Complementary Medicines Australia
Submission to the Department of Health

Reducing Regulation in the Health Portfolio

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To:

The Director Implementation, Compliance and Communication Section Deregulation Unit
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1. Introduction

Complementary Medicines Australia (CMA) welcomes the opportunity to provide a submission to the consultation 'Reducing Regulation in the Health Portfolio'.

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. The Australian complementary medicines industry generates $3.5 billion annually, which is expected to grow to $4.6 billion in 2017-2018.[1] CMA promotes appropriate industry regulation and advancement to ensure consumers have access to complementary medicines of the highest quality.

In general, the current framework for the regulation for complementary medicines is appropriate, but there are a number of aspects of the current system in Australia that are not commensurate with the low risk posed by complementary medicines. This has led to the creation of substantial regulatory and financial burden, particularly on small and medium-sized businesses.

Many of the recent criticisms with the current system arise because complementary medicines do not fit seamlessly within a regulatory model designed primarily to accommodate over-the-counter and prescription medicines. However, industry is of the firm belief that the current regulatory burden of compliance can be reduced without risking the safety and quality of complementary medicines available to Australian consumers.

CMA would like to acknowledge the Australian Government's commitment to adopt the principle that if a system, service or product has been approved under a comparable international standard or risk assessment, then domestic regulations should not impose any additional requirements for approval in Australia, unless it can be demonstrated that there is a good reason to do so. In line with this, CMA also welcomes the work of the Therapeutic Goods Administration (TGA) towards participation in international harmonisation to streamline regulatory requirements.

The complementary medicines industry holds a great deal of potential to contribute to Australia's health system through a focus on preventative health in Australian public policy, as well as to the strength of the economy with the appropriate recognition by the government.

For the complementary medicines industry, as for other Australian industries, putting the right regulatory environment in place will nurture, promote and enable competitiveness and innovation. 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.

[1] National Institute of Complementary Medicine, Retrieved from: http://www.nicm.edu.au/health_information/information_for_consumers/understanding_cm

2. Light touch / right touch regulatory environment

The Australian complementary medicines industry is commonly regarded as one of the most strictly regulated in the world. The escalating red tape of recent years has contributed to the stifling of product innovation, lowered productivity, reduced job creation and minimised incentive for industry investment. Industry recognises that significant work has been undertaken on the TGA Reforms: A Blueprint for TGA's Future, but has found that a number of the changes have increased the regulatory burden, without delivering a corresponding improvement in consumer safety or access to improved or innovative health products.

CMA was pleased to provide a submission to the Expert Panel Review of Medicines and Medical Devices Regulation, in particular to *Chapter Nine: Regulation of Complementary Medicines*. Please find our response to the Expert Panel attached.

In addition, please find below a summary of our industry's top three deregulation recommendations. With the implementation of these recommendations, our industry expects to save approximately $70 million per annum, which could be used for investment in growth, enhanced competitiveness and innovation.[2]

Deregulation of Ingredient Approvals

The primary factor inhibiting the growth of the Australian complementary medicines industry is considered by industry to be the lack of availability of many dietary supplement ingredients that are commonly used in overseas jurisdictions.

As a relatively small market, with costly and lengthy regulatory requirements, Australia is seen as unattractive and uneconomical for investment by both multinational and domestic companies. A combination of industry information and anecdotal reporting indicates that as consumers become more product-savvy they are increasingly turning to complementary medicines bought on international websites in order to access innovative products that contain ingredients currently not available in Australia. This is exposing consumers to products that may have been manufactured in unregulated and unsanitary conditions.

CMA supports mutual recognition of overseas regulatory decisions with regard to new ingredients, providing that the overseas regulator is established and reputable. For instance, Canadian assessment in the Natural Healthcare Products (NHP) category covers quality, safety, and efficacy of ingredients before products can be licensed for use. The TGA requires assessment of quality and safety for complementary medicines ingredients. Therefore, NHP ingredients should be accepted without further assessment by the TGA. In fact, an expedited process has occurred recently with the TGA conducting an evaluation of a species of Garcinia for use in listed medicines based on information from international regulatory counterparts in Canada. In this manner, regardless of differences in regulatory classification/listing requirements, established and reputable regulators, with appropriate processes for assessing new ingredients should

[2] CMA, Light Touch Right Touch for Complementary Medicines

be trusted, thus allowing for reduced TGA assessment by introducing a pathway to automatic or expedited adoption.

Deregulation of Marketing Approvals

Advertising reforms:

Both consumers and industry want advertising that provides accurate and adequate information about complementary medicines, whilst preventing misleading claims.

Advertising of complementary medicines is currently regulated via complex and inefficient processes. Approval for advertising is delegated by the TGA to two bodies, which often requires advertisers to seek two sets of approvals across a media campaign. The system is already limited as only a sub-set of advertising media are included; most notably the rapidly growing area of internet advertising is not covered.

Advertising complaints are also heard by separate bodies, which produces rulings that are often inconsistent with the approval previously provided for the advertisements. In effect, this means that an advertiser has to go through a preapproval process to ensure compliance, but then has no certainty that their advertisement will not be the subject of a complaint and subsequent sanctions from the Complaints Resolution Panel (CRP) and the TGA. Criticism has often been levelled at the CRP due to its lack of transparency and timelines, limited penalties and lack of appeals process.

CMA proposes that current advertising regulatory standards be maintained (such as compliance with the Therapeutic Goods Advertising Code 2007) but for removal of the onerous regulatory burden that exists because of the current pre-approvals system. It must be highlighted that the following recommendations would need to be implemented as a package of measures, strengthening the complaints system, and allowing the abolition of advertising pre-approvals.

- CMA proposes that industry associations are supported, through a co-regulatory model, in being able to enforce sanctions against non-complaint companies. To achieve this, CMA strongly recommends that the TGA requires sponsors to subscribe to an Industry Code of Practice for marketing as a requirement of listing on the Australian Register of Therapeutic Goods (ARTG). This helps move the onus away from the TGA for regulating the marketing of products and provides industry with the ability to deal with non-complaint participants.

- The CRP should be abolished and be replaced with a co-regulatory complaints handling model, potentially using mechanisms already in place to handle such matters across other advertised goods.

- CMA supports the implementation of an accreditation/licensing scheme for sponsors, as a cost-effective solution to ensuring that before a sponsor is able to list products on the ARTG they have undertaken a reasonable level of compliance training.

Access to higher level claims:

A new food standard to regulate nutrition content claims and health claims on food labels and in advertisements became law on 18 January 2013 – Standard 1.2.7 Nutrition, Health and Related Claims. Under this standard, foods are able to make stronger health claims (such as lowering high cholesterol), while having both lower manufacturing and evidence requirements, than complementary medicines listed on the Australian Register of Therapeutic Goods.

At this stage, the pathway for a complementary medicine to be able to make stronger health claims is via the registration process. This process requires a substantial data package, similar to that required for the registration of new pharmaceutical drugs, which is inappropriate for low-risk products. Registration also requires safety and toxicology data, even when the compound may have already been approved for use in listed complementary medicines sold on the Australian market (and therefore already deemed safe to be consumed in accordance with the product's dosage instructions). This is a major regulatory hurdle and an impediment to companies investing in clinical trials to validate their products, as the safety and toxicology package required could be considered as too large an investment relative to the potential returns.

CMA strongly supports a modified registration pathway for complementary medicines (entirely formulated using ingredients permitted for use in listed products) seeking to make higher level indications and health claims without the prohibitive additional cost of redundant product safety and toxicology testing. This modified registration pathway for products containing listed ingredients would remove the prohibitive additional cost of redundant product safety evaluation and be an incentive to expand the clinical research base on existing products.

Applications would be proposing only a new indication and would therefore not require the provision of a comprehensive evaluation report. Rather, an evaluation would be conducted on the evidence to support the proposed indication. Quality and safety risks would be low, given GMP requirements and ingredient safety assessments.

CMA proposes a distinct administrative category for a modified AUST R (comprising of already approved listed ingredients), to ensure the system remains streamlined and to have the flexibility of eliminating the need for a minimum two rounds of requests for information from the regulator in relation to an application.

Evidence requirements for advertising claims on listed medicines:

The TGA has recently updated the guidelines for the evidence required to support indications for listed medicines. Unfortunately, the new guidelines and associated checklists have introduced a significant regulatory burden for companies to remain compliant with evidence substantiation for their products. For example, the current evidence requirement, especially for weight loss, biomarker claims and other scientific indications (e.g. blood pressure, blood glucose and cholesterol) are disproportionally excessive to the claims that are available. The evidence base required for making

indications/claims on natural medicines should be commensurate with the low risk associated with these products.

The requirements for evidence substantiation, coupled with revised pharmacovigilance expectations for listed medicines, means that the administrative burden of compiling, monitoring, and maintaining records is substantially increasing costs and slowing innovation and efficiency. CMA strongly supports a revision of the guidelines (in addition to the checklists) to ensure they are relevant, user-friendly and consistently interpreted by users.

A deregulatory approach to evidence requirements should apply to products with low level, health maintenance and structure function type indications, removing some of the regulatory burden for this category of lowest risk medicines. Australian Consumer Law remains as a strident backdrop ensuring consumer goods are promoted in a way that is truthful and not misleading.

Deregulation of Manufacturing Complexity

The *Complementary Medicines Industry Survey 2014* highlighted that the complementary medicines manufacturing sector feels the pressures of excessive red tape, with 83 per cent of manufacturers claiming excessive regulatory burden as the biggest challenge affecting their business.[3]

Complementary medicines are currently manufactured under the Pharmaceutical Inspection and Co-operation Scheme (PIC/S) GMP, which is essentially designed for pharmaceutical manufacturing. As the PIC/S standard evolves and is updated, the new additions and changes become increasingly burdensome for low risk complementary medicine product manufacturers. There have been a number of exceptions and specific interpretations by way of guidance documents to fit complementary medicines manufacturing to the PIC/S Code. This can make certain requirements overly complex and difficult to be consistently audited against. Developing and implementing further Australian specific complementary medicines concessions with each review of PIC/S Code is generally required, is resource intensive for both the TGA and industry, and is unsustainable in the long term.

Manufacturing standards for complementary medicines should be aligned with the PIC/S Code of GMP, but adoption of revisions of the PIC/S Code should occur on an opt-in basis, rather than an automatic adoption and subsequent development of the necessary exemptions and/or interpretations.

[3] CMA, Complementary Medicines Industry Audit 2014

3. Other Considerations

Protection of Innovation via Regulatory Mechanisms

Data protection is a well-established methodology in the regulatory systems of most developed countries, including Australia, to provide adequate incentive for product innovation, recognising that significant investment is required to generate and provide data to gain regulatory approval. However, for the complementary medicines industry, the commercial reality of 'difficult-to-obtain patent protection' to recoup clinical trial costs has and always will limit the amount of clinical trials being conducted to provide scientific evidence for complementary medicines. In this area, complementary medicines are always at a disadvantage when compared to pharmaceuticals.

The current situation is preventing businesses from reinvesting in their Australian operations and driving manufacturing, and R&D, offshore. In addition, it prohibits Australia from attracting global complementary medicines companies for foreign investment.

A possible solution is to develop Regulatory Protection mechanisms for CMs in addition to the standard and innovation patents to stimulate investment and innovation. Please see our submission to the Expert Review panel for examples of how this could be achieved.

Integration of complementary medicines into the health care system

Complementary medicines play a significant role in allowing individuals to maintain a high level of physical and psychological wellness, and have the potential to assist in the reduction of the ever-increasing healthcare costs associated with chronic disease.

Complementary medicines have long been used for health maintenance and in disease prevention and treatment, particularly for chronic disease. Despite this, as indicated in the WHO Traditional Medicines Strategy 2014-2023, complementary medicines are often an undervalued and underutilised part of health services and health policy despite their potential importance and contribution[4]. The WHO highlights a growing global recognition by many countries for the need to develop a cohesive and integrative approach to healthcare that allows governments, health care practitioners, and most importantly, consumers, to access complementary medicines in an effective and safe manner.

The use and further development of complementary medicines provides an opportunity to counteract spiralling health care costs through more effective disease prevention and preventable chronic disease management, and potentially less reliance on the hospital system and the PBS.

[4] World Health Organization, WHO Traditional Medicine Strategy 2014-2023

4. Conclusion

Complementary medicines play a significant role in allowing individuals to maintain a high level of physical and psychological wellness, and have the potential to assist in the reduction of the ever-increasing healthcare costs associated with preventable chronic diseases. As highlighted in the WHO strategy, complementary medicines have a long history of use in health maintenance and in disease prevention and treatment. In Australia, the complementary medicines industry has much to offer in terms of contribution to the preventative health agenda.

The complementary medicines industry supports regulation of complementary medicines products that is appropriate and commensurate with the low level of risk these products represent. 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.