CMA Submission: Options for the future regulation of “low risk” products

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Introduction

Complementary Medicines Australia (CMA) welcomes the opportunity to provide feedback on the Department of Health's Therapeutic Goods Administration (TGA) consultation paper "Options for the future regulation of low risk products", dated March 2017.

On 8 April 2015, CMA made a comprehensive submission to the Expert Panel Review of Medicines and Medical Devices Regulation, announced by the then Minister for Health, the Hon Peter Dutton MP and the Assistant Minister for Health, Senator the Hon Fiona Nash and chaired by Emeritus Professor Lloyd Sansom AO. On 15 September 2016, following consultation with industry, consumers and healthcare professionals, the Government provided its response, which largely accepted the Medicines and Medical Devices Regulation (MMDR) recommendations.

The acceptance of recommendation forty-eight approves that the Australian Government review a range of complementary medicines currently listed in the Australian Register of Therapeutic Goods (ARTG), with the 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 *Therapeutic Goods Act 1989* (the Act).

CMA supports the main themes of the MMDR; that is to identify ways to improve access to therapeutic goods for consumers and ensure that the regulatory settings are appropriately aligned to risk and to remove unnecessary regulatory and administrative burden for industry, whilst maintaining the safety of therapeutic goods in Australia. Removal of over-regulation will help the Australian complementary medicines industry to gain its position as an innovative and competitive market that is able to meet growing consumer demands.

Executive Summary

CMA is concerned that the options for the future regulation of products deemed to be lower risk, if accepted by Government, will have a number of unintended consequences for the complementary medicines industry and consumers. This includes the potential increase to the complexity of the regulation of certain products types by restricting options to additional regulatory frameworks such as Food Standards Australia and New Zealand (FSANZ) and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). A decision to mandate the removal of certain product types (such as complementary medicines) from the auspices of the Act, does not align with the main intentions of the Medicines and Medical Devices Regulation (MMDR) review and instead will provide for increasing regulatory burden upon industry. Further, in some instances the removal of certain product types from the Register, even when considered lower risk, will change the inherent safety and quality profile of the goods potentially, enhancing the risk to the general public as demonstrated by recent adverse events in the US in relation to homoeopathic products.

The Act establishes a risk-based framework for the regulation of therapeutic goods in Australia, and it is within this risk based framework that lower risk therapeutic products, such as complementary medicines, are best situated so as to continue to uphold the gold standard in regulatory oversight that the TGA provides for the informed choice, health and safety of consumers.

What is low risk?

In determining what may be considered as "low risk", the Therapeutic Goods Administration (TGA) worked with consultants from van Gelder & Monk to develop a product assessment tool. Using the "wisdom of crowds" the tool confirmed the opinions of the consultants around the risk level of particular product types.

Of relevance to members of CMA, the following product types were considered along a risk spectrum:

- Classified as **very low risk**
  - Oral homoeopathic products
  - Aromatherapy products
- Classified as **low risk**
  - Rehydration or formulated sports products
  - Lozenges – relief of sore throats, contain anti-microbial active ingredients (OTC)
- Classified as **Medium risk**
  - Oral vitamin and mineral products (eg. water soluble vitamins & minerals such as calcium have a lower risk profile)

Review of certain complementary medicine products

While the regulator insists that the intention of the review is not to fundamentally change the definition of a medicine, as defined in the Act, should any number of the proposed options be accepted by Government that would be the result. To declare certain vitamins, minerals, homoeopathic preparations and other goods as not therapeutic goods would also alter the definition of a complementary medicine as outlined in the *Therapeutic Goods Regulations 1990* and supported by the TGA's Regulatory Guidelines (ARGCM). That is, 'complementary medicine' means a therapeutic good consisting wholly or principally of one or more designated active ingredients, each of which has a clearly established identity and a traditional use. For a complementary medicine, a designated active ingredient means an

active ingredient, or a kind of active ingredient, mentioned in Schedule 14 (to the Regulations).

This list includes the following designated active ingredients (those bolded are subject to this review).

1. an amino acid

2. charcoal

3. a choline salt

4. **an essential oil**

5. plant or herbal material (or a synthetically produced substitute for material of that kind), including plant fibres, enzymes, algae, fungi, cellulose and derivatives of cellulose and chlorophyll

6. **a homoeopathic preparation**

7. a microorganism, whole or extracted, except a vaccine

8. a mineral including a mineral salt and a naturally occurring mineral

9. a mucopolysaccharide

10. non-human animal material (or a synthetically produced substitute for material of that kind)

including dried material, bone and cartilage, fats and oils and other extracts or concentrates

11. a lipid, including an essential fatty acid or phospholipid

12. a substance produced by or obtained from bees, including royal jelly, bee pollen and propolis

13. a sugar, polysaccharide or carbohydrate

14**. a vitamin or provitamin**

The above definition, regardless of inherent risk profile or TGA resources ought not be significantly altered.

Vitamins and minerals

The consultation paper appropriately outlines that there is a variant of risk across the spectrum of vitamins and minerals that are regulated as complementary medicines in Australia; this could be said for individual ingredients generally. Many of these individual ingredients, however, are combined with ingredients of a different risk profile, such as fat soluble vitamins and herbal substances, in finished product formulations. Therefore, the inclusion of all the currently listed permitted ingredients within the regulatory system offers consumers the highest quality and safety standards that the Australian regulator is known for globally.

Medicine sponsors already have the option to elect to develop products that would fit more appropriately within other frameworks, such as Food Standards Australia New Zealand (FSANZ). Those that have chosen to meet the requirements of the TGA for listed medicines have already invested substantially into appropriate quality manufacturing systems and meeting regulatory requirements. It is important that the difference in manufacturing quality of the medicines framework is recognised for oral complementary medicines, especially when specific therapeutic indications are made.

The Government has also agreed that the TGA develop a monograph system (MMDR recommendation forty-six) that has the potential to improve the availability and accuracy of information on commonly used active ingredients for consumers and improve efficiencies for industry. Such monographs would document the evidence supporting the efficacy of the ingredients for specific indications and other relevant information.

CMA believes that the development of the monograph system, along with the current avenues provided by the high level health claims standard of FSANZ, offer ample choice

with regards to diversity of product formulation and regulatory frameworks.

CMA supports Option 1 - Status quo should be maintained .

Option 2 – Exemption from listing in the ARTG and or GMP

Under this option, certain vitamin and mineral products would be exempt from Part 3-2 of the Act – exemption from the requirements of listing and/or 3-3 of the Act – exemption from the requirements of medicinal level GMP. However, all vitamins and minerals would remain as therapeutic goods and are therefore still subject to all other regulatory requirements.

The disadvantages of the removal of ARTG listing/removal of medicinal level GMP:

- Consumer concern of a potential lowering of the quality and safety of a number of complementary medicines.
- Impact medicine sponsors where the product listing on the ARTG assists in meeting export requirements for other products.

The advantages of the removal of certain vitamins and minerals from ARTG listing:

- Reduction in fees, charges and post market monitoring across *some* products. Combination products not adequately addressed.
- Efficient access to market.

It should be emphasised that the above should also be the aims of the successful implementation of the monograph system for commonly used active ingredients, as described above.

Advantages of maintaining status quo for vitamins and minerals used in complementary medicines:

- Australians can continue to have confidence in the quality and safety of complementary medicines.
- Implementation of MMDR recommendation forty-six – monograph system for commonly used active ingredients, which would likely include, for example, commonly used water soluble vitamins such as vitamin C.

- The ability to utilise the monographs for the substantiation of evidence to support indications, where appropriate.

Homoeopathic products

In Australia, medicines containing homoeopathic preparations are considered to be low-risk medicines and are regulated under the Act. While certain homeopathic products, depending on their potency, are not required to be on the Australian Register of Therapeutic Goods and are not assessed by the TGA prior to their entry into the Australian marketplace, this does not exclude them from other provisions of the *Therapeutic Goods Act 1989* in relation to quality and safety standards. This exemption from ARTG listing does not apply, however, where the homoeopathic preparation is part of a medicine containing other (listed) ingredients requiring inclusion on the ARTG.

While the consultation paper address a number of products listed on the register as homoeopathic products, it does not adequately address product formulations which may include a combination of vitamin, minerals, herbal and homoeopathic preparations, which would represent a number of listed complementary medicines on the Australian market. For consistency, it is important that the regulations for homeopathic products maintains the ability to list on the ARTG (unless exempt), that homeopathic preparations contain only ingredients specified in the Permissible Ingredients Determination and meet any other requirements specified in relation to that ingredient, are subject to Good Manufacturing Principles (Part 3-3 of the Act) and any other applicable legislative requirements.

The regulator has stated that the intention of the review is not to fundamentally change the definition of a medicine as defined in the Act, which CMA supports. Homoeopathic preparations and homoeopathic standards are defined in the Act, and the TGA's Regulatory

Guidelines (ARGCM) provides medicine sponsors, manufacturers, healthcare professionals and consumer's guidance on the appropriate regulatory oversight of these products.

The consultation paper outlines an 'issue' that by continuing to regulate this type of product under the current regulations would imply Government endorsement of said products. This is simply not true and not the intent of the current regulatory framework for listed complementary medicines. The same concern would have to be applied to all other complementary medicines that have been listed on the ARTG, as these products (due to their lower risk profile) are able to enter the market prior to an evaluation of the evidence by the regulator.

It should be noted that as part of the reforms to complementary medicines the Government has accepted recommendation 39, to establish a new pathway for the listing of a complementary medicine, where the sponsor can elect to have the regulator assess the evidence related to a higher level indication(s) prior to its release on the market. Recommendation 38 has also been accepted, which will establish a list of permitted indications, from which sponsors must exclusively draw, for listed medicinal products in the ARTG. This will include the ability to specify indication(s) where there is supporting evidence for its use within a traditional paradigm, such as traditional Chinese medicine, Western herbal medicine and homeopathic paradigm etc.

CMA supports a hybrid of Option 1 and Option 2 combined, provided no other regulatory changes are made to the regulation of homoeopathic products in Australia.

Due to critical issues identified with regards to the National Health and Medical Research Council's (NHMRC) review of the effectiveness of homeopathy for treating health conditions, CMA provides a separate detailed submission to the regulator on homoeopathic products.

Rehydration or formulated sports products

The consultation paper highlights options for the review of rehydration or formulated sports products stating that due to their similarity with the food regulations they pose a source of confusion for the regulator and suppliers.

Recently, the TGA published the food-medicine interface guidance tool (FMIGT) to assist manufacturers and importers to know whether certain products are regulated as therapeutic goods or foods due to the different regulatory requirements that apply.

CMA supports the option to further review this category of products to ensure that oral rehydration products with specific therapeutic purposes, including those targeted to sports people, are maintained on the Register.

Note: utilising the guidance tool above to assess this type of product will most likely lead to a determination that, due to electrolyte drinks meeting the FSANZ Standard 2.6.2 (non-alcoholic beverages and brewed soft drinks), the tool will trigger the following response in the absence of a consideration for its therapeutic purpose(s) seen at question 6 onwards of the tool.

Q 4: Is the product "goods for which there is a standard in the Foods Standards Code" Y/N?
Yes - The product is not a "therapeutic good". It is likely to be "food" within state/Territory food regulation legislation and/or regulated under other state/territory legislation

It is also noted that should certain electrolyte or sports drinks (making only food claims) currently on the register transition to FSANZ there may need to be some changes made to the food standards to address this type of product so that existing products could transition without having the financial and regulatory burden of having to reformulate.

Aromatherapy

In Australia, medicinal products containing such ingredients as certain herbs, vitamins and minerals, nutritional supplements, homoeopathic medicines and **aromatherapy products** are referred to as 'complementary medicines' and are regulated as medicines by the Therapeutic Goods Administration (TGA) under the *Therapeutic Goods Act 1989* (the Act) and the supporting *Therapeutic Goods Regulations 1990* (the Regulations).

The consultation paper highlights that certain product types can be represented across a myriad of regulatory regimes (TGA, FSANZ, NICNAS), depending on their overall presentation and level of indications or claims made. To address the area of food-medicine-cosmetic interface, the Government has produced educational materials such as the TGA's Food-Medicine Interface Guidance Tool and the NICNAS Cosmetic Guidelines and Process Map (December 2016).

Whilst it is acknowledged that products that fall into the interface area can be complex, it appears that the main reason for triggering a review into the options for low risk products is the "questionable use of TGA resources". However, all complementary medicine products entered onto the Australian Register of Therapeutic Goods are subject to fees and charges, which are fully cost recovered by the regulator for activities such as post market monitoring and pharmacovigilance.

CMA supports Option 1 – maintain essential oils that make therapeutic claims as therapeutic goods on the Register.

This would benefit the majority of suppliers that are already established in the market and meet the current regulatory obligations for this type of product.

With reforms to complementary medicines appropriately implemented as part of the MMDR package, the TGA will continue to operate effectively and efficiently, while also maintaining appropriate public health and safety protections.

Thank you for the opportunity to provide the Regulatory Reforms Team with feedback. CMA would welcome the opportunity to discuss any matters relating to this submission.

About Complementary Medicines Australia

Complementary Medicines Australia (CMA) is the peak industry body for the complementary medicines industry, representing members throughout the value chain: manufacturers, raw material suppliers, distributors, retailers, practitioners and consultants. CMA promotes industry viability and growth, and a marketplace where consumers can enjoy the positive health benefits of high quality complementary medicines. We are the principal reference point for members, the government, the media and consumers to communicate about issues relating to the complementary medicines industry.

Complementary medicines include vitamins, mineral and nutritional supplements, homoeopathic, aromatherapy products and herbal medicines (unless specifically exempt). The term 'complementary medicines' also comprises traditional medicines, including traditional Chinese medicines, Ayurvedic, Australian Indigenous and Western herbal medicines. Traditional and long-term use is taken into account in establishing safety as a medicine.

Over the last few decades, the complementary medicine sector has evolved into a major industry which requires complex supply chains, clinical trials, global marketing and export acumen. The majority of complementary medicines are indicated for the relief of symptoms of minor, self-limiting conditions, maintaining health and wellbeing, or the promotion or enhancement of health. Increasingly, complementary medicines are being found to contribute to improved health outcomes, through increased effectiveness, safety and cost-effectiveness, and integration with conventional medical care.