



*Complementary Medicines Australia submission:*

## **Permitted Indications Determination**

**Submission (1) of a multi-part submission:**

**Health maintenance claims regarding cholesterol, triglycerides, blood sugar and blood pressure.**

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## Introduction

Complementary Medicines Australia (CMA) is exclusively committed to a vital and sustainable complementary medicines sector, and represents stakeholders across the value chain, including manufacturers, raw material suppliers, distributors, consultants, retailers and allied health professionals.

The increasing consumer demand for complementary medicines has resulted in the industry becoming a significant pillar in preventative healthcare, both economically and as an employer. Over the last few decades the Australian complementary medicines sector has evolved into a major world class industry supporting domestic jobs, research, manufacturing and exports.

CMA welcomes the opportunity to review and provide comments on the draft list of permitted indications for listed medicines, and the opportunity to propose additional indications or evidence qualifiers. The following submission is in relation to a particular subset of indications. Further submissions to the draft list may follow.

## Indications referring to substrates or other markers

### Included indications in Draft List (July)

The draft list of permitted listable indications includes some indications referring to cholesterol, blood sugar and triglycerides. These are shown in Table 1 below.

Body part/system	Complete Indication	Specific requirement applying to use of the indication
CARDIOVASCULAR - BLOOD	Helps maintain/support cholesterol health	Must not be for lowering or raising blood cholesterol levels from outside of the normal healthy range
CARDIOVASCULAR - BLOOD	Helps reduce the oxidation of LDL cholesterol	Must not be for lowering or raising blood cholesterol levels from outside of the normal healthy range
CARDIOVASCULAR - BLOOD	Helps reduce intestinal absorption of cholesterol from dietary sources	Must not imply lowering or raising the cholesterol levels from outside of the normal healthy range
CARDIOVASCULAR - BLOOD	Helps maintain/support blood sugar/glucose health	Must not be for lowering or raising blood sugar/glucose levels from outside of the normal healthy range
CARDIOVASCULAR - BLOOD	Aid/assist/helps the transport of glucose into the cells	Must not be for lowering or raising blood sugar/glucose levels from outside of the normal healthy range
CARDIOVASCULAR - BLOOD	Aid/assist/helps glucose/sugar/carbohydrate metabolism	Must not be for lowering or raising blood sugar/glucose levels from outside of the normal healthy range
CARDIOVASCULAR - BLOOD	Helps in the maintenance of healthy blood lipids/blood fats	Must not be for lowering blood lipids, blood fats and triglycerides

These indications refer to normal body substrates and processes and CMA agrees with their continued inclusion in the list of permitted indications. It is consistent with the approach to other biological structures and substrates described throughout the permitted indication list.

### **Excluded indications in Draft List (July), and application for these indications**

Indications commonly used in listed medicines for some decades referring to the normal levels of these biological substrates such as glucose and cholesterol have been omitted from the list. Included in Table 1 of Appendix 1 at the end of this document are a list of indications for addition to the list. Below is a discussion of the suitability of these kinds of indications, including discussion of an additional specific requirement applying to use of the indications.

#### **Serious conditions**

Health benefits for ‘serious forms’ of diseases, conditions, ailments or defects are not eligible for listing. The TGAC restricts advertising of serious forms of 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.*

‘Levels’ of these substrates are not intrinsically diseases, conditions, ailments or defects. Glucose and cholesterol for example are ubiquitous biological molecules. Regulatory mechanisms within the body (production, excretion, transport) operate to keep bodily substrates and processes in balance. A normal range is recognised, above this there is a range recognised as a ‘pre-disease’ state, followed by a range that characterises named disorders such as diabetes, hyperlipidaemia and hypercholesterolaemia. While elevated levels of cholesterol, glucose, etc. may be considered serious disorders, undefined levels or ‘normal’ levels of these substrates are not.

The Royal Australian College of General Practitioners (RACGP) Clinical Guidelines for cholesterol and other lipids<sup>1</sup> recommends that: ‘Adults should have their blood lipids (a fasting sample should be used when assessing elevated triglycerides [TG]) assessed every five years starting at 45 years of age.’ Further, they recommend that for low risk individuals age 45+, lipids should be measured every 5 years, and for moderate risk individuals, every 2 years. When not at high risk of cardiovascular disease requiring pharmacological intervention, individuals may take lifestyle approaches.

It is not inappropriate for individuals before the age of 45 and individuals over 45 who are low/moderate risk and not recommended for pharmacological treatment, to seek to maintain normal or healthy levels of such substrates via lifestyle measures inbetween the normal, recommended Australian testing protocol. Lifestyle measures may encompass a whole range of approaches, including diet, exercise, meditation, and functional foods or complementary medicines.

### **Indications consistent with low risk principles for listed medicines**

The indications proposed in Table 1 of Appendix 1 to this document are suitable for listing and consistent with low risk principles for listed medicines. They pass the criteria referred to in the TGA’s Permitted Indication Fact Sheet<sup>2</sup>:

Permitted indications must be low risk. Low risk indications may refer to:

Health maintenance: The normal physiological effects of substances on growth, development and normal functions of the body. (E.g. 'Supports healthy liver function').

We are aware that the regulator has raised issues in relation to evidence, but the body of evidence is constantly changing and the holding of appropriate evidence is the responsibility of individual sponsors. It is a discussion that is not materially relevant to the discussion regarding whether the indications are of a suitable nature for listed medicines.

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<sup>1</sup> <https://www.racgp.org.au/your-practice/guidelines/redbook/8-prevention-of-vascular-and-metabolic-disease/83-cholesterol-and-other-lipids/>

<sup>2</sup> <https://www.tga.gov.au/criteria-permitted-indications-fact-sheet>

### **Exclusion of indications inconsistent with list of Permitted Indications**

The omission of these indications represents an inconsistency within the list of permitted indications. Many indications in the list refer to other biological substrates/conditions that occur within normal ranges such as oxygen, thyroid hormone, oestrogen, testosterone, vitamins and minerals. Like blood glucose, cholesterol and blood pressure, all these substances may exist in the body in normal or abnormal ranges and abnormal levels give rise to recognised medical conditions that require medical intervention. These other substrates/conditions have not been omitted from the permitted indications list, they have only been omitted in the abnormal range. In addition, as for blood glucose and cholesterol, all require testing to assess the normality of the range.

We also draw your attention to the inclusion of indications within the draft list of permitted indications that refer to the maintenance of cardiovascular health. Helping support/maintain lipid, cholesterol, blood sugar and blood pressure levels are just one part of cardiovascular health and it is reasonable to include indications referring to these items.

### **Comparable Australian food regulation and overseas regulators**

Many food items contain health claims that are far higher than the indications that CMA are requesting to remain in the list of permitted indications. These food items are also available for self-selection by consumers. It doesn't appear to be a concern of the Australian government that consumers attempting to reduce cholesterol with food items presents a serious risk to consumers seeking adequate care by health care professionals for serious conditions.



Indications relating to the reduction of blood lipid and blood glucose levels have similarly been included in herbal monographs published by comparable regulators (eg Health Canada monographs for garlic, flaxseed and *Irvingia gabonensis*).

The claims for all such products are higher than those being proposed in this submission.

### Low risk indications

Indications must not claim to be effective in all situations. As such the proposed indications are mitigated by the use of qualifying terms such as ‘assists in the maintenance’ or ‘helps to support’.

Indications must be considered in terms of whether it would pass the test of how a reasonable person would interpret and act upon provided information. CMA does not believe that it would be possible for a reasonable person to interpret the proposed indications as for the treatment of seriously abnormal levels of such substrates. Nor does it appear that any reasonable person would go against the advice of a medical practitioner and inappropriately self-treat serious conditions with listed medicines, or avoid usual medical care because they are taking a listed medicine.

### **Consumer information and transparency**

There is a great deal of information relating to the use of complementary medicine substances in connection with influencing physiological processes. Removal of such indications removes transparency for the consumer under circumstances where no harm is being caused. However, it may introduce risk for consumers if they are not aware that certain supplements may influence these physiological processes. It is inherently safer to include such indications with a risk mitigating statement as proposed below, so that consumers have the choice to not purchase such a product, or so that they may be reminded to check with their medical practitioner.

### **Additional risk mitigators**

At a certain point during the last decade, the TGA began requiring the use of the term ‘in healthy individuals’ to satisfy concern that listed medicines would not be used by persons with potentially serious conditions such as hyperlipidaemia. In recent times it appears that use of the term has not been considered sufficient to ensure safe use, although it has not been clear that this has been connected to any identified problem with the use of the goods by individuals. Although as outlined above CMA believes the situation is low risk, we acknowledge the concern in this regard and therefore are proposing to replace the existing qualifier with a stronger disclaimer to even further mitigate risk. Use of a label advisory statement could be:

- *Not for treatment of high cholesterol/blood sugar/blood pressure/triglycerides.*

OR:

- *‘Please see your doctor if concerned about your cholesterol/blood sugar/blood pressure/triglycerides’.*

CMA does not believe both label statements is necessary and would be difficult due to label constraints, therefore we are suggesting the use of one or the other statement.

### **Regulatory Impact**

The removal of these long used indications, that are consistent with low risk principles for listed medicines, represents a change in regulation that has regulatory impacts. It also does not appear to be in response to any primary problem or consequences that have been occurring. It has impacts upon Australians who are being blocked from receiving appropriate information and affecting their ability to make positive choices for maintaining their own health. There are questions outlined in the [Australian Government Regulation Impact Statement Preliminary Assessment Form: Is a RIS Required?](#). It does not appear that the concern for this group of indications matches a problem of any magnitude, and does not appear that the removal or banning of these indications is warranted. The stronger disclaimer proposed in this submission will already constitute an increase of regulation, and we propose that this increase is sufficient to address concerns.

### **Summary**

The proposed indications do not meet the requirements of being a serious form of a disease, ailment, condition or defect. They do meet the TGA requirements for health maintenance claims. Excluding the indications, that have been safely used for decades, reduced transparency for consumers, possibly introduces risks, and reduces their ability to choose acceptable lifestyle interventions to maintain their health. Therefore, it has regulatory impacts upon individuals, as well as many businesses that have these indications on their products without any harm having been caused. However, CMA has proposed increased regulation to address the concerns by way of label advisory statements to further mitigate the possibility of any risk.

## Appendix 1.

Table 1. Proposed Permitted Indications

Body part/system	Complete Indication	Specific requirement applying to use of the indication
CARDIOVASCULAR - BLOOD	Assists in the maintenance of a normal/healthy LDL:HDL cholesterol ratio	(label advisory statement)
CARDIOVASCULAR - BLOOD	Assists in the maintenance of cholesterol within the normal range	(label advisory statement)
CARDIOVASCULAR - BLOOD	Assists in the maintenance of normal/healthy cholesterol levels	(label advisory statement)
CARDIOVASCULAR - BLOOD	Assists in the maintenance of cholesterol within the normal/healthy range and improve the LDL:HDL ratio	(label advisory statement)
CARDIOVASCULAR - BLOOD	Assists in the maintenance of normal blood pressure	(label advisory statement)
CARDIOVASCULAR - BLOOD	Helps to support normal blood pressure	(label advisory statement)
CARDIOVASCULAR - BLOOD	Assists in the maintenance of triglycerides within the normal range	(label advisory statement)
CARDIOVASCULAR - BLOOD	Assists in the maintenance of normal blood lipid/blood fat levels	(label advisory statement)
CARDIOVASCULAR - BLOOD	Assists in the maintenance of normal healthy blood sugar levels	(label advisory statement)
CARDIOVASCULAR - BLOOD	Assists in the maintenance of normal healthy glycaemic controls	(label advisory statement)
CARDIOVASCULAR - BLOOD	Assists in the maintenance of normal healthy blood sugar/glucose balance	(label advisory statement)