Australian Government
Department of Health
Therapeutic Goods Administration

Spotlight on Complementary Medicines MMDR Reforms

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Review of Medicines and Medical Devices Regulation (MMDR)

- **July 2015:** the Expert Panel released their recommendations arising from the review
  - **19 recommendations** to improve the regulation of complementary medicines
- **September 2016:** Government response released
  - accepted the majority of the review's recommendations in full or in-principle
  - identified the need for consultation with stakeholders in progressing the reforms

5 streams of work

Stream 1	Enhancing the listing framework
Stream 2	Improving transparency for consumers
Stream 3	Increased flexibility for sponsors and improving the evidence base
Stream 4	Increased flexibility and predictability for industry
Stream 5	Enhanced post-market monitoring and compliance actions

Stream 1: Enhancing the listing framework

Recommendation	Government Response
Recommendation 34: Capacity to refuse to list	Supports the intent of the recommendation
Recommendation 37: Online searchable catalogue of permissible ingredients	Accepts the recommendation
Recommendation 38: Establishing a list of permitted indications	Accepts the recommendation

Recommendation 38: Permitted indications

Recommendation 38

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 38, 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**
- The "**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 period proposed

Permitted indications on product 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**'

Development of the permitted indications list

- A draft list of permitted indications has been published on the TGA website
- Stakeholders have the opportunity to review, comment and propose new indications
- Supporting materials have been published to help stakeholders understand how regulatory requirements for listed medicines will change
- The list is open for comments and suggestions until **31 October 2017**
- New indications proposed after this time will incur a fee

Criteria for permitted indications

- 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

Low Level Indications	What this means	Examples
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*

Low Level Indications	What this means	Examples
A non-serious disease, ailment, defect or injury (other than prevention or alleviation)	Those low risk conditions that are **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*

Implementation: Proposed approach

- Sponsors will be required to certify that indications for their medicine are from the permitted indications list and they hold supporting evidence
- Consistent with current Evidence Guidelines, qualifying terms can be used by sponsors to align indications with the evidence they hold
- Indications will have a consistent structure and terminology to describe therapeutic uses appropriate for listed medicines
- Sponsors will select ‘core permitted indications’ (action and target only) with optional qualifiers

Selecting permitted indications when listing a medicine

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

Transition arrangements

- 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**

Stream 2: Improving transparency for consumers

Recommendation	Government Response
Recommendation 43: Requirement to publish efficacy evidence	Supports the intent of the recommendation
Recommendation 44: Publication of disclaimers on promotional material where product has not had efficacy assessed	Supports the intent of the recommendation and will conduct further consultation on ways to better educate consumers however the Government will not require sponsors to place a disclaimer on product labels
Recommendation 45: Publication of a 'claimer' where product has had efficacy assessed by TGA	Accept in principle
Recommendation 46: Adopt or develop evidence monographs	Accepts the recommendation

Recommendation 45: Claimers for assessment of efficacy

Recommendation 45

Where a medicinal product is listed in the ARTG following an assessment by the TGA of an application under Option Two (refer to Recommendation 39), the sponsor is able to indicate on all promotional materials and on the product label, that the efficacy of the product has been independently assessed for the approved indications.

Government response

Accepts-in-principle Recommendation 45, noting that the design and use of the promotional statements will require careful consideration by the TGA and further consultation with stakeholders.

Label ‘claimer’: Key features

- A claimer **can be used** by medicines that have had TGA pre-market assessment:
  - medicines assessed via the assessed listed medicines pathway (refer to Recommendation 39)
  - Registered complementary medicines

- A claimer **cannot 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

Label ‘claimer’: Key features

- Must be supported by the appropriate **scientific 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. prescription medicines)
- Must not be more prominent or detract from the label information mandatorily required by the current Labelling Order

Claimer: Next steps

- Consumer testing
  - visual claimers
  - wording options
    - *E.g. 'Efficacy assessed by the TGA'*
- Targeted consultation
- Education campaign

Stream 3: Increased flexibility for sponsors and improving the evidence base

Recommendation	Government Response
Recommendations 35/36: Continue to evaluate ingredients on safety, evidence and quality with two new methods for assessment of ingredients	Accepts both recommendations
Recommendation 39: Three pathways for inclusion of Listed medicines on the ARTG	Accepts the recommendation
Recommendation 40: Develop two new pathways for Registered complementary medicines	Accepts the recommendation

Recommendation 39: Three assessment pathways for complementary medicines

Recommendation 39

The Panel recommends 3 options by which sponsors may seek ARTG entry for complementary medicines:

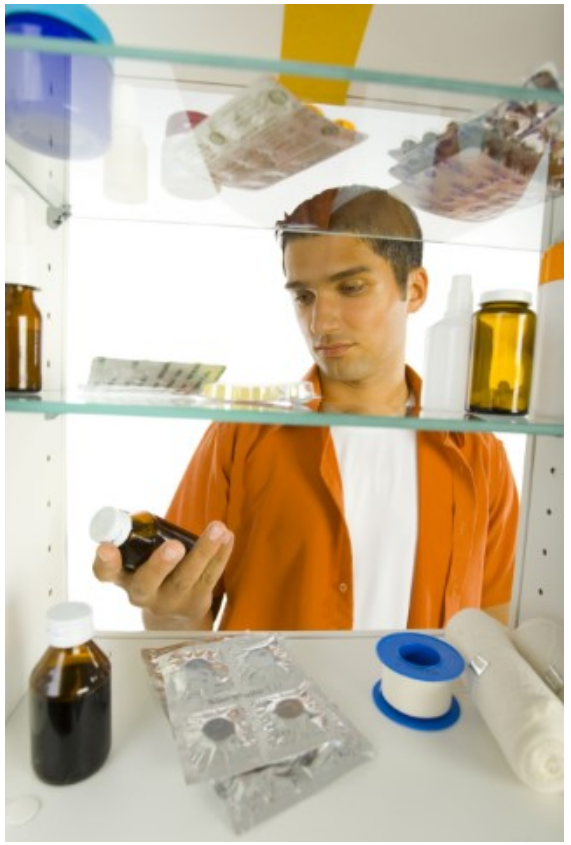
- **Option 1**: Listing in the ARTG following self-declaration by the sponsor regarding safety, quality and efficacy (current Listing pathway)
- **Option 2**: Listing in the ARTG following self-assessment of the safety and quality but a TGA assessment for efficacy (**New pathway**)
- **Option 3**: Registration in the ARTG following full TGA assessment of safety, quality and efficacy (current Registered pathway)

Recommendation 39: Three assessment pathways for complementary medicines

Government response

The Commonwealth **accepts** the recommendation, noting that legislative amendments are required to implement Option Two.

Implementing this recommendation would increase transparency for consumers, provide additional flexibility for sponsors and support innovation.



Assessed listed medicines pathway: Key features

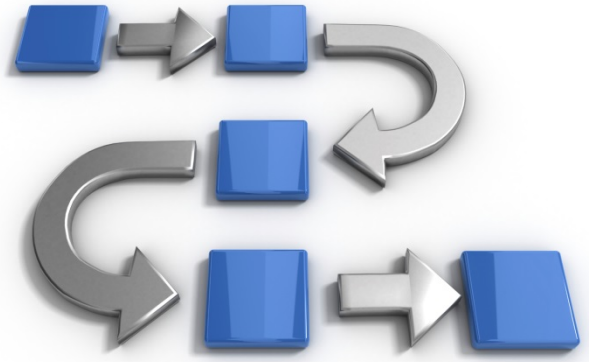
- A new assessment pathway sitting between the existing listed medicine (low risk) and registered medicine (high risk) pathways

- Maintains low risk status based on their ingredients, the way they are presented and the potential harm associated with their use

- Can use ‘intermediate claims’ which are not included on the permitted indications list:
  - *Low level indication: ‘May help relieve muscle aches and pains’*
  - *Intermediate level indication: ‘ May help relieve arthritis’*

Assessed listed medicines pathway: Key features

- **Still required to comply** with GMP requirements
- Claims must be supported by appropriate **scientific evidence**
- TGA evaluates the evidence for efficacy **before** it is listed
- Option to include a **claimer** on all promotional material stating it has been independently assessed



Proposed approach: Assessment pathways

Listed Medicines	New Pathway	Registered Medicines
Permitted ingredients	Permitted ingredients	Not limited to selecting from permitted ingredients list
Good Manufacturing Practice	Good Manufacturing Practice	Good Manufacturing Practice
Low level permitted indications only	At least one ‘intermediate indication’	May have higher level indications
No pre-market assessment	Pre-market assessment of evidence for efficacy	Full pre-market assessment
	Ability to claim that efficacy has been assessed	

Proposed approach: Indications

Listed medicines	New pathway	Registered medicines
Low level indications May refer to: • health enhancement • health maintenance • prevention/alleviation of dietary deficiency • a health benefit for a **non-serious** disease or condition *(symptomatic relief)* *E.g: maintain/support healthy bones*	**Intermediate level indications** May refer to: • a health benefit for a **serious** disease (i.e. restricted representations) • prevention, alleviation or management of a **non-serious** disease or condition *(of a higher risk to consumers than low level indications)* *E.g: prevention of osteoporosis*	**High level indications:** May refer to the: • prevention • Alleviation, • cure or • management Of a **serious** form of a disease, ailment, defect or injury (restricted reps)
Must not refer to a prohibited representation		

Establishing efficacy

- Sponsors will be required to meet **minimum evidence requirements**
- Existing approaches to establish efficacy for listed and registered complementary medicines will be retained
- For the new pathway:
  - There will be flexibility in how the evidence requirements can be met (*de novo* vs. well established ingredients)
  - Sponsor will **self-assess** the **safety and quality**

    (permitted ingredients, compliance with quality standards and GMP)

Next steps

- TGA will conduct a **pilot** of the new pathway prior to implementation in **2019**
  - Expressions of interest via the TGA website **late 2017**

- Minimum data requirements for product efficacy will be developed standardise pre-market assessments

- Further consultation to develop evidence guidelines

Stream 4: Increased flexibility and predictability for industry

Recommendation	Government Response
Recommendation 41: Develop legislative timeframes for pre-market assessments	Accepts the recommendation
Recommendation 42: Management of variations	Accepts the recommendation
Recommendation 47: Expand review and appeal rights	Supports the intent of the recommendation
Recommendation 50: Incentives for innovation of complementary medicines	Accepts in principle

Recommendation 50: Incentives for innovation

Recommendation 50

The Panel recommends that the Australian Government gives consideration to improving the competitiveness of the Australian complementary medicines industry by providing incentives for innovation

Government response

The Commonwealth **accepts-in-principle** Recommendation 50, noting the cross government responsibility for innovation policy

Incentives for new ingredients: Key features

- The current process for new ingredient applications does not protect the resources invested by applicants

- Proposal to allow for a 2 year **market exclusivity** period for new complementary medicine ingredients approved for use in listed medicines.

- Implementation will:
  - Encourage research into emerging areas of complementary medicines.
  - Provide incentive for industry to innovate and bring new products to market.

Stream 5: Enhanced post-market monitoring and compliance actions

Recommendation	Government Response
Recommendation 49: Enhanced post market monitoring scheme	Accepts the recommendation, noting that the intent of some elements of the recommendation can be achieved within existing mechanisms

Recommendation 49: Enhanced post-market compliance

Recommendation 49

The Panel recommends a more comprehensive post-market monitoring scheme for listed medicinal products, including complementary medicinal products. Such a scheme should include:

- an increase in the number of products subject to random/targeted reviews
- integration of available datasets, including eHealth and hospital records, to provide a more streamlined and cost effective approach to post-market monitoring
- provision for electronic reporting of adverse events
- enhanced collaboration with overseas regulators to share information relating to safety or efficacy of comparable products.

Recommendation 49: Enhanced post-market compliance

Government response

The Commonwealth **accepts** Recommendation 49, as the development of a more comprehensive post-market monitoring scheme will enhance consumer protection and complement existing post-market monitoring processes. The Commonwealth notes that the intent of some elements of the recommendation can be achieved within existing mechanisms.

Enhanced post-market compliance: Key features

How are we going to do this?

- Greater targeting of sponsors with a significant history of non-compliance
- Enforcing sanctions and penalties for repeat non-compliance
- Improved guidance for sponsors about their regulatory obligations
- Provide more information on the TGA website to encourage higher levels of compliance

Phased implementation 2017 - 2019

In 2017

- Online searchable catalogue of permitted ingredients
- Review and appeal rights for ingredient assessment

By 2018

- Permitted Indications
- New assessment pathways for registered complementary medicines and new ingredients
- Risk-based approach to medicine variations

By 2019

- The New Pathway
- Label claimer

MMDR consultations

- **Targeted stakeholder** consultations commenced October 2016.
- **Public consultations** throughout 2017.
- The proposed reforms arising from **recommendations 38, 39, 45 and 50** are addressed in our **first public consultation paper.**
- Outcomes from this consultation are on the TGA website.

MMDR consultation – Business process improvements

Second public consultation due for release September 2017

- Broadening the range of sources of evidence for new ingredient assessment (Recommendation 35)
- Use of evaluation reports from comparable overseas regulators (Recommendations 36 & 40)
- Introduction of legislated timeframes for ingredient assessment (Recommendation 41)
- Enhancing post-market compliance (Recommendation 49)

See the **MMDR public consultation forecast** on the TGA website for further information

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/complementary-medicines-reforms

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