



Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Email: ARTG.Excipients@tga.gov.au
Attached – TGA Coversheet

Re: TGA Consultation: Increased online access to ingredient information

The Health Care Consumers' Association (HCCA) is a health promotion charity and the peak consumer advocacy organisation in the Canberra region. HCCA provides a voice for consumers on health issues and provides opportunities for health care consumers to participate in all levels of health service planning, policy development and decision making.

HCCA involves consumers through:

- consumer representation, and consumer and community consultations,
- training in health rights and navigating the health system,
- community forums and information sessions about health services, and
- research into consumer experience of human services.

HCCA is a member-based organisation and for this submission we consulted broadly with our members. HCCA welcomes the opportunity to provide input to the TGA's consultation. Overall, we support the proposal to provide increased public access to ingredient information online.

Responses to Consultation Questions

1. Which is your preferred option? Why?

HCCA supports option 1A – to publish the names of excipients except those used in flavour or fragrance proprietary ingredient mixes.

Consumers will benefit from increased transparency of information on non-active ingredients currently included in therapeutic goods marketed in Australia. Access to information, such as ingredient information about medicines and other therapeutic goods, is part of the Australian Charter of Healthcare Rights (2nd Edition)¹. A consumer also told us that

¹ <https://www.safetyandquality.gov.au/publications-and-resources/resource-library/australian-charter-healthcare-rights-second-edition-a4-accessible>

This would be consistent with 'freedom of information' policy that enables people to make an informed choice about taking/using a medicine in line with their own information about their allergies or sensitivities.

Disclosure of this extra information about ingredients in therapeutic goods should be as comprehensive as possible, while acknowledging that some flavours, inks, and colouring agents used in therapeutic goods are sold under proprietary restrictions as to their components (although common allergen warnings, as outlined in the consultation paper on p5, are still required).

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

Consumers seek to avoid particular ingredients for a range of reasons, including allergies. Providing increased and comprehensive access to ingredient information online will benefit consumers. Below we outline some key issues we think the TGA must consider in implementing increased online access to ingredient information.

Format of ingredient information

HCCA proposes that the greatest benefits for consumers will be realised by having the excipient information included in the Australian Register of Therapeutic Goods (ARTG) searchable not only by finished product, but by excipient component across the ARTG. That is, a consumer should be able to:

- (a) search the ARTG for a product and receive details of all ingredients of a therapeutic good; and/or
- (b) conduct a search across the ARTG for all therapeutic goods containing one or more excipients that the consumer believes may be the cause of their allergic or other adverse reactions.

Results of searches should be able to be printed in convenient tabular form for use by consumers.

While we recognise that the TGA acknowledges some excipient ingredients are proprietary formulations whose constituents are unlikely to be able to be detailed, an important exception is where preservative systems are used in products such as creams and lotions. A consumer told us

In my experience, sensitivity reactions to preservative systems used in cosmetics and therapeutic goods are common. Consumers must be able to search the ARTG to discover products that use specific preservative systems that have caused, or are like to cause, skin sensitivity and the like.

We would also like to highlight the importance of ensuring that the format of ingredient information is accessible for people with disabilities – such as interoperability with programs designed to assist those with hearing or vision impairment. HCCA proposes that user testing is particularly important in this area.

Keeping ARTG information up-to-date

Consumers highlighted concerns about ensuring the timeliness of formulation changes of products being reflected in the ARTG database. A consumer gave the following example

If a sponsor of therapeutic goods changes the preservative system used in a cream product, how long does it take for that change to be reflected in the ARTG (and therefore in consumer-based searches of non-active ingredients)? Does the sponsor need to seek approval from the TGA before making the formulation change, or does the sponsor notify the TGA that the formulation has been changed within a prescribed period? This 'timing' issue may be critical for consumers who, for example, may suffer from a skin sensitivity to specific excipients.

We believe it is important for the TGA to carefully consider what the steps are in this process and how the timeframes can be implemented to ensure the online information keeps step with the current ingredients in therapeutic goods. It will be important for this information to be communicated to all stakeholders, including industry and consumers.

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

HCCA supports collaboration with the TGA in communicating the changes to consumers, and believe that once the information is made available, this will be an important step. We are happy to be contacted by the TGA in relation to this work. HCCA has discussed collaborating with our member organisation, PWD ACT (People With Disabilities ACT) who also have an interest in this work.

Concluding comments

Thank you for the opportunity to provide feedback to this consultation process. HCCA looks forward to seeing how our consumer feedback is incorporated and we would be glad to discuss any aspect of our feedback in more detail. You can contact:

Kathryn Briant, Policy Officer HCCA
kathrynbriant@hcca.org.au or ph. (02) 6230 7800.

Thank you for the opportunity to put forward consumer views on these issues.

Yours sincerely

Kathryn Briant
Policy Officer
Xx October 2019