Australian Government
Department of Health
Therapeutic Goods Administration

Criteria for permitted indications

Indications are statements that describe a therapeutic use for a medicine. The *Therapeutic Goods Act 1989* defines a 'therapeutic use' as any 'use in, or in connection with, influencing, inhibiting or modifying a physiological process in persons'.

Permitted indications are indications that are appropriate for low risk listed medicines that are not assessed pre-market. They will be assessed against the criteria outlined in this fact sheet.

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'***)
- **Health enhancement:** The beneficial effects of substances on the physiological and/or psychological state of the body above and beyond normal growth, development and functions of the body (***e.g. 'Stimulates digestive function'***)
- **Prevention or alleviation of a non-serious vitamin or mineral dietary deficiency** (***e.g. 'Helps prevent dietary vitamin D deficiency'***)
- **Non-serious form of a disease, condition, ailment or defect:** Indications can refer to self-diagnosable, self-manageable conditions, where a delay in medical treatment would not be detrimental to the consumer. Indications may relate to reduction in risk, frequency, duration or relief without resolution of the underlying non-serious disease, ailment, defect or injury (***e.g. 'Helps reduce occurrence of eczema/dermatitis'***)

Low risk indications **cannot** refer or imply to a **prohibited representation** or a **restricted representation** except for in the prevention of skin cancer through the use of sunscreens.

Permitted indications must comply with the Therapeutic Goods Advertising Code

Indications must be capable of complying with the Therapeutic Goods Advertising Code when included on the product label or promotional materials. For example, to comply with the Advertising Code, an indication must not:

- × **mislead**, or be likely to mislead consumers (e.g. 'Improves the IQ of your unborn child')
- × imply that the medicine is **infallible, unfailing, magical, miraculous,** or that it is a certain, or guaranteed **cure**. (e.g. 'Cures eczema')
- × contain any claim, statement or implication that it is **effective in all cases** of the condition (e.g. 'Prevents headaches 24/7')

Permitted indications must be consistent with the relevant treatment paradigm

The indication must be consistent with the **relevant treatment paradigm** and the evidence base supporting its use (i.e. scientific evidence or a history of traditional use). For example, indications based on a 'tradition of use' must not use terminology that would require a scientific procedure or investigation to verify, such as: 'increase bone density'.

It is possible for a medicine to include both scientific and traditional indications where the sponsor has the evidence to support both.

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