Complementary medicines MMDR reforms Assessment pathways

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Review of Medicines and Medical Devices Regulation

• In March 2015 the Expert Panel conducting the MMDR review made 19 recommendations to improve the regulation of complementary medicines.

• On 15 September 2016, the Australian Government released its response to the MMDR review.

• The Government accepted the majority of the review’s recommendations in full or in-principle and announced a program of reform to facilitate their implementation.

• The Government response identified the need for consultation with stakeholders in progressing the reforms.
### 5 streams of work agreed and costed

<table>
<thead>
<tr>
<th>Stream 1</th>
<th>Enhancing the listing framework</th>
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<tbody>
<tr>
<td>Stream 2</td>
<td>Improving transparency for consumers</td>
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<td>Stream 3</td>
<td>Increased flexibility for sponsors</td>
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<td>Stream 4</td>
<td>Increased predictability for pre-market approval</td>
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<td>Stream 5</td>
<td>Enhanced post-market monitoring and compliance actions</td>
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Indicative timeframes

Phased implementation in the next 12 to 24 months

By 12 months

• Permitted indications
• An online catalogue of ingredients approved for use in listed medicines
• New assessment pathways for registered complementary medicines and new ingredients
• Risk-based approach to medicine variations

By 24 months

• New listing pathway
• Label claimer
Interdependencies

• Implementation planning for the reforms is progressing.
• First stakeholder consultations have commenced.
• Delivery of many reforms is dependent on:
  – feedback from consultations
  – inter-related reforms
  – passage of legislative amendments and regulatory changes.
MMDR consultations

• Targeted stakeholder consultations commenced October 2016.
• Public consultations proposed throughout 2017.
• The proposed reforms arising from recommendations 38, 39, 45 and 50 will be addressed in our first public consultation paper.
• Other MMDR recommendations relating to complementary medicines will be the subject of consultation in late 2017.
• See the MMDR public consultation forecast on the TGA website for further information.
First consultation: Complementary medicine assessment pathways

Recommendation 38
- A list of permitted indications for lowest risk medicines

Recommendation 39
- Introduce a three-tiered risk-based framework

Recommendation 45
- Allow sponsors to claim their medicine has been assessed for efficacy

Recommendation 50
- Incentivise industry innovation

ARCS Webinar February 2017: Complementary Medicines Reforms
Principles guiding complementary medicine reforms

• **Confidence** in TGA regulation of complementary medicines must be maintained.
• The level of regulation of medicines will be **commensurate with risk**.
• There will be increased **transparency** on the level of assessment undertaken by the TGA for consumers.
• The reforms should encourage improved sponsor **compliance with regulatory** requirements.
• **Clear guidance** on application processes and requirements will be provided for all stakeholders.
• The reforms should support innovation and improve the **evidence base** for complementary medicines.
Recommendation 38 - Permitted indications

Purpose

• To allow listed medicines to **only** use permitted indications that are appropriate for products with no pre-market assessment.

Expected benefits

• Reduce the incidence of non-compliant listed medicines on the ARTG.
• Transparency for consumers and industry about indications considered appropriate for listed medicines.
Permitted indications

- Removal of free text box in ELF
- No requirement for ‘word for word’ on medicine label
- We will develop a comprehensive list of permitted indications in consultation with industry based on agreed criteria
- Sponsors will be able to apply for new indications (fee applicable)
Proposed criteria for permitted indications

• Must be a therapeutic indication (describe a therapeutic use).

• Must be a low level indication, that is, must **only** refer to:
  – health enhancement, e.g. ‘May reduce fatigue’
  – health maintenance, e.g. ‘Helps support healthy joints’
  – prevention of dietary deficiency, e.g. ‘May prevent calcium deficiency’
  – a non serious form of a disease or ailment etc., e.g. ‘Helps ease chesty coughs’

• Cannot contain a prohibited or restricted representation.

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

• Must be consistent with the treatment paradigm (scientific/tradition of use).
Permitted indications – implementation

• Sponsors will be required to certify that indications for their medicine are from the permitted indications list and that they hold supporting evidence.

• Consistent with current Evidence Guidelines, qualifying terms will be used so that sponsors can identify the context of therapeutic use and align indications with evidence.

Three options for implementation of list:
1. A prescriptive list comprising all indications elements as a complete indication.
2. Core permitted indications (action and target only) with modifiable qualifiers.
3. Build a unique indication from pre-approved indication components.
Permitted indications – preferred option

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: 'in healthy individuals'
Effectiveness: 'may temporarily'
Time of use: 'after exercise'

EXAMPLE

<table>
<thead>
<tr>
<th>Tradition of use</th>
<th>Core permitted indication</th>
<th>Specifying qualifiers</th>
</tr>
</thead>
<tbody>
<tr>
<td>N/A</td>
<td>'Relieves muscle aches and pains'</td>
<td>Healthy target population: ‘in healthy individuals’</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Effectiveness: 'may temporarily'</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Time of use: ‘after exercise’</td>
</tr>
</tbody>
</table>

Final permitted indication on product label
May temporarily relieve muscle aches and pains after exercise in healthy individuals.
Recommendation 39: Three assessment pathways for complementary medicines

Purpose
Introduce a new product assessment pathway sitting between the existing listed medicine (low risk) and registered medicine (high risk) pathways.
• Allow higher-level claims than standard listed medicines.
• Pre-market efficacy assessment of evidence.

Expected benefit
• Apply a level of regulation that is commensurate with the potential risks to public health and safety posed by complementary medicines.
## Proposed complementary medicine assessment pathways

<table>
<thead>
<tr>
<th>Listed Medicines</th>
<th>New Pathway</th>
<th>Registered Medicines</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Permitted ingredients</td>
<td>• Permitted ingredients</td>
<td>• Not limited to selecting from permitted ingredients list</td>
</tr>
<tr>
<td>• Good Manufacturing Practice</td>
<td>• Good Manufacturing Practice</td>
<td>• Good Manufacturing Practice</td>
</tr>
<tr>
<td>• Low level permitted indications only</td>
<td>• At least one ‘intermediate indication’</td>
<td>• May have higher level indications</td>
</tr>
<tr>
<td>• No pre-market assessment</td>
<td>• Pre-market assessment of evidence for efficacy</td>
<td>• Full pre-market assessment</td>
</tr>
<tr>
<td></td>
<td>• Ability to <strong>claim</strong> that efficacy has been assessed</td>
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## Indications proposed to accepted through the new pathway

<table>
<thead>
<tr>
<th>Listed medicines</th>
<th>New pathway</th>
<th>Registered medicines</th>
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<tbody>
<tr>
<td><strong>Low level indication</strong> that may refer to:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• health enhancement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• health maintenance</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• prevention of dietary deficiency</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• a disease, ailment, defect or injury, other than a serious form of those diseases</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Intermediate level indications</strong> that may refer to:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• a serious disease (i.e. restricted representations); or</td>
<td></td>
<td></td>
</tr>
<tr>
<td>• the prevention or alleviation of disease, ailment, defect or injury, other than a serious form of those diseases.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>A high level indication</strong> may refer to the prevention, alleviation, cure or management of a serious form of a disease, ailment, defect or injury (i.e. restricted representations)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>A high level indication</strong> must not contain a prohibited representation.</td>
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Proposed evidence dossier requirement for new pathway

• Sponsor self-assessment of the product’s safety and quality (permitted ingredients and GMP).

• Sponsor submission of a high quality efficacy package for TGA pre-market assessment. Two possible data packages:
  – **Method 1**: Clinical data on the *finished product*; OR
  – **Method 2**: A data package containing:
    ▪ evidence for efficacy of all ingredients; AND
    ▪ evidence for efficacy of the product formulation; AND
    ▪ justification of the combination of ingredients
Recommendation 45: Claimers for assessment of efficacy

Purpose
Allow medicines that have undergone pre-market evaluation to indicate on medicine labels and promotional material that the efficacy of the product has been assessed for the approved indication/s.

Expected benefits
- Increased evidence base for complementary medicines.
- Increase transparency for consumers in relation to the level of assessment for the different application pathways.
- Provides a marketing advantage for sponsors.
Proposed criteria for use of claimers

• A claimer **can be used** by medicines that have had TGA pre-market assessment:
  – Complementary medicines assessed via the new pathway
  – Registered complementary medicines.

• A claimer **can not be used** by medicines that have not had a pre-market assessment:
  – Listed medicines – including those that have been subject to a post market compliance review
  – “Grandfathered” medicines.
Proposed criteria for use of claimers

• Must be supported by the appropriate level of evidence for **all** indications made for the medicine.

• Must not imply superiority of the product over other medicines that have been pre-market assessed (e.g. OTC, prescription).

• Must comply with advertising requirements.

• Must not be more prominent or detract from the label information mandatorily required by the current Labelling Order.
Possible presentation of claimers

Option 1: The claimer as a statement

The positioning of the statement should not detract from essential product information, e.g: the statement should be in font size no bigger than the indications or advisory statements for the medicine.

Option 2: A visual identifier as well as statement

If implemented, the visual identifier must be:

- standardised and easily recognisable by consumers.
- appropriately placed on the label / other promotional material so that it does not detract from essential product information.
Recommendation 50: Incentives for Innovation

Purpose
Improve the competitiveness of the Australian complementary medicines industry by providing incentives for innovation.

Expected benefits
• Encourage innovation and research into complementary medicines.
• Incentives should strengthen transparency for consumers by encouraging generation of evidence based research.
Proposed protection for new ingredients

A limited period of **market exclusivity** could be provided to applicants of **new** ingredients approved for use in listed medicines.

**Timeframe**

After a new ingredient has been approved the exclusivity period may apply for a period of 2 years.

**Additional considerations**

Consideration could also be given to allowing a sponsor of another medicine to apply to the TGA for use of an ingredient during the original applicant’s exclusivity period for that ingredient. Such an application would require its own supportive data.
Protection for efficacy data from clinical studies

It is proposed that a limited period of **data protection** could be provided to applicants of medicines approved via the **new pathway** who provide direct clinical data on the finished product formulation to establish product efficacy.

**Timeframe**

It is proposed that after a new product has been approved via the new pathway, the data protection could apply for a period of **3 years**.
Next steps

- Legislative amendments to the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990*
- Further consultation
- Transitional arrangements
- Sponsor education
- Updated guidelines
Questions?
Find out more:

www.tga.gov.au/mmdr

MMDR.consultation@health.gov.au