# SUBMISSION

# TGA CONSULTATION: REFORMS TO THE REGULATORY FRAMEWORK FOR COMPLEMENTARY MEDICINES – ASSESSMENT PATHWAYS

March 2017

NICM

The science of integrative medicine

# PREAMBLE

NICM is Australia's leader in integrative medicine research and policy development. NICM was established with bilateral support from the Commonwealth Coalition Government and the New South Wales Labour Governments in 2007. As an *Excellence in Research Australia* (ERA) 5 ranking institute, NICM is globally recognised for its world class research, from preclinical studies to translation to healthcare. NICM provided an extensive submission to the *Australian Government Review of Medicines and Medical Devices Regulation* in 2015.

NICM's response to each of the consultation questions arising from the *TGA Consultation Paper: Reforms to the regulatory framework for complementary medicines – Assessment pathways*, released in February 2017, are outlined below.

To allow this document to be self-contained, the consultation proposals and tables referred to in the proposals have been included in Appendix 1.

# ESTABLISHING A RISK-BASED HIERARCHY FOR THERAPEUTIC INDICATIONS

**3.1**
**Do you agree with the proposed indication hierarchy and the criteria proposed to distinguish the three medicine pathways? [See Proposal one (Appendix 1)]**

NICM agrees in principle with the indication hierarchy and strongly supports the introduction of a new pathway that underpins the three medicine pathway system.

The indication hierarchy and the implementation of a new medicine pathway fulfils three of the areas of reform to the regulation of complementary medicines supported and outlined in the NICM submission to the Review of Medicines and Medical Devices Regulation in 2015. That is to: 1) provide greater incentives to encourage research-based innovation in complementary medicines; 2) streamline regulations to reduce the administrative burden upon industry and the regulator while not compromising the safety and quality of Australian complementary medicine products; and 3) support the National Strategy for the Quality Use of Medicines through clear communication of evidence to health professionals and consumers.

NICM fully supports the introduction of the new pathway as it provides a critical step in the process of supporting research and innovation in Australia for the complementary medicine industry. NICM sees that the introduction of this new pathway needs to be intrinsically coupled with the provisions in the reforms for the protection for new ingredients and the protection for efficacy data. Together these regulatory reforms will provide incentives that will drive research-based innovation in complementary medicines in Australia, which will improve the evidence-base for complementary medicines and contribute to improving the health of all Australians.

Specific and non-specific indications should be consistent with the determinations and descriptions provided in the TGA Evidence Guidelines (Guidelines on the Evidence Required to Support Indications for Complementary Medicines, TGA, v2.1 July 2014).

**3.2**
**Do you envisage any difficulties with criteria used to include or exclude products from the new pathway? [See Proposal two (Appendix 1)]**

The Consultation Paper notes that "a sponsor could also turn a low level (permitted) indication into an intermediate level indication by making it more definitive in nature" (page 14) which will thereby make it different from the 'standard' permitted indication. However, there may be circumstances where a sponsor may seek (for scientific accuracy) to retain the same 'standard' indication, yet demonstrate its increased value with new scientific data under the new pathway. In the latter case the claim, rather than indication, may be modified, eg, 'rapidly bioavailable', 'clinically proven in Australian patients', etc.

The challenges in applying this change will depend very much on the new list of 'standard' low level indications approved for Listed medicines. The TGA would need to minimise the risk of forcing a large proportion of products onto the new pathway. The reference to biomarkers in some currently approved Listed medicines may be a case example. Under the current proposal these would be required to be regulated under the new pathway. Depending on the wording of these indications this may be appropriate but would require stakeholder consultation.

# APPROACHES TO ESTABLISHING EFFICACY

**3.3**
**What other considerations may need to be taken into account in implementing the new pathway?**

NICM believes that for a small number of Listed products that meet public interest criteria, the TGA should undertake a premarket assessment of efficacy. A prime example would be folate-containing medicines indicated for reducing the risk of having a child with neural tube defects.

While the new medicine pathway creates an opportunity for sponsors to develop unique new indications for individual medicines, the development of these public interest indications would be generic for any product meeting specific TGA criteria.

Listed complementary medicines meeting criteria for these "special" indications would be those where a clear case, based on scientific evidence can be made that a substance at a specific dose (or dose range), reduces the burden of illness or has a clear health benefit that would make a substantive contribution to the health of Australians. NICM does not consider that this would be a significant regulatory burden on the TGA as the number of listed complementary medicines that would meet these criteria are limited. Researchers, institutions and industry could provide the appropriate evidentiary triggers for the TGA to consider the development of these "public interest" listed medicines.

**3.4**
**Do you agree with the proposed methods to establish efficacy for products included via the new pathway? [See Proposal three (Appendix 1)]**

NICM agrees in principle with the proposed methods, noting that some of the clinical data provided for herbal medicines under Method 1 may be data that demonstrates bioequivalence to other clinical proven medicines using contemporary approaches in genomics, proteomics, metabolomics, lipidomics and systems biology.

Given the scientific advances in bioequivalence the qualifier that Method 2 can only be used for defined chemical entities may be too limiting and any sponsor who has credible scientific evidence of bioequivalence on any product should be allowed to include it in an evidentiary package for evaluation.

**3.5**
**Is the proposed approach to establish efficacy for current listed products that have a restricted representation exemption appropriate?**

NICM reiterates the recommendation to ensure that those generic products (such as containing folate) that have appropriate scientific evidence should undergo premarketing assessment of efficacy by the TGA and given restricted representations where deemed in the public interest.

NICM considers that the development of evidentiary packages to underpin indications that currently have a restricted representation exemption to be in line with the indication hierarchy and the development of the three medicine pathway.

NICM defers to the negotiation between the TGA and industry to determine the appropriate transitional arrangements for the regulatory implementation.

# CRITERIA FOR PERMITTED INDICATIONS

**3.6**
**Are the evidence requirements appropriate for the new pathway? [See Proposal four and Tables 2 and 3 (Appendix 1)]**

NICM agrees in principle with the outline and intention of the evidence requirements. It notes that pharmacopeias (listed in Category B) are not generally sources of efficacy data and, while critical in quality determination and therefore safety evaluation, are out of place in a table of proposed categories of evidence.

**3.7**
**Do the proposed levels of assessment align with the proposed risk-based hierarchy?**

NICM agrees that the levels of assessment are consistent with risk. It notes that the assessment itself is predicated on the quality and relevance of the standards set for clinical and bioequivalent evidence.

**3.8**
**What other considerations may need to be taken into account in implementing the new pathway?**

NICM recommends to the TGA that the introduction of the new pathway needs to be considered to be intrinsically coupled with the provisions in the reforms for the protection for new ingredients and the protection for efficacy data. Introduction of the new pathway without reforms to these protections would be a significant disincentive for sponsors to utilise the new pathway and substantively restrict incentives for research-based innovation in complementary medicines.

**4.1**
**Are the proposed criteria for inclusion of an indication on the permitted indications list appropriate? [See Proposal five and Tables 5 and 6 (Appendix 1)]**

NICM agrees that the proposed criteria for the inclusion of an indication on the permitted indications list for low level listed medicines are appropriate. These indications are consistent with the determinations and descriptions provided in the Evidence Guidelines (Guidelines on the Evidence Required to Support Indications for Complementary Medicines, TGA, v2.1 July 2014). Please note comments in 3.1 and 3.2.

**4.2**
**What other considerations should be taken into account in implementing the permitted indications list?**

NICM recommends to the TGA that Australia adopt the development of evidence monographs based on the experience of other legislative jurisdictions with equivalent standards. A current example of good practice in complementary medicines monographs are the Health Canada Ingredient and Product Monographs and associated Natural Health Products Ingredients Database; and the European Medicines Agency Monographs for herbal medicinal products.

NICM believes that these and other appropriate sources of monographs could easily be adapted for the Australian regulatory environment including aligning indications with the evidence guidelines. This would provide a TGA resource to assist sponsors in effectively complying with the indications hierarchy and evidentiary requirements.

# IMPLEMENTATION OF THE PERMITTED INDICATIONS LIST

**4.3**
**Is Option 2 for selecting indications for inclusion on the ARTG and on product labels and promotional material suitable to address the objectives for permitted indications? [See Proposal six and Figures 2, 2.1 and 3 (Appendix 1)]**

NICM recommends that the TGA adopt Option 3 outlined in the consultation where sponsors can build a unique identification from pre-approved indication components. Option 3 provides a greater opportunity for alignment of the product indication with specific evidence. As an alternate, Option 2 may be acceptable. Option 1 will likely prove too inflexible to be accurately reflective of product data.

**4.4**
**What other considerations should be taken into account in implementing the permitted indications list?**

NICM would recommend to the TGA that it build on the work already done in creating a list of permitted indications for low-level medicines supplemented through TGA-Stakeholder consultation. This would help ensure a list of indications more reflective of current and future industry directions.

# CRITERIA FOR THE USE OF A CLAIMER

**5.1**
**Do the proposed criteria for the use of a claimer address the objectives for the recommendation? [See Proposal seven (Appendix 1)]**

NICM supports the use of a claimer by sponsors of complementary medicines and agrees that the proposed criteria for the use of a claimer address the objectives for the recommendation.

**5.2**
**What other considerations should be taken into account in implementing this recommendation?**

NICM recommends that a limited number of claimers be developed by the TGA and only those approved be used. This will restrict the wording on claimers, prevent inappropriate exaggeration and help ensure consumer confidence through recognition of approved claimers.

**5.3**
**Will the use of a claimer on complementary medicines have any unintended consequences?**

NICM believes that the use of a claimer is one of the incentives offered to industry for using the new medicine pathway and as such provides greater incentives for research-based innovation in complementary medicines in Australia.

NICM considers that the risks associated with the use of claimers can be limited through ensuring that TGA specified claimers are approved for use.

# PRESENTATION OF CLAIMERS

**5.4**
**Should the claimer be presented as a visual identifier as well as a statement?**

In line with the proposal to the TGA to restrict the number and wording on claimers to those approved by the TGA, NICM also supports the use of visual claimers approved and stipulated by the TGA. This should be for optional use by the sponsor.

TGA approved visual and statement claimers would provide greater consumer confidence and recognition of the new medicine pathway.

**5.5**
**Do you have any views on the possible wording or design of the label claimer?**

NICM recommends that any wording or design be community tested and performance based to ensure that the consumer of the medicines understands the wording and design and it is appropriate for use in the context intended.

**5.6**
**What other considerations should be taken into account in implementing the claimer?**

NICM recommends that claimers should be simple, standardised and used uniformly by industry and guidelines for approved wording, size and placement should be developed. In making this recommendation NICM considers that while the use of a claimer is an incentive for industry to use the new medicine pathway that it is critical that any claimer be recognised and correctly identified by the consumer.

# PROTECTION FOR NEW INGREDIENTS

**6.1**
**Is the proposed process and mechanism to provide market protection for new ingredient applicants appropriate? [See Proposal eight (Appendix 1)]**

NICM supports the process and mechanism outlined to provide market protection for new ingredient applications. NICM recognises that the current systems disadvantages the sponsor that proposes a new ingredient by allowing other competitors to market the new ingredient without having paid any of the costs or research and development and/or those costs associated with the regulatory application.

**6.2**
**Is the proposed 2 year period of exclusivity an appropriate period to reward the innovation and allow for a return on the investment made?**

NICM considers that the proposed 2 year period of exclusivity appears an appropriate period.

**6.3**
**Should multiple applicants be able to apply for exclusive use of the same new ingredients using their own data during the exclusivity period?**

NICM considers that multiple (sequential or parallel) applications for the same new ingredients for Listed medicines should be accepted by the TGA for evaluation. The principal challenge for the regulator will be around determining whether ingredients are sufficiently identical (compositional guidelines) and that subsequent applications will have a shorter remaining period of exclusivity.

**6.4**
**What other considerations should be taken into account in implementing the proposed incentive for innovation?**

Consideration may be given to the process undertaken by FSANZ in examining the issue of exclusivity of use of novel foods.

# PROTECTION FOR EFFICACY DATA

**6.5**
**Is the proposed process and mechanism to provide data protection for efficacy data appropriate? [See Proposal nine (Appendix 1)]**

NICM fully supports the process and mechanism outlined to provide data protection for efficacy data and considers this to be integral to the implementation of a new medicine pathway.

**6.6**
**Is the proposed 3 year data protection period for efficacy data appropriate to reward innovation and allow for a return on the investment made? Is it excessive?**

NICM would like to see this expanded to five years, which will be more reflective of the costs and time associated with adequate research and development to secure a sound scientific evidence base. This is quite different to the work required for the Listing approval of a new ingredient.

**6.7**
**Should protection be available for new uses of existing substances and/or be available for information that is not in the public domain?**

NICM believes that this is one area where scientific research comes to the fore, exploring the possibility of new therapeutic uses for existing substances based on the plausibility of identified constituents, putative or demonstrated mechanisms of action and innovative thinking.

Given that these new uses are required to be demonstrated in robust scientific studies to be used as the basis of a claim for data protection, NICM would recommend that such claims for the new uses of existing substances be also considered for data protection.

**6.8**
**What other considerations should be taken into account in implementing the proposed incentives for innovation?**

Emphasis for product data protection and marketplace exclusivity should be clearly based on new robust scientific research.

# TRANSITION ARRANGEMENTS

**7.1**
**Do you agree with the proposed principles to support transition arrangements?**

NICM considers that proposed principles to support transition arrangements appear reasonable and support the development of a responsible and viable complementary medicines industry.

**7.2**
**What other factors should we consider?**

NICM supports a full TGA-Industry consultation of the transition arrangements to ensure that the public interest and commercial requirements are balanced in the final implementation decision.

# APPENDIX 1: TGA CONSULTATION PROPOSALS AND TABLES

**Proposal one: A risk based Approach for therapeutic indications**

| Listed Medicines | New Pathway | Registered Medicines |
|---|---|---|
| Low level indications drawn exclusively from permitted indications list.<br><br>A low level indication may refer to:<br>■ health enhancement<br>■ health maintenance<br>■ prevention of dietary deficiency<br>■ a disease, ailment, defect or injury other than a serious form of those diseases.<br><br>A low level indication must not:<br>■ refer to, or imply, the prevention, alleviation, or cure of any form of a disease, ailment, defect or injury<br>■ contain a prohibited representation<br>■ contain a restricted representation<br>■ have been specified in a non-permitted indications list. | Intermediate level indications that exceed the permitted indications list but are not high level indications.<br><br>Intermediate level indications may refer to:<br>■ a serious disease (i.e. **restricted representations**); or<br>■ the prevention or alleviation of a disease, ailment, defect or injury other than a serious form of those diseases.<br><br>Intermediate level indications may include those indications specified in a non-permitted indications list.<br><br>An intermediate level indication must not:<br>■ refer to the prevention, diagnosis, cure or alleviation of a serious form of disease, disorder or condition<br>■ contain a prohibited representation. | High level indications.<br><br>A high level indication may refer to the prevention, alleviation, cure or management of a serious form of a disease, ailment, defect or injury (i.e. **restricted representations**).<br><br>A high level indication must not:<br>■ contain a prohibited representation. |

TGA Consultation Paper: Reforms to the regulatory framework for complementary medicines – Assessment Pathways (Page 13)

**Proposal two: Products excluded from the new pathway**

We propose that the following products will **not** be accepted for evaluation through the new pathway:

- Products that **only** have 'standard' permitted indications.
- Products that have indications based **solely** on evidence of traditional use, unless they also provide adequate scientific evidence supporting the indications.

The new pathway is also not proposed to be a provisional approval pathway pending the outcome of clinical trials (i.e. evidence of efficacy is required at the time of application to TGA).

TGA Consultation Paper: Reforms to the regulatory framework for complementary medicines – Assessment Pathways (Page 14)

**Proposal three: Approaches to establishing efficacy**

The existing approaches to establish efficacy for listed and registered complementary medicines will be retained for low and high level indications respectively. We propose that efficacy data on the finished product will be required for products to be eligible to be included on the ARTG via the new pathway at a similar standard that applies to registered complementary medicines.

Sponsors must comply with either of the following approaches to establishing efficacy:

**Method 1**: Clinical data on the finished product that supports the specific indication.

**OR**

**Method 2**: A data package containing:

1. evidence for efficacy of all ingredients; and
2. evidence for efficacy of the product formulation, established through bioequivalence data to existing products [consisting of evidence of release via dissolution data and absorption of the active ingredient via bioavailability data)[1] or, in some instances, comparative dissolution (against established data) demonstrating release of the active ingredient with appropriate scientific justification;
3. justification of the combination of ingredients (including potential interactions).

Note: Method 2 can **only** be used for products that are composed of defined chemical entities such as vitamins, amino acids and minerals (i.e. herbs and herbal extracts, animal products, and probiotics are ineligible for inclusion via Method 2).

Refer to **Attachment 1** for case studies of products and evidence packages suitable for evaluation via the new pathway.

TGA Consultation Paper: Reforms to the regulatory framework for complementary medicines – Assessment Pathways (Page 15)

1 See: Guidance 15: Biopharmaceutic Studies (2 April 2015), available at: <https://www.tga.gov.au/guidance-15-biopharmaceutic-studies>.

**Proposal four: Evidence requirements**

The existing evidence requirements for listed and registered complementary medicines will be retained to establish efficacy for low and high level indications respectively (see **Tables 2** and 3).

We propose that sponsors seeking to include complementary medicines on the ARTG via the new pathway meet the minimum evidence requirements outlined below (**Tables 2** and **3**).

TGA Consultation Paper: Reforms to the regulatory framework for complementary medicines – Assessment Pathways (Page 17)

| Table 2: Proposed categories of evidence | | | |
|---|---|---|---|
| **Category A** | **Category B** | **Category C** | **Category D** |
| Traditional Reference text | Non-systematic, generalised reviews – including databases | Observational studies e.g. cohort and case control studies | Double blind randomised controlled trials (including cross-over trials) |
| Herbal Monograph | Publicised international Regulatory Authority Articles | Comparative studies (non-control). | Systematic reviews |
| Herbal Pharmacopoeia | Evidence based reference text – scientific | | |
| Materia Medica | Scientific Monographs | | |
| Publicised International Regulatory Authority Articles – Traditional only | Pharmacopoeias | | |

TGA Consultation Paper: Reforms to the regulatory framework for complementary medicines – Assessment Pathways (Page 17)

| Table 3: Proposed minimum literature requirements | | | | |
|---|---|---|---|---|
| | **Listed Medicines** | | **New pathway** | **Registered medicines** |
| **Indication** | **Traditional** | **Low Level scientific** | **Intermediate Level Indications** | **High level Indications** |
| Evidence Category (required evidence) | Minimum of two independent sources from Category A<br>OR<br>A minimum of one from Category B | Minimum of two independent sources from Category B<br>Plus (where required)A minimum of one from Category C | **Primary indication**<br>Minimum of one from Category D<br>OR<br>Minimum of 2 independent sources from Category B, AND a minimum of one from Category C | **Primary indication**<br>Minimum of one from Category D |
| Evidence Category (supplementary evidence) | Minimum 1 from Category A to support indications (where relevant) | Minimum of 1 from Category B to support specific indications (where relevant) | **Secondary (low level) indications**<br>One from Category D<br>OR<br>Minimum of 2 independent sources from Category B, AND a minimum of one from Category C | **Secondary indications**<br>One from Category D<br>OR<br>Minimum of 2 independent sources from Category B, AND a minimum of one from Category C |

TGA Consultation Paper: Reforms to the regulatory framework for complementary medicines – Assessment Pathways (Page 18)

| Proposal five: Criteria for permitted indications |
|---|
| We propose that the criteria for low level indications will determine whether an indication is appropriate for inclusion in the permitted indications list as outlined above (**Tables 5 and 6**). |

TGA Consultation Paper: Reforms to the regulatory framework for complementary medicines – Assessment Pathways (Page 24)

**Table 5: Indications appropriate for inclusion in the permitted indications list**

| A low level indication may refer to: | What this means | Examples |
|---|---|---|
| **Health enhancement** | Beneficial effects of substances on the physiological/ psychological state of the body, above and beyond normal growth, development and functions of the body. | ■ May increase energy/reduce fatigue<br>■ Helps stimulate digestive function<br>■ May enhance mental alertness |
| **Health maintenance** | Normal physiological effects of substances in growth, development and normal functions of the body. | ■ Helps maintain healthy digestive function<br>■ Helps maintain healthy hair, skin and nails<br>■ May support healthy lung function<br>■ Assists with normal liver function<br>■ Helps support healthy connective tissue/joints |
| **Prevention of dietary deficiency** | Prevention of mild dietary deficiency (i.e. not prevention of diseases resulting from severe deficiency). | ■ When taken regularly, may prevent vitamin D/calcium deficiency<br>■ Helps reduce the risk of iodine deficiency<br>■ Helps prevent dietary vitamin B12 deficiency |
| **A disease, ailment, defect or injury other than a serious form**<br>**(other than a reference to the prevention, alleviation of disease)** | Those low risk conditions that are non-serious and self-manageable.<br>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. | ■ Helps reduce the severity of common cold symptoms<br>■ For the management of mild dermatitis symptoms<br>■ Helps relieve muscle aches and pains<br>■ May relieve post-menopausal/PMS symptoms<br>■ Helps reduce the frequency of common cold sore outbreaks<br>■ Helps ease chesty coughs |

Note: The examples provided in this table are a guide only and will be reviewed against the finalised criteria for permitted indications to determine their suitability for inclusion in the permitted indications list.

TGA Consultation Paper: Reforms to the regulatory framework for complementary medicines – Assessment Pathways (Page 22)

| Table 6: Indications not suitable for inclusion in the permitted indications list | | |
|---|---|---|
| **A low level indication may refer to:** | **What this means** | **Examples** |
| **Refer to, or imply, the treatment, prevention, alleviation or cure of any form of a disease, ailment, defect or injury** | Treatment, prevention, alleviation and cure have a more definitive meaning which are not suitable for permitted indications as they may lead to a delay in seeking medical treatment and adverse consequences for the patient. | ■ Prevents indigestion<br>■ Treats dehydration<br>■ Treats cold sores<br>■ Alleviates Irritable Bowel Syndrome |
| **Contain a prohibited representation** | Any reference regarding the treatment, cure or prevention of the following diseases:<br>■ Neoplastic<br>■ Sexually Transmitted Diseases<br>■ HIV AIDS and/or HCV<br>■ Mental illness | Any reference to:<br>■ depression/anxiety/low mood<br>■ cancer<br>■ genital warts/prevention of the transmission of herpes virus |
| **Contain a restricted representation** | Any reference (even by implication) to a serious disease, condition, ailment or defect specified in Table 1 of Part 2 of Appendix 6 of the Therapeutic Goods Advertising Code<br>Serious, in this context means those diseases, conditions, ailments or defects that are:<br>■ Generally accepted not to be appropriate to be diagnosed and/or treated without consulting a suitably qualified healthcare professional, and/or<br>■ 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 | ■ Reduces risk of atherosclerosis<br>■ Reduces elevated blood glucose (referring to diabetes and or unhealthy biomarkers)<br>■ Helps naturally decrease high blood pressure<br>■ Alleviates arthritis symptoms, such as inflammation and pain<br>■ Reduces symptoms of reflux<br>■ Beneficial for anaphylaxis |
| **Have been specified in a non-permitted indications list** | Those indications that the TGA will have determined to be unsuitable for inclusion in the permitted indications list e.g. on public health grounds. | Indications referring to areas of public health importance, for example:<br>■ certain biomarkers that are predictive of a serious disease, e.g. diabetes, cardiovascular disease<br>■ smoking cessation<br>■ obesity<br>■ vulnerable populations (e.g. 4 week old infants) |

TGA Consultation Paper: Reforms to the regulatory framework for complementary medicines – Assessment Pathways (Page 23 and 24)

| Proposal six: Implementation of permitted indications |
| --- |
| We believe that **Option 2** may strike the best balance between ensuring that all indications in the permitted indications list comply with the regulatory requirements and allow industry sufficient flexibility to differentiate their products in the market by aligning indications with the evidence held for their medicine. This option would also help contain the size of the permitted indications list.<br>Under this option, the TGA would develop a comprehensive list of traditional and scientific 'core' indications and specifying qualifiers for further consultation with stakeholders. |

TGA Consultation Paper: Reforms to the regulatory framework for complementary medicines – Assessment Pathways (Page 29)

**Figure 2: Option for modifying a core permitted indication**

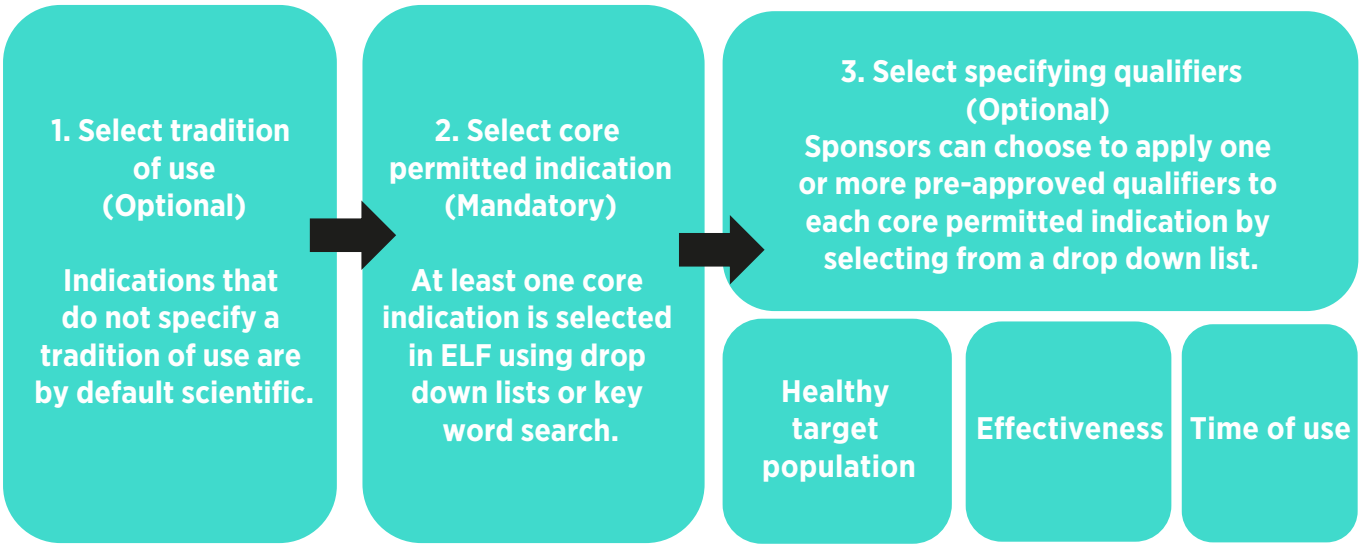
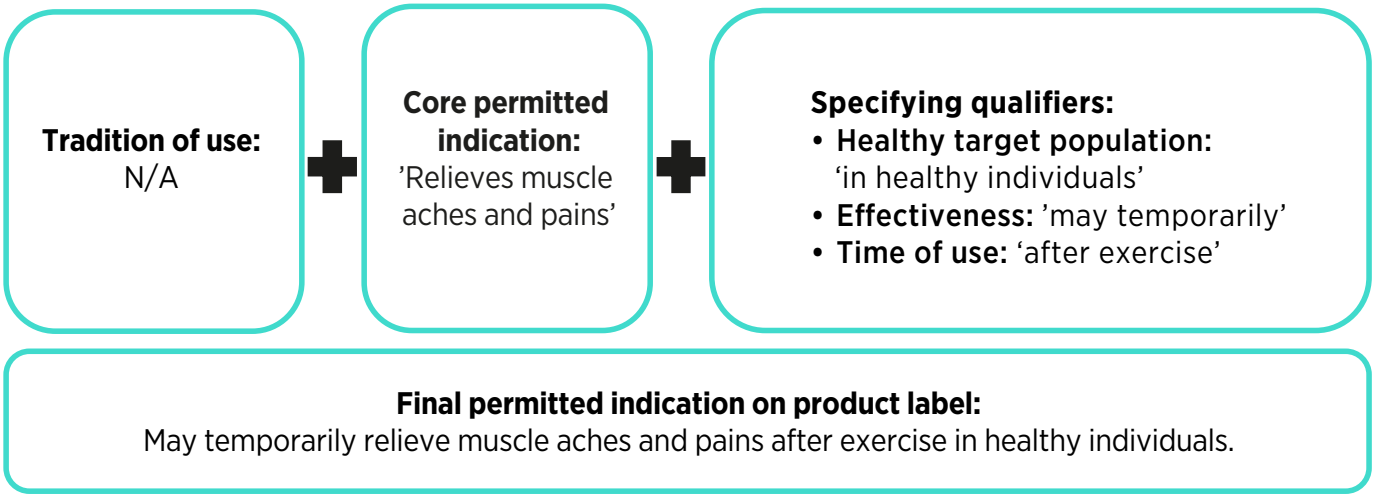



**Figure 2.1: Example indication**




TGA Consultation Paper: Reforms to the regulatory framework for complementary medicines – Assessment Pathways (Page 28)

**Figure 3: Building a unique indication from pre-approved indication components**

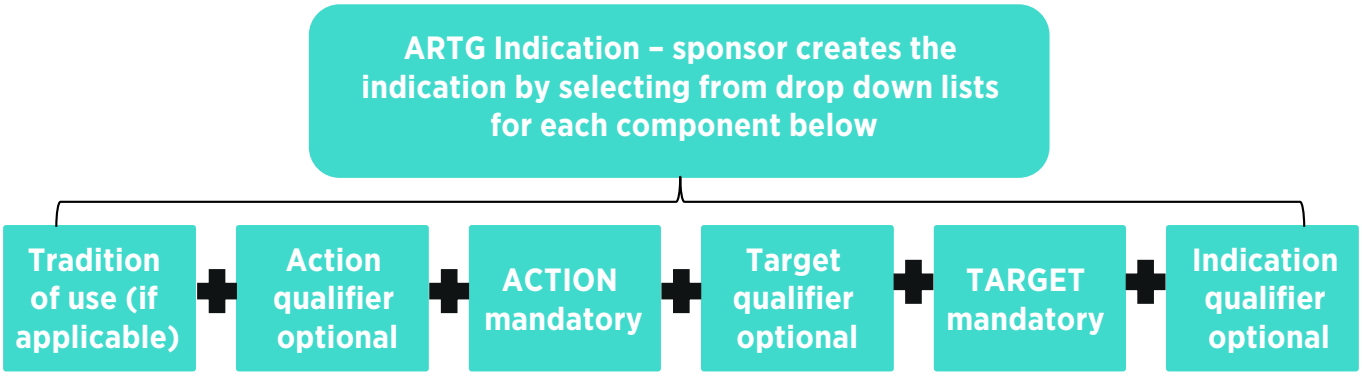



**Figure 3.1: Example indications**

| Tradition of use | Action qualifier | ACTION | Target qualifier | TARGET | Indication qualifier |
|---|---|---|---|---|---|
| Traditionally used in Western herbal medicine | To help | Stimulate | Healthy | Digestion | - |
| - | May help | Relieve | Symptoms of | Eye strain | Associated with prolonged computer use |

**Final permitted indications on product label:**

1. This product has been traditionally used in Western herbal medicine to help stimulate healthy digestion.
2. May help relieve symptoms of eye strain associated with prolonged computer use.

TGA Consultation Paper: Reforms to the regulatory framework for complementary medicines – Assessment Pathways (Page 29)

**Proposal seven: Use of a claimer**

We propose that a claimer may only be used on complementary medicine labels and/or other product promotional materials following TGA approval as part of a pre-market assessment process.

TGA Consultation Paper: Reforms to the regulatory framework for complementary medicines – Assessment Pathways (Page 31)

**Proposal eight: Protection for new ingredients**

We propose that:

- A limited period of market exclusivity will be granted to applicants for new ingredients approved for use in listed medicines.
- There would be a 2 year exclusivity period.

TGA Consultation Paper: Reforms to the regulatory framework for complementary medicines – Assessment Pathways (Page 36)

**Proposal nine: Protection for efficacy data**

We propose that:

- A limited period of data protection is granted to applicants of products with new ingredients supported by direct clinical data on the finished product formulation.
- There would be a 3 year protection period

TGA Consultation Paper: Reforms to the regulatory framework for complementary medicines – Assessment Pathways (Page 39)


140 mL
120
100
80
60
40
20

nicm.edu.au

p. +61 2 4620 3284
e. nicm@westernsydney.edu.au
a. Locked Bag 1797 Penrith NSW 2751 Australia

WESTERN SYDNEY
UNIVERSITY