



*Complementary Medicines Australia submission:*

## **Permitted Indications Determination**

**Submission (3) of a multi-part submission:**

**Mild and Medically Diagnosed Conditions**

**October 2017**

**To:**

Complementary Medicines Reform Section  
Complementary and OTC Medicines Branch  
Therapeutic Goods Administration  
PO Box 100  
Woden ACT 2606  
[complementary.medicine.reforms@health.gov.au](mailto:complementary.medicine.reforms@health.gov.au)

**From:**

Complementary Medicines Australia  
PO Box 450  
Mawson ACT 2606

Telephone: 02 6260 4022

Facsimile: 02 6260 4122

E-mail: [carl.gibson@cmaustralia.org.au](mailto:carl.gibson@cmaustralia.org.au)

Website: [www.cmaustralia.org.au](http://www.cmaustralia.org.au)

## 1. Mild and Medically Diagnosed Indications

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.*

Conditions that can be self-diagnosed or self-managed may be included in listable indications.

### **Medically Diagnosed**

As per the draft permitted indications list, certain indications that refer to medically diagnosed conditions may be listable. As per the newly published terminology, reference to 'medically diagnosed' conditions:

For a limited number of conditions, it may be appropriate for a person to self-manage and assess the symptoms of their condition after an initial diagnosis has been made by a medical practitioner (where other diseases and conditions have been ruled out), for example: irritable bowel syndrome. In these circumstances, the indication target (that is, the disease, condition, ailment or defect) may be qualified with 'medically diagnosed'. A required label statement will be 'If symptoms persist or worsen, consult your doctor'.

The medically diagnosed indications refer to conditions that, once diagnosed (and with or without medical treatment), are self-manageable and do not refer to or imply effectiveness in resolution of the underlying condition. Given the qualifier that the indications apply only to 'medically diagnosed' conditions, persons using a product bearing such indications must have consulted a medical practitioner and had an initial diagnosis where the symptoms can subsequently be self-diagnosed / recognised. As such, and as reflected in AATA 388, the first limb of the serious disorder definition is not made out. With respect to the second limb of the definition; at the time of the medical consultation appropriate education, therapy and advice will have been provided and the medical practitioner will have determined whether regular follow-up (supervision) is required. The potential outcomes in terms of supervision intensity range from:

- no planned follow-up
- regular short or longer term review
- constant surveillance (eg through hospital admission)

The degree and regularity of follow-up reflects the practitioner's judgement regarding the capability of an individual to undertake safe ongoing evaluation and management of their condition. If the practitioner considers follow-up to be unnecessary, then the practitioner has clearly determined that the individual is capable of evaluating accurately and managing the condition safely without regular supervision by a qualified healthcare professional. Examples of these conditions from the permitted indication list are mild shingles, cold sores, mild chicken pox and sinusitis. As neither the first or second limb of the serious disorder definition is satisfied, these conditions are not serious disorders.

Certain chronic disorders that require medical diagnosis (eg to exclude potential serious differential diagnoses) may be able to be self-managed by consumers in the absence of regular HCP follow-up. Examples of such conditions included in the draft list are fibromyalgia/fibrositis, mild arthritis/osteoarthritis, mild gastritis, etc. In situations where conditions do not impair functioning or quality of life and do not require ongoing treatment with prescription medicines, regular supervision is likely to be considered unnecessary and the definition of 'serious disorder' is not satisfied.

The 'medically diagnosed' qualifier is an important mechanism of supporting the appropriate use of listed medicines and mitigating risk by ensuring that certain differential diagnoses have been excluded and that the patient is educated and capable of self-managing their condition. For those medically diagnosed conditions that do not satisfy the criteria for a serious disorder, it is important to also consider whether use of a product bearing such indications will discourage a person from complying with a prescribed treatment regime, or prevent or delay them seeking medical advice if their condition should worsen. This is unlikely but represents a potential risk that should be accounted for under the precautionary principle. This risk can be adequately mitigated in two ways and is consistent with the current TGA approach:

- restricting permitted indications to refer only to symptomatic relief or a health benefit of such conditions; and

- the inclusion of an advisory statement to consult their healthcare professional if symptoms persist or worsen.

It is of note that some indications that were previously approved for listing by the TGA in this category, have been omitted from the draft list of permitted indications (eg benign prostatic hypertrophy, tinnitus and chronic fatigue syndrome). As with other listable conditions, conditions such as these frequently do not require regular HCP follow-up once diagnosed. Their exclusion from the draft list is inconsistent with the definition of a serious disorder. As most individuals with the conditions are likely to be affected by ‘non-serious’ forms of the condition without need for regular HCP review (unless symptoms worsen), they do not meet the definition of serious form, are not restricted representations and as such should not have been removed. Risks associated with reference to these disorders can be mitigated by prefixing the condition with the term ‘medically diagnosed’ and appropriate advisory statements as is the case in other indications in the list. Some further indication-specific information is included below.

***Medically diagnosed ‘Benign Prostatic Hypertrophy’***

- Is a benign condition associated with ageing, but requires medical diagnosis to exclude serious conditions – it therefore needs a ‘medically diagnosed’ qualifier.
- Mild and moderate cases according to the accepted clinical assessment tool (AUA-SI and the International Prostate Symptom Score (I-PSS)) can often be self managed.  
*[http://www.auanet.org/guidelines/benign-prostatic-hyperplasia-\(2010-reviewed-and-validity-confirmed-2014\)](http://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(2010-reviewed-and-validity-confirmed-2014))*.
- At mild - moderate stages of the disorder there is minimal risk that consumer self-management will result in delayed medical attention or unexpected serious consequences.
- Comparable overseas regulators:
  - Included in Health Canada monographs without mild qualifier for
    - Saw Palmetto – traditional
    - Pygeum - *Prunus Africana* (scientific).
  - Included in EMEA monographs without mild qualifier for
    - Saw Palmetto (scientific and traditional)
    - Pygeum / *Prunus Africana* (traditional).

**Chronic Fatigue Syndrome**

- Requires medical diagnosis to exclude serious and treatable causes of tiredness and weakness - needs medically diagnosed qualifier.
- Can often be self-managed in mild-moderate cases.
- Minimal risk in terms of effects consumer self-management resulting in delayed medical attention or unexpected serious consequences.

### ***Tinnitus***

- Tinnitus is common may be self-diagnosed, however medical diagnosis is required to exclude potentially serious differential diagnoses – medically diagnosed qualifier needed.
- Mild and moderate cases according to the accepted clinical assessment tool (British Association of Otolaryngologists and Head & Neck Surgeons) can often be self-managed.

*[https://www.researchgate.net/profile/David\\_Baguley/publication/11673848\\_Guidelines\\_for\\_the\\_grading\\_of\\_tinnitus\\_severity\\_The\\_results\\_of\\_a\\_working\\_group\\_commissioned\\_by\\_the\\_British\\_Association\\_of\\_Otolaryngologists\\_Head\\_and\\_Neck\\_Surgeons\\_1999/links/0deec52d7db89c0d7f000000/Guidelines-for-the-grading-of-tinnitus-severity-The-results-of-a-working-group-commissioned-by-the-British-Association-of-Otolaryngologists-Head-and-Neck-Surgeons-1999.pdf](https://www.researchgate.net/profile/David_Baguley/publication/11673848_Guidelines_for_the_grading_of_tinnitus_severity_The_results_of_a_working_group_commissioned_by_the_British_Association_of_Otolaryngologists_Head_and_Neck_Surgeons_1999/links/0deec52d7db89c0d7f000000/Guidelines-for-the-grading-of-tinnitus-severity-The-results-of-a-working-group-commissioned-by-the-British-Association-of-Otolaryngologists-Head-and-Neck-Surgeons-1999.pdf)*

- At mild-moderate stages of the disorder there is minimal risk that consumer self-management will result in delayed medical attention or unexpected complications.

### **Mild**

We note the very recent note added by the TGA a week prior to the closing of the consultation on 24-10-2017 regarding 'mild':

The target qualifier 'mild' is used to exclude serious forms of disease, ensuring that the indication only makes reference to a non-serious form of a disease, condition, ailment or defect, for example: 'mild arthritis'. The qualifier 'mild' cannot be used for conditions that require ongoing medical management, such as rheumatoid arthritis, asthma. Where a permitted indication includes the term 'mild' this **must** also be included on the medicine's label.

### **‘Mild’ in relation to self-management of ongoing / chronic conditions**

It appears that the approach taken in the draft list is also to exclude some chronic conditions that require different degrees of follow up at different stages of disease is to use the qualifier ‘mild’ to exclude more serious forms of the condition. While this is a useful approximation in some ways, its use in this context can be not meaningful or potentially misleading to consumers.

Box 1 provide examples where this is particular issue. In cases such as these where there are clinically recognised stages, and more than one stage is appropriate for self-management, it is more appropriate to take one of two approaches:

- Reflect the stages specifically, such as ‘mild to moderate’, where ‘mild’ alone would be misleading or not meaningful; or,
- Recognising that more advanced stages of these non-threatening but progressive illnesses are going to be treated medically in almost every practical case, remove the qualifier as something that is unnecessary or not meaningful.

## Box 1

**Osteoarthritis (OA)** is a chronic condition with a predictable natural history. Indications in the draft list of permitted indications that refer to osteoarthritis are qualified by the term ‘mild’. Although the intent of this may be to exclude applicability to consumers with regular HCP supervision, a consumer’s understanding of the word ‘mild’ may differ greatly. In addition, the term ‘mild osteoarthritis’ has a specific diagnostic meaning and is defined by the Lequesne Index or WOMAC<sup>1,2</sup>. It is very unlikely that ‘mild OA’ defined by these clinical tools equates with the TGA intent. An individual who has some mild pain after extended sitting/standing and mild difficulty with tasks such as picking up objects from the floor and getting into a car, could very easily achieve a score of 5 or more on the Lequesne Index. Such an individual would be classified as having ‘moderate osteoarthritis’ but may not require prescription medicines, surgical treatment or regular HCP supervision. Inclusion of the ‘mild’ qualifier in cases like this is not only inappropriate, it restricts consumer choice and accessibility to potentially beneficial healthcare.

**Benign Prostatic Hypertrophy (BPH)** represents a similar conundrum. Severity of BPH is assessed as ‘mild’, ‘moderate’ or ‘severe’ according to the AUA-SI and the International Prostate Symptom Score (I-PSS). Watchful waiting is recommended for individuals with mild BPH and patients with moderate or severe symptoms (AUA-SI score  $\geq 8$ ) who may not be bothered by their symptoms.<sup>3</sup> The onus here is on patient-led assessment of symptoms and it is possible that individuals with more than ‘mild’ BPH are not under regular HCP supervision.

**Tinnitus** is a common disorder that is characterised by ringing in the ears. It may be a condition or a symptom of a condition that requires medical diagnosis. Tinnitus is classified according to severity from slight to catastrophic. Most people with tinnitus fall within the mild - moderate range whether there may be some impact on sleep but minimal impact on daily activities.<sup>4</sup> Once diagnosed mild to moderate tinnitus can be self-managed. Indeed the mainstay of treatment for persistent, bothersome tinnitus are supplements such as *Ginkgo biloba* and zinc.<sup>5</sup>

<sup>1</sup> Bellamy N, Buchanan WW, Goldsmith CH et al. Validation Study of WOMAC: A health status instrument for measuring clinically important patient relevant outcomes to antirheumatic drug therapy in patients with osteoarthritis of the hip or knee. *J Rheumatol* 1998; 15: 1833-40.

<sup>2</sup> Lequesne MG, Mery C, Samson M et al. Indexes of severity for osteoarthritis of the hip and knee: validation-value in comparison with other assessment tests. *Scand J Rheumatol* 1987; (Suppl. 65): 85-9.

<sup>3</sup> American Urological Association. Management of Benign Prostatic Hyperplasia (BPH).

[http://www.auanet.org/guidelines/benign-prostatic-hyperplasia-\(2010-reviewed-and-validity-confirmed-2014\)](http://www.auanet.org/guidelines/benign-prostatic-hyperplasia-(2010-reviewed-and-validity-confirmed-2014))

<sup>4</sup> Guidelines for the grading of tinnitus severity: the results of a working group commissioned by the British Association of Otolaryngologists, Head and Neck Surgeons, 1999. *Clin Otolaryngol Allied Sci*. 2001 Oct;26(5):388-93.

<sup>5</sup> Clinical practice guideline: tinnitus. *Otolaryngol Head Neck Surg*. 2014 Oct;151(2 Suppl):S1-S40

Indications can, by the definition of serious form, refer to stages of a condition for which regular HCP supervision is not required. Where a condition exists in mild, moderate and severe forms, then an assessment needs to be made for each of these stages as to whether regular HCP supervision is required to manage each stage. Importantly, these stages must be based on accepted standard clinical assessment tools for the condition and any indications should align with this. If it qualifies as non-serious for some stages, then the qualifier should refer to those stages. For some conditions, indications can potentially be extended to ‘moderate’ forms of the condition as in Box 1 above. Indications should be restricted to relief or management of symptoms or a health benefit of a condition and not refer to or imply cure and the product must, of course, carry all appropriate advisory statements.

Based on the above observations, we propose the following indications are suitable for listed medicines.

**Proposed indications:**

- a. Symptomatic relief of mild to moderate osteoarthritis
- b. Symptomatic relief of mild to moderate temporomandibular joint pain
- c. Symptomatic relief of mild to moderate osteoarthritis of the temporomandibular joint
- d. Symptomatic relief of mild to moderate medically diagnosed Benign prostatic hypertrophy
- e. Symptomatic relief of mild to moderate medically diagnosed Tinnitus
- f. Symptomatic relief of mild to moderate medically diagnosed Chronic fatigue syndrome

Where there are specific symptoms related to the conditions, these can be combined with existing indications in the list.

All indications in this list would be accompanied by the (S) statement advising consumers to consult their healthcare professional if symptoms persist or worsen.

In cases like this, the ‘mild’ qualifier seems to have been inserted to exclude more advanced stages of chronic conditions like osteoarthritis, TMJ pain and IBS. A more practical approach recognises that the ‘mild’ (or moderate) qualifier provides minimal useful or meaningful information given that individuals with advanced stages of these conditions and well informed and educated about their condition, used to

self-managing it and are extremely unlikely to forego seeking medical attention if required. Any risk of this is further mitigated by restricting indications to symptomatic relief and mandating the inclusion of an advisory statement to consult their healthcare professional if symptoms persist or worsen.

Therefore, it is worth serious consideration whether the qualifiers for mild (or moderate) are redundant in practice.

#### **‘Mild’ - other**

The word ‘mild’ occurs before a number of other conditions or symptoms where it is unclear what it means or how it would be interpreted by a consumer. Examples include mild nerve pain, mild sciatica, mild limb numbness and mild migraine. Presumably the term ‘mild’ in such cases is a reference to symptom severity, which alone causes some problems as symptom severity is subjective and may not correlate with severity of disease, however the progression or worsening of symptoms may. For example, mild numbness may occur early in conditions like carpal tunnel syndrome or diabetic neuropathy, whilst numbness following pressure on a nerve from sitting awkwardly may be temporarily quite severe. **The if symptoms persist (S) warning statement has historically been the mechanism for preventing the inappropriate use of medicines in worsening conditions and we contend that it is far less confusing and far more meaningful and effective in mitigating risk and supporting responsible use of listed medicines.**

‘Mild’ also seems to be used to distinguish when usually benign conditions have the potential to become complicated, in which case it seems like a useful addition. Examples are relief of symptoms of shingles, chicken pox, and sciatica.

Considering these observations, the use of the ‘mild’ qualifier is sometimes useful or meaningful, and sometimes inconsistent and potentially confusing to consumers. It is worth noting that many of these conditions are routinely accepted in indications for low risk medicines by comparable regulators without qualification.

**In many cases, where the qualifier mild is not necessary or potentially confusing, it would be preferable and more informative to consumers to remove the ‘mild’ qualifier and ensure the continued use of the symptoms label advisory statement.**

Accordingly, Appendix 1 contains a list of comments (no change) or proposed changes to indications in the draft list.

**‘Mild’ should only be used as a qualifier when:**

- the meaning is clear and meaningful to a consumer, easily understood or applied by them; and
- it is important and meaningful to exclude use in non-mild cases in that it would not cause a consumer to delay seeking professional attention when it is required, such as when usually benign conditions may become more complicated – but only when not adequately reflected in the ‘if symptoms persist’ warning statement.

**! Note on Evidence and the ‘Mild’ Qualifier.**

The distinction of ‘mild’ in indications may cause a perceived mismatch between available evidence and indication as research groups are unlikely to have created and studied an artificial ‘mild’ subgroup of a particular condition. Where a qualifier is being used to prevent the inappropriate use of listed medicines, this does not necessarily equate to evidence - the suitability of which must be examined on its merits and whether it can truthfully translate to lower level indications. **It is important that the application of ‘mild’ to prevent inappropriate use of the medicine in the population does not restrict the study populations that can be used for evidence to support the indications.** Evidence should only be considered not transferable where more severe forms have a sufficiently different disease process that the evidence would not be transferable. Where there is meaningfulness in transferability from a moderate or higher study group, it must continue to be recognised as relevant and applicable.

Helps decrease/reduce/relieve symptoms of mild dehydration	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	No proposed change.
Helps temporarily relieve mild fluid retention	Label statement: If fluid retention persists seek medical advice (or words to that effect)'.	No proposed change.
Helps decrease/reduce/relieve crepitus associated with medically diagnosed mild temporomandibular joint dysfunction	Label statement: If symptoms change or worsen consult your healthcare practitioner (or words to that effect)	<b>'Mild' not meaningful to consumer, passes 4 criteria, and is adequately covered by if symptoms persist or worsen advisory.</b> <b>2&amp;3 removed from revised list, similar to many other conditions included in this list.</b> <b>CMA requests that if other symptom/inflammation relief can be applied to named non-serious conditions, the ability to link indications in this way must be specified in a published document so it is clearly covered by 'words to the effect'.</b>
Helps decrease/reduce/relieve headache associated with mild medically diagnosed temporomandibular joint dysfunction	Label statement: If symptoms change or worsen consult your healthcare practitioner (or words to that effect)	
Helps decrease/reduce/relieve inflammation associated with medically diagnosed mild temporomandibular joint dysfunction	Label statement: If symptoms change or worsen consult your healthcare practitioner (or words to that effect)	
Helps decrease/reduce/relieve pain associated with mild medically diagnosed temporomandibular joint dysfunction	Label statement: If symptoms change or worsen consult your healthcare practitioner (or words to that effect)	

Helps decrease/reduce/relieve symptoms of mild mouth ulcers	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be recommended for recurrent or persistent mouth lesions which may have an underlying serious condition.	No proposed change.
Helps reduce occurrence of mild mouth ulcers	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious forms of ulcers such as gastric, peptic or duodenal ulcers.	
Helps decrease/reduce/relieve pain associated with mild mouth ulcers	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious forms of ulcers such as gastric, peptic or duodenal ulcers.	
Decrease/reduce/relieve mouth/oral mucosa mild inflammation	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	
Relieve mild fever	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Label statement: Not to be used for children under 5 years of age.	Distinction between mild and moderate or severe fever probably not self-evident or meaningful to consumers. It would be far more meaningful and reflective of the action of complementary ingredients to revert to

		typical LM indication, such as 'assists in relieving fever'.
Helps decrease/reduce/relieve joint discomfort/pain/ache associated with mild arthritis/osteoarthritis	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious forms of arthritis e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis.	Mild osteoarthritis should be changed to mild-moderate to be consistent with clinical stages that are non-serious / appropriate for self-management, as outlined in this submission particularly Box 1.
Helps decrease/reduce/relieve joint inflammation/swelling associated with mild arthritis/osteoarthritis	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious forms of arthritis e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis.	
Helps enhance/improve/promote joint function in mild arthritis/osteoarthritis	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious forms of arthritis e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis.	
Helps decrease/reduce/relieve joint stiffness/inflexibility/immobility associated with mild arthritis/osteoarthritis	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious forms of arthritis e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis.	
Helps enhance/improve/promote joint mobility in mild arthritis/osteoarthritis	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious forms of arthritis e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis.	

Helps enhance/improve/promote/increase muscle strength to support mild arthritic joints	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious forms of arthritis e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis.	
Helps decrease/reduce/relieve mild rheumatic aches and pains	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious forms of arthritis e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis.	
Helps decrease/reduce/relieve symptoms of mild arthritis/osteoarthritis	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious forms of arthritis e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis.	
Helps decrease/reduce/relieve progression of joint wear and tear in mild arthritis/osteoarthritis	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious forms of arthritis e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis.	
Helps decrease/reduce/relieve mild joint inflammation/swelling	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious forms of arthritis e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis.	No proposed change.
Helps decrease/reduce appearance of mild varicose veins	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious cardiovascular conditions.	No proposed change.

Helps decrease/reduce/relieve the feeling of leg heaviness associated with mild varicose veins	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious cardiovascular conditions.
Helps decrease/reduce/relieve itchy legs associated with mild varicose veins	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious cardiovascular conditions.
Helps decrease/reduce/relieve aching/tired legs associated with mild varicose veins	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious cardiovascular conditions.
Helps decrease/reduce/relieve pain associated with mild varicose veins	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious cardiovascular conditions.
Helps decrease/reduce/relieve leg swelling associated mild varicose veins	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious cardiovascular conditions.
Helps decrease/reduce/relieve symptoms of mild varicose veins	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious cardiovascular conditions.

Helps decrease/reduce/relieve minor bleeding associated with mild haemorrhoids	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must only be for non-serious forms that are medically uncomplicated.	No proposed change.
Helps decrease/reduce/relieve discomfort associated with mild haemorrhoids	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must only be for non-serious forms of haemorrhoids that are medically uncomplicated.	
Helps decrease/reduce/relieve itching associated with mild haemorrhoids	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must only be for non-serious forms of haemorrhoids that are medically uncomplicated.	
Helps decrease/reduce/relieve swelling associated with mild haemorrhoids	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must only be for non-serious forms of haemorrhoids that are medically uncomplicated.	
Helps decrease/reduce/relieve discomfort/pain associated with medically diagnosed mild gastritis	Label statement: If symptoms change or worsen consult your healthcare practitioner (or words to that effect)	No proposed change.
Helps decrease/reduce/relieve indigestion associated with medically diagnosed mild gastritis	Label statement: If symptoms change or worsen consult your healthcare practitioner (or words to that effect)	
Helps decrease/reduce/relieve abdominal pain associated with medically diagnosed mild gastritis	Label statement: If symptoms change or worsen consult your healthcare practitioner (or words to that effect)	
Helps decrease/reduce/relieve symptoms of mild gastritis	Label statement: If symptoms change or worsen consult your healthcare practitioner (or words to that effect)	

Helps decrease/reduce/relieve headache associated with mild gastric complaints	Label advisory statement: If symptoms persist consult your healthcare practitioner (or words to that effect)..	
Decrease/reduce/relieve mild abdominal spasm	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)' Must not be for serious digestive disease such as Gastro Oesophageal Reflux Disease (GORD).	
Helps decrease/reduce/relieve mild gastrointestinal pain	Label statement 'S - If symptoms persist consult your healthcare practitioner (or words to that effect)'.	No proposed change.
Helps decrease/reduce/relieve mild gastrointestinal tract Inflammation	Label statement 'S - If symptoms persist consult your healthcare practitioner (or words to that effect)'.	
<del>Decrease/reduce/relieve mild muscle cramps-mild removed</del>	<del>Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.</del>	‘Mild’ not meaningful to consumer, unlikely to prevent undesirable outcomes, and is adequately covered by if symptoms persist or worsen advisory.
<del>Helps decrease/reduce/relieve mild leg cramps-mild removed</del>	<del>Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect).</del>	
May Helps decrease/reduce/relieve mild muscle spasms/twitches/tremors	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must not be for serious musculoskeletal conditions such as Parkinson’s disease.	
Helps reduce/decrease mild muscle inflammation/swelling	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	
Relieve symptoms of mild limb spasms	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	
Relieve feeling of mild limb numbness	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	

Relieve mild tissue oedema	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	
Aid/assist/helps in the management of mild soft tissue trauma	Label advisory statement: If symptoms persist consult your healthcare practitioner (or words to that effect).	'Mild' not necessary – is self-evident. Self-management is restricted by level of pain so would not be attempted above a mild level, overall not meaningful to consumers.
Helps decrease/reduce/relieve symptoms of mild soft tissue trauma	Label advisory statement: If symptoms persist consult your healthcare practitioner (or words to that effect).	
Helps decrease/reduce/relieve symptoms of mild tenosynovitis	Label statement: If symptoms change or worsen consult your healthcare practitioner (or words to that effect)	
Helps decrease/reduce/relieve frequent need to urinate associated with mild anxiety	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	
Helps relieve mild anxiety	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	No proposed change.
Helps decrease/reduce/relieve headache associated with mild anxiety	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	
Helps decrease/reduce/relieve irritability associated with mild anxiety	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	

Helps decrease/reduce/relieve muscle tension associated with mild anxiety	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	
Helps decrease/reduce/relieve nausea associated with mild anxiety	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	
Helps decrease/reduce/relieve disturbed sleep associated with mild anxiety	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	
Helps decrease/reduce/relieve gastrointestinal discomfort associated with mild stress	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	Mild stress. Stress is not a condition with recognised diagnosable stages. Its use is unnecessary and confusing. 'Mild' unnecessary.
Helps decrease/reduce/relieve mood swings associated with mild stress	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	
Helps decrease/reduce/relieve sleeplessness/restless sleep associated with mild stress	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	
Helps decrease/reduce/relieve sweating associated with mild anxiety	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	No proposed change.
Helps decrease/reduce/relieve symptoms of mild anxiety/stress	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	

Helps reduce occurrence of mild anxiety symptoms	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	
Helps decrease/reduce/relieve tiredness associated with mild anxiety	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	
Helps decrease/reduce/relieve tension associated with mild anxiety	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	
Helps decrease/reduce/relieve worry associated with mild anxiety	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	
Helps decrease/reduce/relieve mild dizziness/vertigo	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	No proposed change.
Helps decrease/reduce/relieve cold hands/feet associated with mild migraine	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	'Mild' not meaningful to consumers and doesn't perform a useful or necessary function above and beyond the 'if symptoms persist' qualifier.
Helps decrease/reduce/relieve dizziness associated with mild migraine	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	
Decrease/reduce duration of mild migraine	Label statement required: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	
Helps decrease/reduce/relieve mild migraine symptoms	Label statement required: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	

Helps decrease/reduce/relieve symptoms of sensitivity to light/sound associated with mild migraine	Label statement required: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	
Relieve facial pallor associated with mild migraines	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	
Helps decrease/reduce/relieve nausea and vomiting associated with mild migraine	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	
Helps decrease/reduce/relieve symptom of weakness associated with mild migraine	Label statement 'S - If symptoms persist consult your healthcare practitioner (or words to that effect)'.	
Helps decrease/reduce/relieve symptoms of mild tension headache	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	
Helps decrease/reduce/relieve symptoms of mild nerve pain/neuralgia	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect). Must not be for mental illness, disorders or conditions	
Helps decrease/reduce/relieve pain associated with mild sciatica	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect).	No proposed change.
Helps decrease/reduce/relieve symptoms of mild sciatica	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect).	
Helps decrease/reduce/relieve symptoms of mild vaginitis	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect).	
Helps decrease/reduce/relieve mild vaginal itch	Label statement: 'If symptoms persist consult your healthcare practitioner' (or words to that effect).	

Helps decrease/reduce/relieve mild bronchial cough	<p>Label statement: Adults only OR Not to be used in children under two years of age without medical advice (or words to that effect)</p> <p>Label statement: If coughing persists consult your doctor (or a healthcare professional) (or words to that effect)</p> <p>Must not be for serious forms of respiratory disorders/diseases (such as asthma, pneumonia, COAD, COPD).</p>	No proposed change.
Helps decrease/reduce/relieve mild bronchial irritation	<p>Label statement: Adults only OR Not to be used in children under two years of age without medical advice (or words to that effect)</p> <p>Label statement: If symptoms persist consult your healthcare practitioner (or words to that effect).</p> <p>Must not be for serious forms of respiratory disorders/diseases (such as asthma, pneumonia, COAD, COPD).</p>	
Decrease/reduce/relieve mild fever associated with common colds	<p>Label statement: Adults only OR Not to be used for children under 5 years of age.</p> <p>Label statement: If symptoms persist consult your healthcare practitioner (or words to that effect).</p> <p>Must not be for serious forms of respiratory disorders/diseases (such as asthma, pneumonia, COAD, COPD).</p>	
Helps decrease/reduce/relieve mild fever associated with common colds and flu	<p>Label statement: Adults only OR Not to be used in children under five years of age without medical advice (or words to that effect)</p> <p>Label statement: If symptoms persist consult your healthcare practitioner (or words to that effect).</p> <p>Must not be for serious forms of respiratory disorders/diseases (such as asthma, pneumonia, COAD, COPD).</p>	

Helps decrease/reduce/relieve mild upper respiratory tract congestion	<p>Label statement: Adults only OR Not to be used in children under two years of age without medical advice (or words to that effect)</p> <p>Label statement: If symptoms persist consult your healthcare practitioner (or words to that effect).</p> <p>Must not be for serious forms of respiratory disorders/diseases (such as asthma, pneumonia, COAD, COPD).</p>	Remove 'mild'. Mild is ambiguous to consumers and undefined, confuses evidence requirements, and isn't necessary due to (S) statement.
Helps decrease/reduce/relieve symptoms of mild allergies	<p>Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.</p> <p>Must not be for serious allergic conditions such as anaphylaxis</p>	Indications should be divided to account for seasonal allergies (no mild qualifier required) and other allergies.
Helps reduce occurrence of symptoms of mild allergies	<p>Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.</p> <p>Must not be for serious allergic conditions such as anaphylaxis</p>	
Helps decrease/reduce/relieve symptoms of mild sinusitis	<p>Label statement: Adults only OR Not to be used in children under two years of age without medical advice (or words to that effect)</p> <p>Label statement: If symptoms persist consult your healthcare practitioner (or words to that effect).</p> <p>Must not be for serious forms of respiratory disorders/diseases (such as asthma, pneumonia, COAD, COPD).</p>	No proposed change.

Helps decrease/reduce/relieve nasal congestion associated with mild sinusitis	<p>Label statement: Adults only OR Not to be used in children under two years of age without medical advice (or words to that effect)</p> <p>Label statement: If symptoms persist consult your healthcare practitioner (or words to that effect).</p> <p>Must not be for serious forms of respiratory disorders/diseases (such as asthma, pneumonia, COAD, COPD).</p>
Helps decrease/reduce/relieve symptoms of mild laryngitis	<p>Label statement: Adults only OR Not to be used in children under two years of age without medical advice (or words to that effect)</p> <p>Label statement: If symptoms persist consult your healthcare practitioner (or words to that effect).</p> <p>Must not be for serious forms of respiratory disorders/diseases (such as asthma, pneumonia, COAD, COPD).</p>
Helps decrease/reduce/relieve inflammation associated with mild laryngitis	<p>Label statement: Adults only OR Not to be used in children under two years of age without medical advice (or words to that effect)</p> <p>Label statement: If symptoms persist consult your healthcare practitioner (or words to that effect).</p> <p>Must not be for serious forms of respiratory disorders/diseases (such as asthma, pneumonia, COAD, COPD).</p>
Helps decrease/reduce/relieve discomfort/pain associated with mild laryngitis	<p>Label statement: Adults only OR Not to be used in children under two years of age without medical advice (or words to that effect)</p> <p>Label statement: If symptoms persist consult your healthcare practitioner (or words to that effect).</p> <p>Must not be for serious forms of respiratory disorders/diseases (such as asthma, pneumonia, COAD, COPD).</p>

Helps decrease/reduce/relieve pain/discomfort associated with mild tonsillitis	Label statement: Adults only OR Not to be used in children under two years of age without medical advice (or words to that effect) Label statement: If symptoms persist consult your healthcare practitioner (or words to that effect). Must not be for serious forms of respiratory disorders/diseases (such as asthma, pneumonia, COAD, COPD).	
Relieve symptoms of mild viral upper respiratory tract infections	Label statement: Adults only OR Not to be used in children under two years of age without medical advice (or words to that effect) Label statement: If symptoms persist consult your healthcare practitioner (or words to that effect). Must not be for serious forms of respiratory disorders/diseases (such as asthma, pneumonia, COAD, COPD).	As it's quite difficult for a consumer to differentiate between mild or other stages of URTIs, this is not meaningful and perhaps confusing. It would be better to remove 'mild' and replace with a timeframe where advice should be sought if symptoms haven't resolved.
Helps reduce occurrence of mild upper respiratory tract infection	Label statement: Adults only OR Not to be used in children under two years of age without medical advice (or words to that effect) Label statement: If symptoms persist consult your healthcare practitioner (or words to that effect). Must not be for serious forms of respiratory disorders/diseases (such as asthma, pneumonia, COAD, COPD).	
Helps decrease/reduce/relieve cough associated with mild upper respiratory tract infection	Label statement: Adults only OR Not to be used in children under two years of age without medical advice (or words to that effect) Label statement: If symptoms persist consult your healthcare practitioner (or words to that effect). Must not be for serious forms of respiratory disorders/diseases (such as asthma, pneumonia, COAD, COPD).	

Helps decrease/reduce/relieve the severity of symptoms of mild upper respiratory tract infections	Label statement: Adults only OR Not to be used in children under two years of age without medical advice (or words to that effect) Label statement: If symptoms persist consult your healthcare practitioner (or words to that effect). Must not be for serious forms of respiratory disorders/diseases (such as asthma, pneumonia, COAD, COPD).	
Relieve mild acne	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	'Mild' not required due to lack of serious complications and (S) warning.
Relieve symptoms of mild acne	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	
Helps decrease/reduce/relieve blisters associated with mild eczema/dermatitis	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must only be for non-serious forms that are medically uncomplicated.	No proposed change.
Helps decrease/reduce/relieve scaly/crusty skin associated with mild eczema/dermatitis	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must only be for non-serious forms that are medically uncomplicated.	
Helps decrease/reduce/relieve dry skin associated with mild eczema/dermatitis	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must only be for non-serious forms that are medically uncomplicated.	
Helps decrease/reduce/relieve itchy/burning skin associated with mild eczema/dermatitis	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must only be for non-serious forms that are medically uncomplicated.	

Helps decrease/reduce/relieve red skin associated with mild eczema/dermatitis	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must only be for non-serious forms that are medically uncomplicated.	
Helps decrease/reduce/relieve symptoms of mild eczema/dermatitis	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must only be for non-serious forms that are medically uncomplicated.	
Helps enhance/improve/promote/increase healing of mild eczema/dermatitis	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must only be for non-serious forms that are medically uncomplicated.	
Helps decrease/reduce/relieve symptoms of mild seborrhoeic dermatitis/cradle cap	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must only be for non-serious forms that are medically uncomplicated.	No proposed change.
Helps decrease/reduce/relieve symptoms of mild psoriasis	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must only be for non-serious forms that are medically uncomplicated.	
Helps relieve itching associated with mild psoriasis	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must only be for non-serious forms that are medically uncomplicated.	
Helps relieve dry skin associated with mild psoriasis	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'. Must only be for non-serious forms that are medically uncomplicated.	
Decrease/reduce/relieve symptoms of mild, superficial skin fungal infections	Label advisory statement: If symptoms persist consult your healthcare practitioner (or words to that effect). Must only be for mild superficial infections.	
		'Mild' not necessary or meaningful as it is covered by

		symptomatic relief, warning statement, and reference to superficial.
Helps decrease/reduce/relieve symptoms of medically diagnosed mild shingles	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	No proposed change.
Helps decrease/reduce/relieve itching associated with medically diagnosed mild shingles	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	
Helps decrease/reduce/relieve pain associated with medically diagnosed mild shingles	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	
Helps healing of mild skin burn/sunburns	BURN1 label statement: 'Immediate treatment of burns should be application of cold water for ten minutes' [or words to that effect] BURN2 label statement: 'Only to be used for minor burns after initial first aid treatment, medical advice should be sought for serious burns' [or words to that effect].	No proposed change to indication, however first warning statement (BURN1) seems unnecessary as it is basic first aid care understood by population and is also covered by second statement (BURN2).
Helps decrease/reduce/relieve symptoms of medically diagnosed fibromyalgia/fibrositis	Label statement: If symptoms change or worsen consult your healthcare practitioner (or words to that effect)	No proposed change.
Helps decrease/reduce/relieve pain associated with medically diagnosed fibromyalgia/fibrositis	Label statement: If symptoms change or worsen consult your healthcare practitioner (or words to that effect)	

Helps decrease/reduce/relieve discomfort/pains associated with medically diagnosed Irritable Bowel Syndrome	Label statement: If symptoms change or worsen consult your healthcare practitioner (or words to that effect)	No proposed change.
Relief of symptoms associated with medically diagnosed Irritable Bowel Syndrome	Label statement: If symptoms change or worsen consult your healthcare practitioner (or words to that effect)	
Helps soothes/relieve rash associated with medically diagnosed chickenpox	Label statement: 'If symptoms persist consult your healthcare practitioner (or words to that effect)'.	No proposed change.
Helps decrease/reduce/relieve burning sensation upon urination associated with medically diagnosed cystitis	Label statement: 'CYST - If pain or irritation persists for more than 48 hours - consult your doctor.'	No proposed change.
Helps decrease/reduce/relieve irritation associated with medically diagnosed cystitis	Label statement: 'CYST - If pain or irritation persists for more than 48 hours - consult your doctor.'	
Relieve symptoms of pain of medically diagnosed cystitis	Label statement: 'CYST - If pain or irritation persists for more than 48 hours - consult your doctor.'	
Helps reduce occurrence of medically diagnosed cystitis	Label statement: 'CYST - If pain or irritation persists for more than 48 hours - consult your doctor.'	
Helps decrease/reduce/relieve symptoms of medically diagnosed cystitis	Label statement: 'CYST - If pain or irritation persists for more than 48 hours - consult your doctor.'	