Dr Bradley McEwen PhD

12 May 2017

Regulatory Reforms Team
Therapeutic Goods Administration (TGA)
PO Box 100
WODEN ACT 2606

Re: Consultation: Options for the future regulation of 'low risk' products
Vitamins and minerals

Dear Regulatory Reforms Team of the Therapeutic Goods Administration,

The Therapeutic Goods Administration (TGA) is regarded as a world leader in the protection of public health. In Australia, vitamins and minerals supplements are regarded as complementary medicines and are regulated as either listed or registered medicines under the Act. The listing process for complementary medicines is a risk-based regulatory process with sponsors submitting applications via the TGA online portal. Manufacturers of listed medicines must meet medicine level Good Manufacturing Practice (GMP). At the time of submitting an application for a listed medicine, the sponsor certifies that their medicine meets all of the requirements of section 26A of the Therapeutic Goods Act 1989. Listed medicines must only include permitted ingredients, meet standards for labelling and quality and are only allowed to make low-level health maintenance and/or health enhancement and supplementation claims. All indications and claims made about therapeutic goods must be capable of substantiation. What this means is that evidence must be held by sponsors which demonstrate the indications and claims are true, valid and not misleading. Higher risk medicines must be registered on the Australian Register of Therapeutic Goods (ARTG).

The listing application process is counterbalanced by post-market regulatory oversight such as post-market compliance reviews, recall procedures and therapeutic good advertising compliance. TGA post-market regulatory activities relate to the monitoring of the continuing safety, quality and efficacy of listed, registered and included therapeutic goods once they are on the market.

The TGA also undertakes Listed complementary medicine compliance reviews. A complementary medicine may be subject to any number of compliance reviews while it remains on the ARTG. Medicines may be randomly selected or targeted for a review. A proportion of newly listed medicines are randomly selected for review by a computer, based on a mathematical model. Listed complementary medicines with potential non-compliance issues may be selected for a targeted review.

Option 1 – Maintain the status quo regulation of vitamins and minerals

Under this option, all complementary medicine (vitamin and mineral) products will continue to be regulated as therapeutic goods and are required to meet the regulatory requirements. I believe that all therapeutic goods should be required to be listed on the ARTG, regardless of their risk. Under the current system, any product making a therapeutic claim is deemed to be a therapeutic good and therefore should conform to the therapeutic goods regulations. Public health and safety are of utmost importance. The Therapeutic Goods Administration is observed to be a world leader in the protection of public health.

The benefits of maintaining the current regulatory process for vitamin and mineral products include:

- the Australian public continue to have confidence and assurance in high-quality vitamin and mineral products
- industry and profession is familiar with the regulatory requirements and do not need to invest in changing their processes
- previous consultation with industry realised a preference that these products continue to be regulated as therapeutic goods as it gives the products "a higher standing" with consumers and in national and international markets.

All levels of evidence should be utilised, such as systematic review, randomised controlled trials, non-randomised experimental trial, cohort studies, case-control studies, retrospective cohort studies, and traditional/empirical. There should be more utilisation of traditional medicine in claims and agree with the TGA that references to traditional uses are to be older than 75 years.

Manufacturers of listed medicines must meet medicine level Good Manufacturing Practice (GMP). Good Manufacturing Practice maintains the standards of manufacturing complementary medicines. For example, if the product was produced by a manufacturer not adhering to Good Manufacturing Practice guidelines and not Listed or Registered on the ARTG, it could potentially lead to adverse effects/events.

I support the TGA's post-market surveillance, especially the monitoring of adverse reactions/events to ensure the ongoing safety of therapeutic products.

The disadvantage of Option 1 is that all vitamin and mineral products in Australia (including some products with very little safety risk) will continue to be regulated as medicines rather than as food or dietary supplements imposing higher standards on quality and manufacturing than food regulation. However, this disadvantage can be seen as an advantage as it will set the bar high for the quality and safety of products in Australia maintaining their internationally known high standard.

Complementary medicine products, such as vitamins, minerals and herbal medicines, are therapeutic goods. Option 2 is not recommended due to consumer perception of the lowering of quality of the products. Option 2 could potentially impact the highly regarded international reputation of Australian goods and impact on the export marketability of these products. This option can result in lower quality products being supplied if manufacturing standards (GMP) are not appropriate. This would lead to an increase in consumer dissatisfaction and a higher potential for adverse events. Option 3 is not acceptable as it may create a consumer perception of the lowering of quality of the products. This option can result in lower quality products being supplied if manufacturing standards (GMP) are not appropriate. This could lead to an increase in consumer dissatisfaction and a higher potential for adverse events.

I propose that if there is evidence of higher level health claims of a nutrient or product and that these claims can be supported by evidence (such as systematic reviews, clinical trials), the sponsor should be able to submit these higher level claims to the TGA for assessment for potential use of the marketing of complementary medicine products. I also propose that a system be developed to differentiate complementary medicine products with higher levels of evidence, e.g. a certified symbol, as this has the potential to improve the quality and efficacy of complementary medicine products.

In addition, health literate and health conscious consumers are capable of making decisions regarding their health care coupled with the wide availability of products Listed or Registered on the ARTG and therefore know that the products are manufactured under GMP standards, e.g. safety and quality. Consumers must be made aware that products not Listed or Registered on the ARTG may not have been assessed for safety or quality and therefore should not be used due to the potential of adverse events. Furthermore, I propose that the TGA and NHMRC promote the benefits of consulting a qualified health care practitioner with training in nutrition, complementary medicine, and the health sciences when making decisions for the health and wellbeing.

Therefore, I recommend Option 1 – Maintain the status quo regulation of vitamins and minerals.

Yours Sincerely,

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