



***Complementary Medicines Australia*** submission to the Therapeutic Goods Administration consultation: *Increased online access to ingredient information (Publication of excipients on the ARTG).*

**October 2019**

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## Introduction

Complementary Medicines Australia (CMA) welcomes the opportunity to provide comment on the TGA's consultation on the draft Therapeutic Goods Advertising Code and associated guidance material.

CMA is committed to a vital and sustainable complementary medicines sector, and represents stakeholders across the value chain – including manufacturers, raw material suppliers, distributors, consultants, retailers and allied health professionals. The consumer demand for complementary medicines has resulted in the industry becoming a significant contributor to preventative and complementary healthcare. Over the last few decades the Australian complementary medicines sector has evolved into a world class industry supporting domestic skilled jobs, research, manufacturing and exports. Australia has emerged as the key exporter to China over our larger and more powerful global competitors are a major force. Adequate and balanced policy are important to ongoing success and the Australian Government must adequately and cautiously preserve existing regulation.

## Position

CMA supports option 2 – maintaining the status quo for listed and complementary medicines. Our members have made it very clear that this will be a significant and ongoing issue for companies and leading Australian businesses if a policy change is enacted, and noted that there is not any strong regulatory case to remove the status quo.

The complementary medicines industry is strongly in opposition to the publication of excipients for listed medicines and registered complementary medicines, and therefore, are only in support of Option 2 – Status quo, for the reasons outlined in this submission. Reasons include;

- Protection of intellectual property, research, and innovation and the propensity for domestic and international copying of formulas, with far reaching negative effects on Australian industry leaders and also on consumers.
- The regulatory problem identified and the Australian Government Public Data Policy Statement does not sufficiently support the newly proposed publication option 1A or 1B.
- There are adequate safety controls and information channels are available for consumers are in place for self-selected medicines, particularly listed medicines for which consumers have a wide market choice.

The safe use of medicines is important, however there is not any serious regulatory case supporting the release of proprietary company knowledge over and above existing adequate controls. Any regulatory changes must be stimulated by a serious problem, which is not the case – with the status quo in place for well over 30 years.

Government policy must be balanced with protecting and sustaining the needs of growing industry in a competitive and easily imitated environment for complementary medicines. Much of the individual success of leading companies can be attributed to the research and development of excipient formulae, which is underpinned by proprietary information. Further, the full and long-term impact on consumers of cheap, non-GMP product imitators that will occur under proposal 1A/1B has not been considered for either industry or consumers.

## Discussion

### Intellectual property, research, and innovation protection

Listed medicines are not protected by patents and chemical entity exclusivity, unlike many registered medicines including prescription medicines. Patents protect companies from having their medicines copied, and therefore protect the income generated by those products. Consequently, for unpatented products, leading Australian companies invest a significant proportion of their research and development into constructing palatable, appealing products, with effective performance characteristics to ensure a unique market position. This may be for several reasons, including to enhance and champion a unique or innovative flagship product, or to differentiate the appearance, performance, or characteristics of a commonly used listed medicine ingredient to differentiate the style and quality of the brand from others in the marketplace.

Listed medicine formulas in Australia are not protected sufficiently by protection of the specific active ingredient content, in stark contrast to the largest international competitor, the United States. Here, a proprietary blend of active ingredients is presented as a single quantity, without detailing of the individual weights of individual active ingredients. This is a very powerful protector of trade knowledge and intellectual property of individual companies. However, this approach removes meaningful information from consumers and it has not been a path pursued by the Australian complementary medicines industry, particularly as formula protections have been in place, namely the protection of excipients.

In Australia, formulation protection is critical to company longevity as substantial resources have been invested in formulating those medicines. These formulation differences often confer a commercial advantage to those companies that invest in the research and development to achieve this, and the income generated pays for that research and development. It also protects Australian companies from loss of investments and sales from domestic and overseas imitators.

Should proprietary information or intellectual property such as non-active ingredients be made public by the Government it will have some immediate and long term effects. In the immediate future it is likely that medicines

will be copied and released for supply, very easily. This will have immediate effects on sales and seriously affect commercial viability.

The consultation paper drew reference to NZ and Canada, however, NZ is a food-based system and Canada are not one of the leading exporters at threat of copying of individual formula. The United States and Germany are the key market competitors and emerging Asia-Pacific countries are also presenting the highest risk of long-term competition, particularly when formulations are easily imitated at a far lower cost with lower manufacturing controls and sold on to Australian and international consumers, decimating a key pillar of Australian business advantage.

Potential long term effects are stifling innovation as there will be little incentive for companies to invest in developing new innovation. The impact of this is stagnation in a [currently expanding industry](#), which has doubled in its rate of growth in the past 10 years, is strongly export focused, and which as at 2018 supported 29 100 jobs and contributed \$4.9 billion in revenue to the Australian economy.

Like many sectors, the intellectual property of medicine companies is critical to their success and therefore growth. The Australian Government department IP Australia actively recognises and encourages sectors and companies to [identify, protect and commercialise](#) their intellectual property. Creating pathways for this to be compromised is contrary to existing governmental policy.

### The regulatory problem

Significant changes to medicine policy regulation based on safety concerns are generally made in response to known signals either domestically or internationally. The TGA consultation document does not list any known reactions or proportions of adverse reactions that can attributed to excipient ingredients in medicines other than those that are already well recognised and therefore required to be declared on medicine labels. The level of risk is not stated in the document, beyond the known rise in allergic disease in Australia. However the proportion of which is contributed by medicines is not stated in the [National Allergy Strategy](#). Therefore, the regulatory issue does not appear to be adequately defined or of such significance or magnitude that it requires providing full public access to excipients, to the large detriment of the industry and with unintended and unexamined serious policy consequences for industry and consumers.

The vast majority of known allergens are included in the First Schedule in the labelling order, the Therapeutic Goods Order No. 92, which was recently expanded to include a comprehensive list of known allergens which require declaration on the label:

### **Allergens required to be declared under schedule 1 of TGO 92**

- Aspartame
- Antibiotics
- Benzoates
- Crustacea
- Egg, egg products
- Ethanol
- Fish and fish products
- Galactose
- Gluten
- Hydroxybenzoic acid esters
- Lactose
- Milk and milk products
- Peanut and peanut products
- Phenylalanine
- Pollen
- Potassium salts
- Propolis
- Royal jelly
- Saccharin
- Sesame seeds and products of
- Sodium salts
- Soya beans and products of
- Sorbic acid and salts of
- Sucralose
- Sugar alcohols
- Sugars – mono, di saccharides
- Sulfites
- Tartrazine
- Tree nuts and products of

This information is immediately available to consumers at point of sale (either on the label or the place of digital purchase) and provides the overwhelming bulk of relevant excipients.

Therefore, the regulatory issue with allergens is already largely addressed and recently improved in respect of common allergens. Rare and idiopathic reactions to remaining ingredients can also occur in relation to active ingredients. If there is a rare and unusual response to a particular medicine, it is best that the consumer communicates with the sponsor so that the events do not go unreported and so that consumers are not operating on partial information or information out of context.

It isn't clear how the additional information will provide any meaningful benefit other than a very slightly faster means of consumers accessing information that they are already able to access through sponsors, if consumers become sufficiently savvy to use the available TGA IT systems. The consultation document states that consumers are seeking more information online. However this is not the experience of CMA members in respect of specific product detail, who say that most consumers contact the company directly about all aspects of their medicines including excipients, being mostly unaware that the ARTG exists or that it is repository for information about medicines. Conversely, all medicine companies are aware of the ARTG and know what to look for and where to find information about competing medicines. Therefore, it appears that the proposed changes are unlikely to solve the issues of consumer access to information and only improve competitor access to proprietary details. The method of sponsors choosing to provide proprietary information on an "as needs" basis to consumers provides an important mechanism to prevent trade property being disseminated to competitors.

### Creation of discorded approach between 'proprietary ingredients' ('PIs') and non PIs

Only some flavours and fragrances are proprietary ingredients. This will create a significant publication discord between PI and non-PIs. Further, flavours, fragrances, and colours represent some of the most significant aspects of the proprietary information about a product.

### Listed Medicines as consumer goods

Listed medicines are drawn from a list of commonly available ingredients. The excipient matrix is the main proprietary difference between complementary medicines. As a result, for most complementary medicines there is a wide range of brands that a consumer can select their ingredient of choice from. Consumers are not under medical obligation to take listed medicines in the treatment or prevention of serious or high risk conditions, and can therefore choose not to take a listed medicine or to choose a sponsor that have the disclosure policies that suit their needs. In the event the product has been recommended by a healthcare practitioner, the consumer still has the choice of product to purchase.

The majority of sponsors will provide an answer if a consumer is seeking a response to a particular rare excipient of concern. Many complementary medicine sponsors go to extensive lengths to gather information on rare substances of concern to consumers to assist their queries, for example, the presence of celery, mint, or other unusual allergens. These types of substances would never be disclosed on an ARTG entry but would be disclosed if requested by a consumer to a sponsor. The publication of excipients on the ARTG not only breaks down that relationship, but may result in incorrect assumptions based on the online publication information.

As consumer goods are largely selected by choice or with a large choice if HCP recommended, with consumer-sponsor communication key to best outcomes, and with excipients as the key proprietary protection of product and business, the Australian CM sector overall consider it critical that the publication of excipients is not mandated.

## Proposal 1A/1B not supported by Government use of data policy

The consultation paper references the [Australian Government Public Data Policy Statement](#), however, this document does not support the proposal. The Statement provides that (relevantly emphasised):

The Australian Government commits to optimise the use and reuse of **public data**; to release **non sensitive data** as open by default; and to collaborate with the private and research sectors to **extend the value of public data for the benefit of the Australian public**.

Where; *'Non-sensitive data is anonymised data that does not identify an individual or breach privacy or security requirements.'*

This data is not public, it is not anonymised, and it is sensitive data. It is the proprietary and innovated data of individual companies, with the exception of prescription medicines which are patent protected and which are also prescribed for high risk medical conditions, unlike consumer goods such as listed medicines. In the case of listed medicines, excipient matrices can be the only proprietary protection for active ingredients that are widely available and unprotected. Australian complementary medicine companies make serious investment into investigating optimal and proprietary dosage format presentations, and they do not consent to release of this data for listed and complementary medicines. Our member sponsors large and small are in contact very regularly with their consumer base when consumers have concerns, and our members have not identified through this decades long process that there are pre-existing, or emerging safety issues that newly warrant full publication of sensitive trade data.

The Statement upholds commercial confidentiality provisions, for example "Australian Government entities will: ... **uphold the highest standards of security and privacy** for the individual, national security and **commercial confidentiality**;"

## Copying of formulas by domestic and international competitors is key issue

It is widely recognised in industry that copying formulas is already widely practiced in Australia, particularly, the less scrupulous copying of formulations of larger companies that are willing to conduct the research, innovation, and marketing of successful products, that are then copied by others. The online availability of excipients will unlock the ability for a total formulation copy and near-identical copies of the leaders in innovation and research to enter the market. It should be noted in this context that the lack of publishing excipient quantities is not protective as this can easily be adjusted once the key excipient ingredients are known.

Industry formulators have also confirmed that once key excipients are known, it provides key information about the use of particular production techniques that may be proprietary. This makes the sharing of proprietary information much more severe than the sharing of excipients alone. Further, it can easily point to the use of particular suppliers



which a company does not wish to be available to competitors wishing to copy formulas.

Formula copying of actives is already known to be unfortunately well known and increasingly attractive. The use of a proprietary excipient matrix with particular colours, flavours, or physical properties is the only way that some companies can ensure the ongoing adequate differentiation of their products that in some cases have been available for decades. Some sponsors already have webpages advising consumers to be cautious of imitator products that are printed in purposefully deceptive packaging to imitate the overall presentation of a well known and successful product, but who are unable to imitate the overall properties and performance characteristics of a product as they do not have access to the excipients (which also provides access to techniques). ARTG publication of excipients would remove these barriers and result in indiscriminate close copies.

### Unintended long-term consequences on consumers and industry

As acknowledged by the consultation paper, we are now, and particularly in the listed medicine space, operating in a global market. Australia has been a highly visible and successful component of that international demand, which has attracted copying not only of formulas but of trademarks in less regulated districts. The online accessibility of excipients would represent the final removal of protected intellectual information for Australian companies, and result in the effective copying of Australian formulas in a non-GMP, far cheaper operating environment. This would not only detriment Australian sales significantly and hurt the local industry, it will further draw Australian consumers to cheap imitator brands that are easily and rapidly available on websites that are aimed at the Australian consumer.

Large warehouses set up in neighbouring countries for the sole purpose of rapid dispatch of low price (and non-GMP) supplements to Australian consumers. Examination of this trend suggests that this is an increasing risk to the Australian consumer, with CMA commissioned surveys revealing that 1 in 5 Australians are now purchasing supplements online. The removal of formulation protection mechanisms allowing low-price but physically identical or similar imitator formulas will significantly speed this process, to the health detriment of local consumers and the subsequent reputational detriment of the Australian Government. The availability of non-GMP or contaminated supplements without regulatory oversight is a far larger long-term risk. CMA members support consumers accessing excipient information, where required, directly from sponsors as per the status quo.

## Public ARTG access to Schedule 1 excipients.

In recognition of efforts to better communicate known allergens and substances of concern, the complementary medicines sector acknowledges that publication of existing allergens and substances of concerns that are in Schedule 1 of the TGO 92 (labelling order) would provide another avenue of ensuring this is communicated. This is agreed as a possible way forward provided that:

- There is no additional red-tape or regulatory burden imposed. Industry is already at maximal capacity in administrative changes under existing reforms and does not support additional burden.
- That it is made clear to consumers that the label and digital point of sale is the more complete list of all substances of concern, under the new policy that occurred with the introduction of the TGO 92 'substances' vs 'excipients'.

## Summary

- Consumers can already access relevant information on excipients, including allergens and substances of concern, through labels and digital point of sale material.
- There are serious commercial impacts of making this information publicly available, however the actual risk posed to consumers of non-active ingredients has not been identified or adequately outlined in terms of the regulatory problem and its magnitude or significance beyond existing regulatory controls on allergens and other substances of concern.
- Other Government policy, including access to public data, intellectual property policy, and the national allergy strategy, do not appear to have any elements strongly in favour of the proposed publication options 1A or 1B.
- It is important that consumers remain in contact with product sponsors if there is an unexpected reaction, so sponsors can communicate appropriate information to the consumer particularly in relation to a 'substance' present rather than an 'excipient'; secondly so that sponsors can record the reaction and monitor any issues or trends arising.
- Other rare occurrences can be identified by contacting the sponsor. Sponsors are incentivised to provide information to consumers, but it is important that sponsors are directly involved with the consumer to prevent dissemination of proprietary information to competitors.
- Industry formulators have provided that with the current information on active ingredients, combined with the list of excipients on the ARTG, would make it extremely easy to create virtually identical competitor formulations, including possible identification of competitor techniques and processes.
- The consequences of disclosing excipients publicly, and therefore full formulation details (aside from excipient quantities, which are largely irrelevant to the concern), will disadvantage researchers and innovators in the listed medicine industry and will have serious anti-competitive effects locally and

internationally that are not justified by the problem outlined when the above points are taken into consideration. This will be a serious political issue for leading Australian sponsors and manufacturers.

- The Australian listed medicine industry is in a fiercely competitive global environment where the primary competitor is the United States, who have even greater proprietary protections by the protection of active ingredients. The comparison to the Canadian system is not relevant to the global marketplace. The NZ system is a food based system and not comparable to Australia.
- The risks to Australian businesses from very close domestic and international copies is extremely large and the industry, particularly industry leading companies, are strongly against a proposal to remove existing protections. There will be unintended consequences on Australian consumers, as it will flood the online digital marketplaces with extremely low cost imitators of Australian products and well-known brands. These products are not required to be produced under GMP and introduce far more serious safety and quality risks to Australians than the current proposal prevents.
- The risk-benefit analysis does not in our view outweigh the significant risks that could result, particularly as the benefit is already served by consumer contact with sponsors. The degree of commercial impact on the listed medicine sector, does not appear to be commensurate with the level of risk identified by the non-active ingredients.
- The status quo could be accompanied by additional information to help consumers identify how to contact sponsors.
- There is no objection to the publication of existing Schedule 1 of TGO 92 excipients on the ARTG, provided that:
  - It does not introduce any new regulatory burden for sponsors who are already at maximum capacity delivering MMDR reforms. and which would be contrary to Government red-tape goals; and
  - It clearly acknowledges that only excipients, rather than ‘substances of concern’, are capable of being captured on the ARTG and therefore it will not be as comprehensive as product labels.

## Conclusion

Thank you for the opportunity to comment on this important consultation. CMA does not support the disclosure of excipient ingredients on the ARTG for listed medicines as it would compromise the commercial viability of the industry unnecessarily and in response to a risk that isn’t strongly supported by the available need. There are potentially large outcomes for industry and consumers that Government have not adequately considered, considering that existing regulatory controls are sufficient. Option 2 is considered the only viable option for listed and complementary medicines, with the potential of the publication of existing Schedule 1 excipients on the ARTG provided there is no additional regulatory burden and that consumers are informed appropriately that labels are the more comprehensive source of information.