two years of age
COU2	If coughing persists consult your doctor
CYST	If pain or irritation persists for more than 48 hours, consult your doctor
DIAR	If diarrhoea persists, seek medical advice
FLRET	If fluid retention persists, seek medical advice
LAX1	Drink plenty of water
LAX2	Prolonged use may cause serious bowel problems
LAX3	Do not use when abdominal pain, nausea or vomiting are present

Code	Label warning description
NEUR	Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida, seek specific medical advice (or words to that effect).
PSOR	Healthcare professional will advise you whether this preparation is suitable for your condition
S1	If symptoms persist consult your healthcare practitioner
NS1	if you are concerned about your nutritional status consult your healthcare practitioner.
S2	If symptoms persist seek a review of your condition by your healthcare practitioner
HS	If you are concerned about your health status, seek the advice of your healthcare practitioner
BSL	If you are concerned about your blood sugar levels, seek the advice of your healthcare practitioner

Appendix 6: Proposed process for adding new permitted indications

Flowchart of proposed process for adding new permitted indications



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