

Permitted indication assessment tool

Proposed Indication

Proposed by

Date

Answer the following questions in relation to the proposed indication	Yes	No
1. Does the indication describe a therapeutic use for the goods?	<input type="checkbox"/>	<input type="checkbox"/>
2. Does the structure of the indication include an action and a target ?	<input type="checkbox"/>	<input type="checkbox"/>
3. Is the indication substantially different to other available permitted indications?	<input type="checkbox"/>	<input type="checkbox"/>
4. Does the indication only refer to: <ul style="list-style-type: none"> · health enhancement · health maintenance · prevention or alleviation of a dietary deficiency; or · a health benefit (such as symptom relief) for a non-serious disease, condition, ailment or defect? 	<input type="checkbox"/>	<input type="checkbox"/>
5. If referring to a disease, condition, ailment or defect, is it <i>self-diagnosable</i> (or appropriate to be self-managed after initial diagnosis by a doctor?) If not applicable, move to next question.	<input type="checkbox"/>	<input type="checkbox"/>
6. If referring to a <i>condition, disease, ailment or defect</i> , is it <i>self-manageable</i> (i.e. it does not require regular supervision by a healthcare professional)? If not applicable, move to next question.	<input type="checkbox"/>	<input type="checkbox"/>
7. Is the terminology of the indication consistent with the relevant paradigm (scientific or traditional)?	<input type="checkbox"/>	<input type="checkbox"/>
8. Is the indication likely to be consistent with a documented tradition of use; or <i>scientifically plausible</i> i.e. possible (able to occur) or probable (likely to occur)?	<input type="checkbox"/>	<input type="checkbox"/>
<p>If you answered NO to any question numbered 1 to 8 the indication is NOT SUITABLE.</p> <p>If you answered YES to questions 1 to 8, continue with questions 9 to 16.</p>		

Answer the following questions in relation to the proposed indication	Yes	No
9. Does the indication contain or imply a prohibited representation (i.e. refer to abortifacient action or the following diseases: neoplastic, sexually transmitted, HIV, AIDS, HCV, mental illness)? (Not applicable for sunscreen indications)	<input type="checkbox"/>	<input type="checkbox"/>
10. Does the indication contain, or imply, a restricted representation (i.e. a serious form of a disease, condition, ailment or defect specified in the Therapeutic Goods Advertising Code)?	<input type="checkbox"/>	<input type="checkbox"/>
11. Does the indication contain any implication that the medicine is infallible, unfailing, magical, miraculous, or that it is a certain, or guaranteed cure?	<input type="checkbox"/>	<input type="checkbox"/>
12. Does the indication contain any claim, statement or implication that it is effective in all cases or would raise unrealistic expectations of effectiveness?	<input type="checkbox"/>	<input type="checkbox"/>
13. Could the indication cause the consumer to delay seeking medical treatment and would this be detrimental?	<input type="checkbox"/>	<input type="checkbox"/>
14. Could the indication mislead , or be likely to mislead consumers?	<input type="checkbox"/>	<input type="checkbox"/>
15. Does the indication conflict with any public health or safety policies or principles (eg: obesity, smoking cessation, excessive alcohol consumption)?	<input type="checkbox"/>	<input type="checkbox"/>
16. Does the indication imply that harm may result from not using medication?	<input type="checkbox"/>	<input type="checkbox"/>
<p>If you ticked YES to any question numbered 9 to 16, your indication is NOT SUITABLE.</p> <p>If you ticked NO to questions 9-16, your indication may be suitable.</p>		

Glossary of terms

Term	Description
action	The therapeutic effect/mechanism/benefit.
consistent with the relevant paradigm	The indication must be consistent with the relevant treatment paradigm and the evidence base (scientific or tradition of use) required to support its use. It is possible for a medicine to include both scientific and traditional indications.
effective in all cases	A permitted indication must meet the requirements of the Therapeutic Goods Advertising Code and not imply definitive efficacy as the efficacy of a listed medicine is not pre-market assessed.
harm may result	All indications must comply with the requirements of the Therapeutic Goods Advertising Code.
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.
health maintenance	The normal physiological effects of substances on growth, development and normal functions of the body.
implication	The indication must be capable of complying with the Therapeutic Goods Advertising Code when included on the product label or promotional materials.
mislead	All indications must comply with the requirements of the Therapeutic Goods Advertising Code. To not be considered misleading, the indication must be able to be supported by currently available scientific knowledge or a documented tradition of use.
prevention or alleviation of a dietary deficiency	Prevention of vitamin or mineral dietary deficiency (not prevention of diseases resulting from severe deficiency e.g. anaemia).
prohibited representation	Listed medicines must not refer to a prohibited representation. Prohibited representations are defined in Part 1 of Appendix 6 of the Therapeutic Goods Advertising Code.
public health or safety policies	Indications that conflict with public health policies are not appropriate as they have the potential to undermine public health & safety. The Government's priorities in public health messaging change depending on trends & needs within the community.
restricted representation	Listed medicines must not refer to a restricted representation. A restricted representation is a 'serious form' of a disease, condition, ailment or defect specified in Table 1 of Part 2 of Appendix 6 of the Therapeutic Goods Advertising Code.
substantially different	Have you checked if another indication included on the list will suit your needs? Please remember that there is no requirement for 'word for word' on your product label.
target	The physiological / psychological factor or process or disease, ailment, condition, defect or injury.
therapeutic use	In relation to listed medicines, a 'therapeutic use' means 'use in, or in connection with, influencing, inhibiting or modifying a physiological process in persons'.