



Therapeutic Goods Administration

Increased online access to ingredient information

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Coeliac Australia (CA) is the National Registered Charity supporting all Australians with coeliac disease (CD). Our vision is to enhance the lives of those living with CD and related conditions. We welcome the opportunity provided by this consultation paper to highlight the needs of Australians living with CD.

CD is an immune based condition in which the body responds abnormally to dietary gluten (a protein found in wheat, rye, barley and oats). This autoimmune reaction causes systemic inflammation and damage to the lining of the small bowel.

The impact of non-compliance with a gluten free diet can include very unpleasant symptoms in the short term e.g. diarrhoea, nausea and/or vomiting, abdominal pain and bloating etc. as well as longer term health complications, including an increased risk of malignancy.

The prevalence of CD has significantly increased over the past 50 years^{i, ii}. Approximately 1 in 70 people in Australia (1.4% of the population) have CD, although the majority of patients with CD remain undiagnosed. It is more common in women than men (1:60 women and 1:80 men)ⁱⁱⁱ and may develop at any age, from childhood (when gluten is first introduced to the diet) through to older years.

Those diagnosed with CD require a strict life-long gluten free diet as the only treatment for their condition. This includes making sure any oral medications (prescription and non-prescription) are free of gluten.

The requirement (as per TGO91 and TGO92) that all prescription and non-prescription medicines must declare if the medicine contains gluten (at levels of 20ppm or more), or if it may be present as a result of the manufacturing process, is of critical importance to consumers with CD. In our messaging to members, we reinforce the fact that they can rely on the information on pack (for over the counter medication) or in the Consumer Medicine Information Leaflet (for prescribed medicines) for the most current information about the presence (or absence) of gluten.

While we are supportive of improving transparency for consumers, we are also concerned that the important messaging about the legislative requirement to include allergen warnings on pack/in the CMI may be confused.

Coeliac Australia's Response

Please find our organisations answers in response the questions posed in the TGA consultation paper: Increased online access to ingredient information (p8 of document) below.

Q1. Which is your preferred option? Why?

We are generally supportive of Option 1, but do not have a strong preference for either 1A or 1B.

In our experience, consumers with CD often contact our organisation and pharmaceutical manufacturers to seek assurance that a product is suitable for them. By promoting the fact that manufacturers are being transparent by providing additional ingredient information, consumers may be less sceptical of the industry and more trusting of the information provided to them.

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

Our main concern with the approach outlined in Option 1 is the potential for consumers to become confused.

The fact that gluten must be declared on pack/in the CMI (and that this legislation has been in place for some time) may be diluted by further (potentially unnecessary information) being available online. This may cause consumers to become confused by too much information, in multiple locations.

Should Option 1 be implemented, the communication with consumers must reinforce the fact that the presence of common allergens must always be declared on pack/in the CMI leaflet.

From what we can see online in the Australian Register of Therapeutic Goods at the moment, allergen warnings are not included? If we are to direct consumers to the ARTG, it is important that all relevant information (including allergen warnings) be included in the register.

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

Yes, CA would be definitely like to be involved in helping to communicate this information to consumers.

ⁱ Ludvigsson JF, Murray JA. Epidemiology of Celiac Disease. *Gastroenterol Clin North Am.* 2019;48(1):1-18.
doi:10.1016/j.gtc.2018.09.004

ⁱⁱ Catassi C, Gatti S, Fasano A. The New Epidemiology of Celiac Disease. *J Pediatr Gastroenterol Nutr.* 2014;59:S7-S9.
doi:10.1097/01.mpg.0000450393.23156.59

ⁱⁱⁱ Robert P Anderson, Margaret J Henry, Roberta Taylor. A novel serogenetic approach determines the community prevalence of celiac disease and informs improved diagnostic pathways. *BMC Medicine* 2013, 11:188
<http://www.biomedcentral.com/1741-7015/11/188>