



SUBMISSION

Increased online access to ingredient information¹

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¹ <https://www.tga.gov.au/consultation/consultation-increased-online-access-ingredient-information>

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INTRODUCTION

The Pharmacy Guild of Australia (the Guild) is the national peak organisation representing community pharmacy. It supports community pharmacy in its role delivering quality health outcomes for all Australians. It strives to promote, maintain and support community pharmacies as the most appropriate primary providers of health care to the community through optimum therapeutic use of medicines, medicines management and related services.

We welcome the opportunity to provide a submission to the consultation process on increased online access to ingredient information.

Option 1 Publish the names of excipient ingredient in the ARTG

1A: Publish names of excipients except those used in flavour or fragrance proprietary mixes

Under Option 1A, the ARTG public summaries for therapeutic goods would display a list of excipient ingredients present in that good, except ingredients that are part of a flavour or fragrance of a proprietary ingredient. Flavour and fragrance mixes would only be displayed either by their proprietary name and number (e.g. 'PI1234 Lemon flavour') or by their purpose (e.g. 'flavour') and would not display their constituent ingredients.

This approach broadly aligns with ingredient information available for foods and cosmetics in Australia. This option is also consistent with practices adopted by New Zealand and Canada for both prescription and non-prescription medicines.

1B: Publish names of excipients except those used in any proprietary ingredient mixes

Under Option 1B, the ARTG public summaries for therapeutic goods would display a list of excipient ingredients used in that good, except those ingredients present as part of any type of proprietary ingredient.

Currently there are 16 types of proprietary ingredients used in therapeutic goods. Aside from the commonly known flavours and fragrances these include colours, printing inks, preservative mixes, coating solutions, capsule formulations and cream bases. Under this option, any combination of ingredients referred to as a proprietary ingredient mix would be included in the public summary either by its proprietary name and number or by its purpose.

Under this option consumers would still have increased access to information about excipient ingredients in therapeutic goods, especially for non-prescription medicines. However, significant gaps in publicly available information would remain, resulting in continued misalignment with the approaches for food and cosmetics.

Option 2 Status quo – no action by the TGA to publish excipient names in the ARTG summaries

Question 1. What is your preferred option? Why?

Our preferred option is Option 1A.

We believe this option provides the most transparent display of ingredients.

If the purpose of this initiative is to provide as much information to the consumer then we do not believe there should be exceptions to the list of excipients. We believe that in the interests of transparency all excipients should be listed and option 1A appears better than 1B in this respect.

Question 2. What are the risks and benefits for each of the options proposed?

There is a risk that if more information is provided for consumers there may be an increase in confusion and unnecessary angst amongst consumers. However we do not believe that hiding information is appropriate and the increased access to excipient information needs to be done in tandem with increased information about the excipients to allay any fears or unwarranted reaction from and on behalf of consumers.

Consumers have a right to know what is in the medicines they are taking but as CHF have stated² there is a low level of health literacy. Consumers need information on how to access the ARTG and to understand the information they find. Most excipients by definition are inert and have no clinical effect. Some excipients may be the cause of allergic reactions but by the same token they may also be inappropriately blamed for an allergy without any evidence. The allergy may in fact be caused by another food or allergen a consumer may have been in contact with. It would be unfortunate if consumers ceased an essential medicine on account of an ill-informed or misplaced belief that the excipients were doing them harm.

We would also argue that most consumers are unaware of the TGA and the work that it does to regulate medicines and medical devices nor would most consumers know about the ARTG and how to navigate it to find the information they need. Most consumers would ask their pharmacist if they had any queries about the contents of the medicines they take.

The improved access to information needs to be accompanied with a public education program to help consumers understand the information that they discover. Pharmacies are the most accessible health care professional for consumers and the experts on medicines information. A consumer's local pharmacist is the best place for them to discuss any concerns they may have with the excipients in a medicine.

Question 3. If Option 1A or 1B is implemented, are you interested in collaborating with us to help communicate this information to consumers?

We would be happy to collaborate with the TGA on communicating this information to pharmacists, pharmacy staff and consumers. We have extensive experience in communication to consumers on health related matters and have recently collaborated with the TGA on a number of campaigns e.g. Assessed listed medicines, changes to codeine scheduling etc.

² <https://chf.org.au/media-releases/health-literacy-good-if-you-are-ill-not-so-much>