NHAA Submission to the Consultation: Options for the future regulation of "low risk" products, May 2017

Submitted by the Naturopaths and Herbalists Association of Australia

National Herbalists Association of Australia t/a Naturopaths and Herbalists Association of Australia
ABN 25 000 009 932
Founded 1920

3/2-4 Holden St
Ashfield, Sydney
NSW 2131 Australia

PO Box 696, Ashfield NSW 1800

Phone: +61 2 9797 2244
Fax: +61 2 8765 0091
Email: nhaa@nhaa.org.au
Web: www.nhaa.org.au

Produced by the Professions Sub-committee of the Board of Directors of the Naturopaths and Herbalists Association of Australia (NHAA). May 2017

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 '*Options for the future regulation of "low risk" products'* released by the Therapeutics Goods Administration (TGA) in March 2017. This submission makes the following comments:

- The TGA low risk classification system is sound in principle and NHAA supports this as an ongoing consultative process.
- Vitamins and minerals are active therapeutic substances and there is the need to ensure their quality manufacture and regulatory oversight through maintaining both their listing on the ARTG and their manufacture to GMP.
- Option one (maintainance of the status quo) is the preferred option regard to vitamins and minerals as discussed within this consultation document.

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

Table of Contents

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:

- Practitioners and the practice of Western herbal medicine and naturopathic medicine are fully integrated into the primary healthcare system in Australia
- The NHAA is recognised as the peak body for Western herbal medicine and naturopathic medicine

- Western herbal medicine and naturopathic medicine is accessible to all
- The integrity of the profession of Western herbal medicine and naturopathic medicine is maintained
- The standards and quality of education of the professions continue to be promoted
- Career opportunities and research pathways for Western herbal medicine and naturopathic medicine professionals are developed and maintained
- The integration of traditional knowledge and evolving science is continued

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 '*Options for the future regulation of "low risk" products'* 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

This submission addresses the section discussing vitamins and minerals only, as professional members of NHAA are expert prescribers of these therapeutic products.

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, including vitamins and minerals. Therefore the proposals within this submission are of significant importance to the NHAA.

This submission discusses the MMDR recommendation 48, the application of the Low Risk Classification System by the TGA, and the options within the section discussing vitamins and minerals. A conclusion completes the submission.

Comments on recommendation 48 of the MMDR

The following statement, sourced from recommendation 48 of the MMDR states:

> The Panel recommends that the Australian Government undertakes a review of the range of complementary medicinal products, currently listed in the ARTG and subject to regulation under the medicines framework, with a view to ensuring that products that might best be regulated under other regulatory frameworks, without undermining public health and safety, are removed from the auspices of the Act.

While the general inference of this recommendation is clear, the intention to reduce unnecessary regulatory burden appears to be informed by economic rationalisation as opposed to ensuring and maintaining high industry standards and ongoing consumer access to safe quality products. For the NHAA this means there are considerations that are additional to inherent product risk with regard to shifting vitamins and minerals away from the ARTG and GMP. This statement is explained in the responses to the relevant sections below.

Comments on the Low Risk Classification System

It is acknowledged the TGA operates a risk-based system of therapeutic goods regulation. Accordingly, the Low Risk Classification System (LRCS) is an appropriate proposal for use as a tool for differentiating risk 'sub-levels' within products that are inherently lacking in severity of risk.

Therefore the LRCS applied in this consultation document descriptively labels vitamins and minerals as 'low' and 'moderate' risk (pages 13 and 14 – incorrectly termed medium?) where any issue with product may be either unlikely to cause injury or may be contributory to minor public harm. Accordingly these vitamins and minerals are categorised into risk potential depending on their water or fat-solubility status (for vitamins) or their toxicity profile (for minerals).

Thus this consultation document takes the position that discretion is required when classifying particular vitamins and minerals in relation to consumer risk. This approach is essentially sound in principle, albeit largely dismissive of the self-prescribing habits of consumers that can lead to over ingestion of product (World Health Organisation, 2000). Therefore, because of the inherent risk rating of these products, the inability to predict consumer behaviour, and the potential introduction of external risk from poor manufacturing standards (Barnes, 2003), the management of concomitant factors alongside inherent risk remains an important consideration with regard to public safety.

In relation to the 'wisdom of crowds' method used in the assessment of information applied within this consultation document, it is important to the NHAA that outcomes derived from this method are developed via the understanding of those who are qualified in, and actively prescribing, the products in question. From the content of this consultation document it is unclear if this is a process that has been followed. There are, for example, numerous NHAA members who are highly qualified and able to be involved in consultation on these matters in the first instance. Greater involvement of relevant expertise and increased transparency around this process is desirable.

Comments on the section titled 'Vitamins and minerals'

This section provides an accurate overview of the current regulatory situation for vitamins and minerals in Australia. As these products are therapeutically active and are used across a range of patient and consumer needs they are classed as complementary medicines and are currently unable to be regulated as food products as per FSANZ 2013 Standard 1.2.7.

Do you have a view on which (if any) of the above options for vitamin and mineral products would be the most appropriate

way forward? If so, please provide details on potential impacts to public health, access in the marketplace, business operations etc. Any alternative recommendations would also be welcome.

OPTION 1: MAINTAIN THE STATUS QUO REGULATION OF VITAMINS AND MINERALS

This option proposes the status quo with regard to the listing of vitamins and minerals on the ARTG and requirements for product manufacturing GMP. Producers of vitamin and mineral products are familiar with these now well-established standards and are currently able to develop consumer goods of high quality because of these. This leads to a well-established international and national reputation for product, leading to a high level of practitioner and consumer confidence. As the consultation document outlines, altering this status quo towards reduced oversight may lead to the perception of a lessening of product quality. For the industry, prescribing practitioners, and consumers; this is self-evidently undesirable as it may lead to the introduction of additional risk.

OPTION 2: EXEMPTION FROM LISTING IN THE ARTG AND/OR GMP

This option proposes removing selected vitamins and minerals from the ARTG while concomitantly eliminating the need for GMP standards of manufacture of the removed product. Because supplemented vitamins and minerals can exert physiological change in the human body and are thus therapeutic in nature (e.g. (Higdon & Drake, 2012; Ross, Caballero, Cousins, Tucker, & Ziegler, 2014), their therapeutic status, stringent quality criteria, and perceived level of assurance for practitioner, staff and consumer use would be called into question.

OPTION 3: DECLARE VITAMINS AND MINERAL NOT TO BE THERAPEUTIC GOODS

This option proposes removing vitamins and minerals from the ARTG while concomitantly eliminating the need for GMP standards of manufacture of the removed product. This proposal lacks feasibility as all vitamins and minerals are capable of exerting physiological change in the human body, and as such vitamins and minerals are undeniably therapeutic goods, as described.

Because healthcare practitioners and consumers use vitamins and minerals in a therapeutic manner, the standards of the ARTG and GMP are preferable. These provide consumers with greater assurance of product quality and oversight than would be present if these goods were removed from the ARTG and subject to FSANZ requirements and consumer law.

Preferred option related to 'Vitamins and minerals'

As discussed under each of the three proposed options within this consultation document, there are sound rationales for the acceptance or rejection of each option. From this review process, option one is the preference for the NHAA. At this point in time there are no alternative recommendations.

Conclusion

This submission has responded to the proposals for changes to the regulation of vitamins and minerals contained within the TGA document '*Options for the future regulation of "low risk" products'.* While it is acknowledged there are differing levels of risk for selected vitamins and minerals, the current level of regulatory oversight and industry guidance from the TGA is appropriate given the well-documented therapeutic nature of the products in question. Thus, for the NHAA, option one is preferred.

References

Barnes, J. (2003). Quality, efficacy and safety of complementary medicines: fashions, facts and the future. Part I. Regulation and quality. *British Journal of Clinical Pharmacology, 55*(3), 226-233.

Higdon, J., & Drake, V. (2012). *An Evidence-Based Approach to Vitamins and Minerals: Health Benefits and Intake Recommendations* (2nd ed.). Stuttgart: Thieme.

Ross, A., Caballero, B., Cousins, R., Tucker, K., & Ziegler, T. (Eds.). (2014). *Modern Nutrition in Health and Disease* (11th ed.). Baltimore: Lippincott, Williams & Wilkins.

World Health Organisation. (2000). *Guidelines for the Regulatory Assessment of Medicinal Products for Use in Self-Medication*. Geneva: World Health Organisation