

ARTG excipients project
Scientific Operations Management Section
Scientific Evaluation Branch
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

Dear madam/sir,

Accord is pleased to provide this submission to the consultation *Increased online access to ingredient information*.

Accord is the peak national industry association representing the manufacturers and marketers of formulated hygiene, cosmetic and specialty products, their raw material suppliers, and service providers. Accord member companies make and/or market fast-moving consumer and commercial goods including hygiene, personal care and specialty products, sunscreens, food contact sanitisers, industrial and agricultural sanitisers, disinfectants and specialty commercial products. Member companies include large global consumer product manufacturers as well as small dynamic Australian-owned businesses. A list of Accord member companies is available on our website: <http://accord.asn.au/about/members>.

Headline statistics¹ for our industry's economic footprint include:

- Accord's membership is approximately 100 companies.
- Collectively, Accord member companies directly contribute more than 12,000 full-time equivalent jobs.
- Nationally, more than 175 offices and more than 65 manufacturing sites are operated by Accord member companies.
- 80% of member companies export products overseas

We note that the purpose of the consultation has been described as a response to "consumer frustrations that they cannot easily access this information through existing mechanisms". However, we remain unsure as to the extent of these frustrations (particularly given that the current system has been in place for many years), and whether they are likely to be resolved by the proposed Option 1.

In the experience of one of our large multinational member companies with a large range of non-prescription therapeutic goods, requests for information on excipients are uncommon, based on real consumer inquiries received. Only 5-6 inquiries of this nature are received each year by the company, across all of their consumer communication channels (phone, email, Facebook). The consumers who have asked this company for excipient information were familiar with allergens or had been asked by their medical provider to ask about very specific ingredients. However, these specific ingredients (e.g. lactose) would already be declared in accordance with the TGO for labelling of therapeutic goods.

¹ Results from Accord Industry Size and Scale Survey 2018

Members have advised that the majority of consumer contacts received on products containing potential allergens are in regard to substances such as lactose, gluten, animal derived ingredients, and are interested in what the product does not contain, rather than what it does. In this respect, the proposed Option 1 may not address the consumer information need suggested by the consultation paper.

Moreover, it has been suggested that not many consumers may be aware of the ARTG as a potential source of information. We are somewhat surprised that the TGA would be considering developing the ARTG as a key information source for consumers seeking information on the ingredients of particular therapeutic goods, as our member companies already make ingredient and allergen information accessible to consumers in various ways such as on product labels, on product websites and also by way of dedicated consumer information contact points (free call lines, email, social media etc.).

Inclusion of excipient ingredient information in the ARTG for non-prescription medicines

There are a range of views across the Accord membership on the options provided in the consultation paper. As detailed above, members are unsure of the consumer need to include excipient ingredient information in the ARTG given the extent to which such sponsors and companies are directly contactable and have specialised consumer information teams which are equipped to address such requests.

One risk of the TGA publishing excipient information is that it potentially introduces confusion in ingredient names – for example, accounting for grades of similar ingredients (macrogol) and differences in INCI nomenclature compared to the AAN system. There is also a risk that ingredients present in trace amounts may be mistaken for intentionally added ingredients (e.g. BHT).

Concerns around maintaining the proprietary nature of proprietary ingredients (PI) were also raised. In relation to the possibility of disclosing the PI name and number, it was noted that this may be able to be traced back to the identity of the ingredient(s). Disclosure of the function of the PI (rather than the name and number) is preferred.

Some Listed products such as sunscreens contain proprietary bases. These bases, as with flavours and fragrances represent valuable IP, and as such, the disclosure of their constituent ingredients would have a significant commercial impact on the sponsors of these products and their suppliers.

If the inclusion of excipient ingredient information in the ARTG was to be implemented, the reasons for doing so should be better justified, and the above factors must be taken into consideration.

We do not support the inclusion of excipient ingredient information in the ARTG for hard surface disinfectants.

Given their intended use pattern, disinfectants are unlikely to be products of concern with regard to allergy as they are not intended to be ingested or applied to the skin, so any contact with the user would be incidental. Any hazardous ingredients, including excipients, are already required to be disclosed in accordance with SUSMP and/or Workplace Health & Safety requirements.

As only a limited number of disinfectants are now included on the ARTG following the recent changes to disinfectant regulation, it would not make sense, and may cause more confusion for consumers to require public excipient disclosure for this small subset of products, when it is not required for the majority of the product category in Australia.

It can also be noted that the overseas requirements referred to in the consultation paper as currently disclosing excipient ingredients, only do so for medicines.

Should you have any questions related to Accord's comments, please don't hesitate to contact me.

Yours sincerely,

[unsigned for electronic transmission]

Rachael Linklater
Manager, Regulatory Science & Technical

10 October 2019