Complementary Medicines Regulatory Reforms
Permitted indications

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Complementary Medicines: Regulatory Obligations Seminar

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Permitted indications

**Recommendation Thirty-Eight**
The Panel recommends that the TGA establishes the list of *Permitted Indications*, from which sponsors must exclusively draw, for listed medicinal products in the ARTG.

**Government Response**
The Commonwealth accepts Recommendation Thirty-Eight, noting that implementation of the list of Permitted Indications will require legislative change and will be subject to consultation with consumers, sponsors and health professionals.
What does *Permitted Indications* mean for sponsors?

- Sponsors listing a medicine on the ARTG will only be able to use indications from a *permitted indications list*.
- “*Free text*” field will no longer be available.
- TGA will also have the ability to create a *non-permitted indications* list e.g. smoking cessation.
- *3 year* transition proposed.
Permitted indications on labels

Indications will not have to be ‘word for word’ on the label or advertising material:
the intent and meaning of the indication must not change
this will give flexibility to sponsors and contain the size of the list

For example:
ARTG indication: ‘Maintain/support bowel regularity’
Label indication - same meaning: ‘X helps maintain regular bowel movements’
Label indication - different meaning: ‘X relieves constipation’
Steps in the development of permitted indications list…

1. We will publish the draft list on TGA website by July 2017

2. TGA inbox for feedback and proposing new indications

3. List will be closed on 1 October 2017 to enable the drafting and publication of the legislative instrument

4. New indications proposed after this time will incur a fee
Criteria for permitted indications

1. Must be a therapeutic indication (describe a **therapeutic use**)
2. Must be a **low level indication**
3. Must be capable of complying with the Advertising Code when included on promotional materials
4. Must be **consistent** with the treatment paradigm (scientific/ tradition of use)
Criteria for permitted indications continued

1. Must be a therapeutic indication (i.e - describe a therapeutic use)

- Therapeutic use for listed medicines means use in, or in connection with, ‘influencing, inhibiting or modifying a physiological process in persons’

- Indications can be:
  - specific (e.g. refer to a named non-serious condition); or
  - non-specific (e.g. general health maintenance)

- Indications can be based on scientific evidence or a tradition of use
Criteria for permitted indications continued

2. Must be a low level indication

• Must only refer to:
  – health enhancement
  – health maintenance
  – prevention or alleviation of dietary deficiency; and/or
  – a health benefit for a non-serious forms of a disease, ailment, defect or injury

• Permitted indications can only refer to conditions that are:
  – self-diagnosable
  – self-manageable

• A delay in medical treatment would not be detrimental to the consumer
<table>
<thead>
<tr>
<th>Low Level Indications</th>
<th>What this means</th>
<th>Examples</th>
</tr>
</thead>
</table>
| Health enhancement                    | 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 | *Helps improve immune system*  
*May increase energy / reduce fatigue*  
*Helps stimulate digestive function* |
| Health maintenance                    | Normal physiological effects of substances in; growth, development and normal functions of the body | *Helps maintain healthy hair, skin and nails*  
*Assists with normal liver function*  
*Helps support healthy connective tissue / joints* |
| Prevention or alleviation of a dietary deficiency | Prevention of mild dietary deficiency *(not prevention of diseases resulting from severe deficiency)* | *When taken regularly, may prevent vitamin D/ calcium deficiency*  
*Helps reduce the risk of iodine deficiency*  
*Helps prevent dietary vitamin B12 deficiency* |
<table>
<thead>
<tr>
<th>Low Level Indications</th>
<th>What this means</th>
<th>Examples</th>
</tr>
</thead>
</table>
| A non-serious disease, ailment, defect or injury (other than prevention or alleviation) | A non-serious and self manageable. May be related to; - reduction in risk/frequency/duration - relief - management or improvement in quality of life …without resolution of the underlying non-serious disease, ailment, defect, condition or injury.                                                                                                                                         | May relieve symptoms of mild osteoarthritis  
Helps reduce the severity of common cold symptoms  
For the management mild dermatitis symptoms  
May relieve post-menopausal/PMS symptoms  
Helps reduce the frequency of common cold sore outbreaks                                                                                                           |
Criteria for permitted indications continued

3. Must be capable of complying with the Advertising Code when included on promotional materials

Permitted Indications when linked to ingredients must not:

- mislead, or be likely to mislead consumers
- contain any implication that the medicine is infallible, unfailing, magical, miraculous, or that it is a certain, or guaranteed cure
- contain any claim, statement or implication that it is effective in all cases of the condition
Criteria for permitted indications continued

4. Must be consistent with the treatment paradigm

- Must be consistent with the evidentiary support (scientific or tradition of use)
  - Indications based on scientific evidence should not use traditional terminology,
    - eg ‘alterative’ or Indications based on a ‘tradition of use’ should not reference a scientific procedure or investigation
    - eg ‘increase haemoglobin in red blood cells’ or ‘increase bone mineral density’
Indications **NOT** suitable for permitted indications list

A *permitted indication*, must not:

- refer to, or imply, the **prevention** or **cure** of any form of a disease, ailment, defect or injury
- contain a **prohibited representation**
- contain a **restricted representation**
- be specified in a **non-permitted indications** list
What is a prohibited representation?

Under the *Therapeutic Goods Advertising Code 2015*, a prohibited representation is defined as:

(i) any representation regarding *abortifacient action*; or

(ii) any representation regarding the *treatment, cure or prevention* of the following diseases:

- **Neoplastic** (i.e. cancer)
- **Sexually Transmitted Diseases** (STD)
- **HIV AIDS** and/or **HCV**; or
- **Mental illness** (e.g. depression, anxiety, low mood)
What is a restricted representation?

A restricted representation is **serious form** of a disease, condition, ailment or defect included in Table 1, Appendix 6 Part 2 of the Therapeutic Goods Advertising Code 2015

- 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
- Musculoskeletal diseases
- Nervous system diseases
- Poisoning, venomous bites and stings
- Renal diseases
- Respiratory diseases
- Skin diseases
- Substance dependence
- Urogenital diseases and conditions
What is a serious form?

‘Serious’, means those 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

• to be beyond the ability of the average consumer to evaluate accurately and to treat safely without supervision by a qualified healthcare professional

Examples

• ‘Reduces risk of atherosclerosis’

• ‘Beneficial for anaphylaxis’
Permitted indications – structure

E.g. Help to maintain/support healthy joints in elderly individuals
Options for implementing the list

1. Prescriptive list

2. Core indications with modifiable qualifiers

3. Build a unique indication from pre-approved indication components
Option 2: ‘Core’ permitted indications (preferred)

1. Select tradition of use (Optional)
   Indications that do not specify a tradition of use are by default scientific.

2. Select core permitted indication (Mandatory)
   At least one core indication is selected in ELF using drop down lists or key word search.

3. Select specifying qualifiers (Optional)
   Sponsors can choose to apply one or more pre-approved qualifiers to each core permitted indication by selecting from a drop down list.

   - Healthy target population
   - Effectiveness
   - Time of use

   **Tradition of use**
   N/A

   **Core permitted indication**
   ‘Relieves muscle aches and pains’

   **Specifying qualifiers**
   **Healthy target population**: ‘in healthy individuals’
   **Effectiveness**: ‘Temporarily’
   **Time of use**: ‘after exercise’

Final permitted indication on product label
E.g. Temporarily relieve muscle aches and pains after exercise in healthy individuals.
Option 3: Build unique indications from pre-approved indication components

**ARTG Indication** – sponsor creates the indication by selecting from drop down lists for each component below

<table>
<thead>
<tr>
<th>Tradition of use</th>
<th>Action qualifier</th>
<th>ACTION</th>
<th>Target qualifier</th>
<th>TARGET</th>
<th>Indication qualifier</th>
</tr>
</thead>
<tbody>
<tr>
<td>If applicable</td>
<td>optional</td>
<td>mandatory</td>
<td>optional</td>
<td>mandatory</td>
<td>optional</td>
</tr>
</tbody>
</table>

**Tradition of use**
- Traditionally used in Western herbal medicine
- Traditionally used in

**Action qualifier**
- To help
- May help

**ACTION**
- Stimulate
- Relieve

**Target qualifier**
- Healthy
- Symptoms of

**TARGET**
- Digestion
- Eye strain

**Indication qualifier**
- Associated with prolonged computer use
Transition to the Permitted Indications List

• From 1 January 2018, all new listed medicines must select permitted indications (free text will be turned-off)

• Sponsors of existing listed medicines will be required to transition their existing indications to ‘permitted indications’ by 31 December 2020:
  ▪ AUST L numbers will not change
  ▪ Fee waiver/reduction if indications changed by 31 June 2019

• Listed medicines that do not transition to permitted indications will be cancelled from the ARTG from 1 January 2021
Indications not on the permitted list?

During the 3yr transition period, sponsors with intermediate indications will be required to:

– transition to the ‘new pathway’ for TGA assessment of evidence; or
– transition to ‘permitted indications’

Sponsors can apply for permitted indications that meet the agreed criteria

– free until 1 October 2017
Applying for a new indication

• Sponsors can apply for new permitted indications to be added to the list
  – A fee will apply

• Evidence to support a proposed indication will not be evaluated by the TGA
  – However, applications will be assessed against the established criteria

• The permitted indication list is likely to be updated on a quarterly basis
How are we developing the permitted indications list?

• A comprehensive list of permitted indications is being developed in consultation with industry based on agreed criteria

• List is based on industry submissions to previous consultations

• Targeted consultation on the list also includes stakeholders concerned with traditional paradigms, such as TCM’s
## Development of the list of permitted indications

<table>
<thead>
<tr>
<th>Indications</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>General indications</strong>  ~ 1300</td>
<td>Can be supported by either scientific evidence or a tradition of use</td>
</tr>
<tr>
<td></td>
<td>e.g. ‘Help relieve dry skin’</td>
</tr>
<tr>
<td><strong>Traditional indications</strong>  ~ 200</td>
<td>Include traditional terms that may be applicable across multiple traditional</td>
</tr>
<tr>
<td></td>
<td>paradigms</td>
</tr>
<tr>
<td></td>
<td>e.g. ‘cholagogue’, ‘alterative’ ‘adaptogen’</td>
</tr>
<tr>
<td><strong>Traditional Chinese Medicine indications</strong>  ~ 200</td>
<td>Contain TCM specific terminology that can only be supported by evidence of TCM use</td>
</tr>
<tr>
<td></td>
<td>e.g. ‘Increase Qi flow’</td>
</tr>
<tr>
<td><strong>Scientific indications</strong>  ~ 200</td>
<td>Can be supported by scientific evidence only.</td>
</tr>
<tr>
<td></td>
<td>e.g. ‘Maintain /support normal/healthy red blood cells’</td>
</tr>
</tbody>
</table>
Initial outcomes of public consultation

• Majority agree for the proposed criteria for permitted indications

• A majority of stakeholders support Option 2 - Core indications with modifiable qualifiers

• A majority of stakeholders agree that the proposed three year transition period is adequate
Questions?