Consumer Healthcare Products Australia

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ARTG excipients project
Scientific Operations Management Section
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Dear Sir/Madam

Consultation: Increased online access to ingredient information

Thank you for the opportunity to provide feedback to this consultation.

CHP Australia is the leading voice and industry body for **manufacturers and distributors of consumer healthcare products**, which includes non-prescription medicines. We strive to advance consumer health through **responsible Self Care** and were previously known as the Australian Self Medication Industry (ASMI).

Our key priorities for the industry include **improving health literacy**, **growing the consumer healthcare products industry** and **increasing access to medicines** where appropriate.

In principle, CHP Australia accepts the expectation of transparency of excipients within a therapeutic product through provision of a qualitative list of excipients in the product's public Australian Register of Therapeutic Goods (ARTG) record, however we would like to be clear that:

- This regulatory proposal will not address the problem statement identified in the consultation paper in relation to allergies to help consumers:
    - *"make informed choices about what products to purchase and which to avoid"*
    - *"identify when specific ingredients may have contributed to an adverse reaction"*.
- This initiative is unlikely to reduce the volume of calls to the TGA or to consumer information lines provided by members and may in fact increase the volume.
- Most consumers and many health professionals will not be aware of the ARTG, so a public awareness campaign will be necessary to alert them where to look for a medicine's excipients and how to access the information.

- Educational information will be vital to assist consumers understand what information will and will not be provided, what it means and what to do if they have further questions from the information provided.

Consultation questions

Q1. Which is your preferred option? Why?

For Other Therapeutic Goods (OTG) our preferred option is Option 2

For non-prescription medicines (both registered and listed, including complementary medicines) our members have been divided between Option 1A and Option 1B typically dependent on whether members are directly impacted by loss of proprietary information. From a principles basis we believe that providing the full ingredients list for any proprietary ingredient is in conflict with the proprietary ingredient process and the framework under which PI suppliers have provided the information to the TGA. We therefore advise the only viable option is 1B.

See details on why these options are preferred under the heading *The options presented*.

Q2. What are the risks and benefits (e.g. commercial, consumer safety, innovation) for each of the options proposed?

The risks and benefits are explored throughout the body of the response.

In summary:

Benefits

- Transparency of the excipient information – where it may be beneficial to healthcare practitioners and consumers with an understanding of what will be provided and a very clear understanding of its limitations.

Risks

- For industry:
    - loss of proprietary information, particularly with respect to aesthetics of a product like flavour or fragrance or to the performance of a product from a PI which contributes to the usability or effectiveness of the good.
    - the potential for reputational damage from consumers perceiving inconsistency between the ARTG record with the product in the market.
- For consumers – a high potential for misinterpretation of the information provided. For example,
    - in not finding the common name or sources of an allergen for which a consumer has a known reaction, not appreciating that the allergen could still be a

component or contaminant of an active or excipient in the medicine, and the mistaken assumption the product is safe,

- in reading the name of a PI in the list of excipients which includes an implied claim 'lactose free' the mistaken assumption is made that the claim relates to the therapeutic good.

Q3. If Option 1A or 1B is implemented, are you interested in collaborating with us to help communicate this information to consumers?

CHP Australia are willing to assist as part of a team in designing the necessary communication to consumers and health practitioners. See more detail on the types of information we believe will be necessary to support this proposal under the heading *Awareness and accompanying information*.

Background

CHP Australia acknowledge that food and cosmetic labelling provide consumers with a list of the ingredients present in the product and these listings also make similar allowances for complex ingredients like proprietary ingredients (PIs). Medicine labels are small in comparison to foods and the amount of information necessary to be provided, particularly for non-prescription medicines, is large relative to both food and cosmetic labels. We agree that the provision of an excipient list on medicine labels is impractical from the perspective of space and appreciate that this is not being considered as an option.

The medicines industry is well into the process of implementing common allergen warnings on labels as part of the implementation of the Labelling Order (TGO 92) and is also required to provide allergen information or to indicate "this medicine may not be right for you, read the label before purchase" as part of new therapeutic goods advertising requirements. Allergen warnings are not required in the advertising of foods or cosmetics.

Our members have for many years been committed to providing effective consumer information lines to address consumer and health practitioner enquiries. Members advise us that large numbers of calls are taken with regards to the contents of medicines. They are providing details on allergen risks and suitability of products for restricted dietary requirements or for cultural/religious requirements. They also advise there are some instances where consumers demand confirmation a product is 'free from X' and it can be difficult explaining the absolute nature of this terminology to the satisfaction of the consumer. Additionally, they advise there are high numbers of calls relating to confirmation the product is suitable for vegans or has religious and cultural certifications.

Based on member experience of the many calls to their consumer information lines we can advise that publishing the name of the excipients on the ARTG is unlikely to address the types of information consumers need to confirm. We therefore do not anticipate that this initiative will

reduce the number of calls received either to our members' consumer information lines or to the TGA. Further, it will not result in any regulatory benefit in terms of cost reduction in the provision of these services.

Awareness and accompanying education

CHP Australia would be interested to understand if TGA have information on the current usage of the ARTG by domains (@domain.com) that are unrelated to the therapeutic goods industry. We would anticipate that the current level of usage of the ARTG by health practitioners would be low and use by consumers rare. This means that significant resource and investment would be required to promote the awareness that ARTG can be accessed to identify the excipients in a medicine.

Additionally, educational information on how to access a product's ARTG record as well as information to accompany the excipient detail will be important. It is unclear how this will be provided to the consumer before reviewing the information within the public ARTG record. The consultation paper does not consider this need or how educational information might be provided. For other databases like DAEN and SARA this educational component is provided via the landing page, with the user required to confirm that they understand certain caveats before proceeding to use the database. The ARTG is already publicly available so it is unclear how the education would be provided. From an educational perspective we advise that:

- It will need to be clear to consumers that the ingredient names will be presented as Australian Approved Names (AANs) i.e. in scientific nomenclature, and those names alone may not provide an understanding to address their concerns. For example, even where the allergen of concern is an excipient included in the medicine as an excipient, the ARTG entry will not provide common names like 'peanut' consumers may need to be looking for *Arachis hypogaea* and instead of Soya bean – *Glycine max*.
- Medicines use different terminologies from food and cosmetics, for example the E numbers that consumers are familiar with in foods are not a terminology used in medicines, so further research may be necessary with regards the ingredient and its likely sources, before the consumer can assume the product is appropriate for them.
- Clarity that the excipients will be listed in alphabetical order and not by descending quantitative order as is the norm for food and cosmetic labelling.
- There is potential that in viewing the ARTG record consumers may identify issues that raise further concerns for them, leading to new types of questions being asked of TGA or of sponsors about products. For example, the apparent mismatch between those declared substances on the label and the excipients listed in the ARTG. The label may state *"contains: Soy, lactose, gluten, sulfites, egg, and pollen"* but these may not be excipients in the product and will therefore not be in the list of excipients in the ARTG. The label statements instead indicate sources of materials used to make the excipient or

components / possible contaminants in those source materials or from the process to produce the excipient. This is a significant issue for members as there has been a concerted effort by the TGA and industry over a prolonged period of time to establish the non-prescription medicine label as the principle source of information (e.g. "Always Read the Label" in advertising).

- Consumers will need advice for what to do if they have questions from the information provided.
- Explanation of terminologies that need to be used around declaration of allergens and the issues with terms like "X free" or "free from X".

The options presented

CHP members would first appreciate understanding if the recent reforms to provide allergen information on labels and in advertising is addressing the issues faced by consumers before further investing in awareness campaigns and education for a proposal which we are unconvinced will address the problem statement.

Members differ in their opinion on the best option to proceed for non-prescription medicines (both registered and listed, including complementary medicines) between 1A and 1B typically dependent on their exposure to loss of proprietary information for their products.

It was a surprise to us that the TGA were prepared in option 1A to make available a list of excipients within any proprietary ingredient (PI), given that the purpose of PIs is to protect the proprietary information with respect to complex starting materials. This is contrary to, and incompatible with, the purpose of the proprietary ingredient system. This was particularly surprising given the TGA has repeatedly refused a request from CHP over several years to require the provision of just those declarable substances within proprietary ingredients to be made available within each PI entry, as was provided many years ago but later removed without advice.

By way of comparison, if a compound ingredient is added to a food at less than 5% then the ingredients of that compound ingredient is not required to be included in the ingredients list unless it contains an allergen, then the allergen needs to be declared. We also note that legislation in Europe requires manufacturers of flavours and fragrances to disclose the potential allergens they might commonly contain. We therefore believe that TGA should investigate requiring all suppliers of PIs to disclose in their applications the potential allergens, consistent with the requirements for sponsors of therapeutic goods, and should use the provisions of section 61 of the Act to release this restricted set of information within the PI entry.

Members with OTG products such as disinfectants and sterilants advise that option 2 (status quo) should remain for disinfectants included on the ARTG. These products are unlikely to be of concern with regard to allergy (incidental dermal contact only). Additionally, with the recent reforms to disinfectant regulation, making those disinfectants previously listed now exempt

goods, the proposal to include excipient information would now only be available for a limited number of disinfectants, creating an uneven requirement for this disclosure. From a loss of proprietary information perspective, it would be those disinfectant products making specific higher-level claims that would be required to share their excipient listing, where exempt disinfectant products, making standard claims, would not. It is also noted that the overseas countries referred in the consultation paper as currently disclosing ingredients, do so only for medicines.

We propose that in principle all proprietary ingredients should be included by purpose only (not by the proprietary name, not by the PI number and not by having to list all the ingredients). To support this proposal, all proprietary ingredient suppliers should be required to provide allergen declarations in their PI entry so that the product sponsor can access and provide the necessary information to the consumer.

The reasons for this are:

- If the formulation of the PI has been given confidentially to TGA by the ingredient supplier, then TGA need to carefully consider the legal obligation to retain the confidentiality of that information.
- There is limited potential benefit for the consumer to see the ARTG name for PIs, such as capsule shells or coating solutions etc.
- Some PI names include claims or implied claims such as 'natural', 'nature identical', 'artificial', 'preservative free', 'bovine free', 'lactose free', 'vege', 'vegetarian', 'halal'. Sponsors of products have no control over the names of proprietary ingredients. If TGA publish the PI names and the name includes a claim or an implied claim, then TGA must be responsible for ensuring that the claim is not misleading and is substantiated. If an ingredient on the excipient list includes a claim of 'vegan' consumers may think the whole product is vegan when it may not be and if that happens it would be as a result of circumstances completely out of the control of the sponsor.
- The groups order allows for the removal or addition of an ingredient that is used only for the purpose of fragrance, flavouring, printing ink, or colouring. Should the names of the ingredients in the PI, or the PI number, or the PI name, for these types of PIs be published in the excipient listing of a product, and then a grouping application be made to change the PI, the change would be reflected immediately in the ARTG entry, but the revised product in the market would not change for some time. During this time the details in the ARTG could be misleading to consumers (as the ARTG entry would only relate to the more recent of the two possible labels in the marketplace). This inconsistency can be avoided by publishing only the purpose of these PIs.
- In general flavours and fragrances tend to be very important attributes of many medicinal products. If the excipients including the PI names and numbers are published for a non-prescription medicine it would be very easy for a competitor to make a copy of the

market leader in a category using the same active ingredient and achieving the same flavour or fragrance profile as that product. In foods and cosmetics flavours and fragrances are only required to be declared as flavour/flavouring or fragrance.

CHP Australia accept that transparency can empower consumers but only when the information is provided with context around how it can be used. We therefore express concerns that this proposal, to provide the list of AANs of the excipients within a product in alphabetical order in the public ARTG record, does not address the proposed problem statement – availability of allergen information. Our concerns are that without context the proposal creates significant potential for consumers to misinterpret the allergy risk of a therapeutic product. Therefore, should TGA decide to proceed with this proposal we recommend that significant educational measures will be required to mitigate that risk. We recommend that careful design and testing of the presentation of the information be conducted with consumers prior to proceeding to implementation. CHP Australia is willing to give support to the design and testing process as well as the awareness and communication requirement.

As the TGA consultation proposal involves modification to the ARTG entry, which is only available online, this recognises the benefits of implementing a digital solution to the problem. However, we feel that there must be a better and more cost-effective digital solution for provision of this information to consumers with appropriate context. It is not hard to imagine that access to real-time additional information about products could be made available using technologies such as QR codes or Apps that can scan barcodes. As indicated above, a complete set of allergen information can only really be provided and maintained by the sponsor. We suggest that the best way to develop an effective solution is to use the combined insights of all stakeholders. We therefore would encourage the TGA to convene a multi-stakeholder workshop to develop such a solution before proceeding further.

Please contact me if you have any further questions or comments on the information provided. CHP Australia looks forward to participating further in delivering effective consumer information. Many thanks again for this opportunity to provide our perspective to this consultation.

Kind Regards

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