NHAA Submission to the Consultation: Reforms to the regulatory framework for complementary medicines: Assessment pathways, March 2017

Submitted by the Naturopaths and Herbalists Association of Australia

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Executive Summary

The Naturopaths and Herbalists Association of Australia (NHAA) is pleased to have the opportunity to present this submission in response to the consultation document '*Reforms to the regulatory framework for complementary medicines: Assessment pathways'* released in February 2017. This submission makes the following comments:

- The purpose, scope, background and assessment pathways are sound in principle and NHAA supports their implementation.
- The complementary medicine assessment pathways are requested to contain a mechanism for revisitation of specific scheduled plant medicines.
- Evidence for efficacy and effectiveness is requested to include a broad range of research methods, including mechanistic studies.
- Market exclusivity must ensure ingredients are not witheld from public availability.
- Protection for efficacy data must ensure those companies unable to afford research trials are not inadvertently disadvantaged in the marketplace, causing an unintended reduction in innovation diversity.

Thank you for preparing this Discussion Paper and reviewing this submission. Please contact the NHAA should you require further information.

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About the NHAA as the submitting entity

The NHAA is a peak professional association representing appropriately qualified Western herbal medicine and naturopathic medicine practitioners. It is the oldest professional association of complementary therapists in Australia, founded in 1920, with a full membership of approximately 940 professional members (total membership with student and companion members is circa 1200). Membership consists of practitioners who choose to use biologically active therapeutic plant substances as their major modality of practice; which includes a variety of allied modalities such as pharmacists, general medical practitioners, nurses, psychologists and other healthcare disciplines.

The NHAA requires its members to adhere to the Association Constitution and Code of Ethics, including standards of practice. The primary aims of the NHAA are to:

- Promote, protect and encourage the learning, knowledge and service delivery of Western herbal medicine and naturopathic medicine
- Disseminate such knowledge through available media and networks
- Encourage the highest ideals of professional and ethical standards
- Promote Western herbal medicine and naturopathic medicine as safe and effective public healthcare
- Engage with legislative tools and their representatives as they relate to the practice of Western herbal medicine and naturopathic medicine in Australia

The vision of the NHAA is Naturopathy and Western herbal medicine for the health of Australia and the mission is to be the leading association in Australia supporting naturopaths and Western herbal medicine practitioners to deliver excellence in healthcare.

Full members of the NHAA have completed training in Western herbal medicine and naturopathic medicine sufficient to meet the educational standards as determined by the Examiners of the Board. These standards are set in consultation with appropriate tertiary educational institutions (aligned to and exceeding the requirements of the Australian Qualifications Framework (AQF) and current Health Training Packages), and all members must adhere to a comprehensive Continuing Professional Education (CPE) program.

The NHAA publishes the quarterly *Australian Journal of Herbal Medicine* and holds annual seminars throughout Australia, with the *International Conference on Herbal Medicine* held biennially. Since its inception, the NHAA and its members have been at the forefront of Western herbal medicine and naturopathic medicine and have been influential in areas ranging from education and practice to ethical, regulatory and industry standards.

A voluntary Board of Directors undertakes the governance of the NHAA, with full members of the Association electing the Board of Directors. Each board member serves a two-year term after which they may stand for re-election.

Background and format to this submission

The *Reforms to the regulatory framework for complementary medicines: Assessment pathways* document is relevant to the NHAA for the following reasons:

- NHAA represents technical experts who are employed by businesses producing and marketing product subject to the proposed reforms
- NHAA represents healthcare practitioners who prescribe product subject to the proposed reforms

- NHAA represents healthcare practitioners who refer patients to pharmacies to access product subject to the proposed reforms
- NHAA represents members who are consumers of products subject to the proposed reforms

As per the described aims, the NHAA has an interest in ensuring Western herbal medicine and naturopathic medicine is safe and accessible for all. By proxy this entails consumer access to efficacious and effective complementary medicine product. Therefore the proposals within this submission are of significant importance to the NHAA.

This submission is formatted in line with the consultation document. Each individual section is headlined and submitted comments, as deemed relevant, are documented in response. Highlighted boxes contain summaries of the NHAA comments to each section, labeled as 'summary comment 1-14'. A conclusion completes this submission document.

Comments on section 1: Purpose and scope

The purpose and scope, along with the described guiding principles, are unremarkable in their intent and direction.

Summary comment 1:

Section 1 contains content appropriate for this consultation document and for the process under consideration.

Comments on section 2: Background

The following statement, sourced from recommendation 39 (and subsequently recommendation 40) of the MMDR review, is included as a segregation tool for the three pathways outlined within this consultation document.

> The Panel recommended that these pathways be established on the basis of a hierarchy of evidence as a graded response to the risk profile of complementary medicines and the associated indications that can be made.

The suggested hierarchy of evidence is sound in principle. The context for change and the objective of the reforms are unremarkable in their substance

Summary comment 2:

Section 2 contains content appropriate for this consultation document and for the process under consideration. The context for change and objective of the reforms are well described and logically coherent in relation to the outcomes of the MMDR review.

Comments on section 3: Assessment pathways for complementary medicines

As stated within the consultation document:

> The classification of a medicine will continue to be based on a number of factors and their relative risk to consumers if a product fails to comply with the regulatory requirements, including:
>
> - the intrinsic risk of the product (e.g. the toxicity of its ingredients)
> - the risks associated with the quality of the product (e.g. requirements for sterility)

- the risks associated with the intended use(s) (indications) of the product (e.g. whether incorrect use could lead to the consumer delaying necessary medical treatment).

Relative risk is a common tool for the assessment of therapeutic products, and intrinsic risk is an appropriate mechanism for determining the safety of a complementary medicine ingredient. From the perspective of the NHAA, questions remain with regard to the inclusion of selected alkaloid-containing plants within specific risk categories (i.e. *Tussilago farfara, Ephedra sinica, Lobelia inflata and Symphytum officinalis)*. This relates to scientific uncertainty related to their toxicity when appropriately prescribed, their unproblematic use in international jurisdictions, and their availability to complementary medicine practitioners competent in their prescription. While this issue lies outside the immediate context of this consultation process, ongoing revision of risk and scheduling classification of these plants is perceived by the NHAA as necessary.

Summary comment 3:

Section 3 (overview) discusses risk assessment as the primary tool for complementary medicine assessment pathways. This is appropriate and is requested to include an active mechanism for revisitation of specific scheduled plant medicines in consultation with appropriate experts.

QUESTIONS 3.1 – 3.3: 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?

The three pathways are distinct and well described. The hierarchy is clearly articulated and the distinguishing criteria are sensible.

3.2 Do you envisage any difficulties with criteria used to include or exclude products from the new pathway?

The main difficulty with criteria used to include or exclude products is the inability to escalate existing some low-level ingredients to intermediate level indications due to their lack of research evidence above current traditional indications. This is particularly true in the domain of plant medicines and the NHAA sees this as a strong hindrance to the growth, development and innovation of the Australian complementary medicines industry. To circumvent this limitation it is requested that methodological flexibility be applied when assessing levels of evidence for certain ingredients. This arises due to the fact that a range of academic disciplines with associated diversity of research methods inquire into current use of traditional medicines. Aligned to this is the necessity to realise that complementary medicine research is underfunded and often rhetorically undermined. Collectively these factors require recognition and negotiation when reviewing evidence portfolios for breadth and depth.

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

Nothing additional noted.

Summary comment 4:

Section 3 questions 3.1 - 3.3: The therapeutic indications pathways are appropriate. The levels of research evidence for intermediate indications (that are not targeted to serious illness) should bridge low and high-level indications and allow for the escalation of traditional usage claims based on a variety of research methodologies and methods (e.g. mixed methods research, observational studies, cohort studies, cases studies, mechanistic studies, and qualitative techniques).

Several of these research methods are discussed in tables 2 and 3 (pages 17-18) of the discussion document.

QUESTIONS 3.4 – 3.5: APPROACHES FOR ESTABLISHING EFFICACY

3.4 Do you agree with the proposed methods to establish efficacy for products included via the new pathway?

The proposed methods are appropriate, most particularly where isolated ingredients are used in product formulation. As per Appendix 1, this approach works well where existing research is available. However, as described in the response to Question 3.2, this can be restrictive when assessing complex plant material such as herbal medicines. It is recommended that a diversity of research material be included as evidential when assessing herbal medicine therapeutic effectiveness. This becomes increasingly relevant when there is a public interest criterion, for example in cases of observational and qualitative research across cultures and populations regularly ingesting plant medicines.

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

Yes, this appears appropriate.

Summary comment 5:

Section 3 questions 3.4 - 3.5: The described approaches to establishing efficacy are appropriate for isolated ingredients but are potentially insufficient to capture therapeutic efficacy and effectiveness in instances of complex plant medicines. See summary comment 4.

QUESTIONS 3.6 – 3.8: EVIDENCE REQUIREMENTS

3.6 Are the evidence requirements appropriate for the new pathway?

It is recommended mechanistic studies are included in category C. in table 2 on page 17.

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

The proposed levels of assessment are appropriate.

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

Table 4 (page 19) for the primary indications appears to omit evidence sources from category B and category C?

Summary comment 6:

Section 3 questions 3.6 - 3.8: Consideration for the inclusion of mechanistic studies within category C is recommended. Table 4 (page 19) does not appear to reflect the inclusion of category B or C evidence.

Comments on section 4: Implementing a list of permitted indications

QUESTIONS 4.1 – 4.2: CRITERIA FOR PERMITTED INDICATIONS

4.1 Are the proposed criteria for inclusion of an indication on the permitted indications list appropriate?

The proposed criteria for inclusion of an indication are appropriate.

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

Nothing additional noted.

Summary comment 7:

Section 4 questions 4.1 – 4.2: The criteria for permitted indications as discussed are appropriate.

QUESTIONS 4.3 – 4.4: 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?

Option 2 appears appropriate.

4.4 What other considerations should be taken into

Nothing additional noted.

Summary comment 8:

Section 4 questions 4.3 – 4.4: The discussion on the implementation of the permitted indications list is appropriate.

Comments on section 5: Claiming evidence of efficacy

QUESTIONS 5.1 – 5.2: 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?

The proposed criteria are appropriate.

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

Nothing additional noted.

Summary comment 9:

Section 5 questions 5.1 – 5.2: The criteria for the use of a claimer as discussed are appropriate.

QUESTION 5.3: USE OF A CLAIMER

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

The use of a claimer is unlikely to have unintended consequences according to the criteria in section 5.

Summary comment 10:

Section 5 questions 5.3: The use of a claimer as discussed is appropriate.

QUESTIONS 5.4 – 5.6: PRESENTATION OF CLAIMERS

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

A visual symbol is likely to add to consumer recognition and is a worthwhile consideration.

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

Nothing additional noted to the discussion.

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

Nothing additional noted.

Summary comment 11:

Section 5 questions 5.4 – 5.6: The presentation of claimers as discussed is appropriate.

Comments on section 6: Incentive for innovation

QUESTIONS 6.1 – 6.4: PROTECTION FOR NEW INGREDIENTS

6.1 Is the proposed process and mechanism to provide market protection for new ingredient applicants appropriate?

The proposed process and mechanism is appropriate.

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?

The 2-year period of exclusivity is appropriate.

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?

Yes, additional applicants should have the right to apply using their own data.

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

There should be a mechanism of assurance that allows the public ongoing access to ingredients i.e. it must not be permissible for an ingredient to have market exclusivity and then to be made publicly unavailable during this time of exclusivity.

Summary comment 12:

Section 6 questions 6.1 – 6.4: Protection for new ingredients is appropriate, providing a mechanism is included to ensure ingredients cannot be made unavailable to the public during their period of market exclusivity.

QUESTIONS 6.6 – 6.8: PROTECTION FOR EFFICACY DATA

6.5 Is the proposed process and mechanism to provide data protection for efficacy data appropriate?

The process and mechanism is appropriate.

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?

The proposed 3-year data protection period is appropriate.

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?

If the existing substance is researched for a novel application and determined to be successful then data protection is appropriate due to the incurred costs of the research. This will assist research innovation.

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

Those producers unable to conduct research trials due to financial constraints are potentially disadvantaged by this data protection proposal, which may lead to market losses. This may cause larger

companies to garner intermediate and high-level indications while smaller companies may exist largely in the low-level indications bracket. So while this section of the discussion document proposes incentives for innovation, it may inadvertently have a detrimental effect on smaller players in the market. This is a hypothetical scenario that requires consideration.

Summary comment 13:

Section 6 questions 6.5 – 6.8: Protection for efficacy data is appropriate, bearing in mind the potential to create monopolisation of the intermediate and high-level claims aspect of data protection by those able to afford research outlays. This may create selective areas of innovation while reducing complementary medicine industry diversity with regard to new product development.

Comments on section 7: Implementation

QUESTIONS 7.1 – 7.2: TRANSITION ARRANGEMENTS

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

The proposed transition principles are appropriate.

7.2 What other factors should we consider?

Nothing additional noted.

Summary comment 14:

Section 7 questions 7.1 – 7.2: The transition arrangements as discussed are appropriate.

Conclusion

This submission has responded to the proposals contained within the TGA *Consultation: 'Reforms to the regulatory framework for complementary medicines: Assessment pathways'.* Overall this consultation document is well prepared and produced and the capacity and willingness for the TGA to integrate stakeholder submissions is applauded. The NHAA has provided input into relevant areas of this consultation and looks forward to ongoing consultation and engagement on this topic.