Allergy & Anaphylaxis Australia

To whom it may concern:

On behalf of Allergy & Anaphylaxis Australia I wish to make a submission on the Therapeutic Good Administration consultation titled ***Increased online access to ingredient information***

Background

Allergy & Anaphylaxis Australia (A&AA) is a charitable, non-profit organisation established in 1993 to support and assist those affected by allergy and anaphylaxis. A&AA is dedicated to assisting individuals, their caregivers and all in the community in the management of allergic conditions including food allergy. A&AA's aim is to enable individuals and their families to enjoy an optimal quality of life whilst minimising risk to their health and wellbeing.

A&AA strives to raise awareness of allergy in the community and provides evidence-based information, resources and services to support children and adults living with allergic disease including food allergy. A&AA has members across all states and territories of Australia. We have a Medical Advisory Board that consists of several allergy specialists who are also members of Australia's peak medical body, ASCIA (the Australasian Society of Clinical Immunology and Allergy).

Submission

A&AA recognises the difficulties faced by those with an allergy, or their carers, in identifying therapeutic goods which are safe for use. **A&AA prefers option 1A as a significant improvement on the current availability of allergen information.**

However the Consultation Paper highlights the current defect in the declaration of allergens and gluten in the PI document and CMI leaflet, in that the composition of proprietary ingredient mixes, allergens, apart from prescribed allergens, (see https://www.tga.gov.au/allergies-and-medicines) are not included.

A&AA would prefer option 1A to 1B, on the basis that option 1B exempts all proprietary ingredient mixes, whereas option 1A exempts only flavours and colours. Nonetheless, for both 1A and 1B, persons with an allergy other than the ones prescribed, cannot totally rely on the information displayed in the ARTG public summaries without making further enquiries about the composition of such mixes.

Option 1A suffers the same defect, albeit limited to flavour or fragrance proprietary ingredient mixes. The Consultation Paper states that that approach "broadly aligns with ingredient information available for foods and cosmetics in Australia". That seems to be correct.

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Recommendations

A&AA considers that the TGA should consider mandating the declaration of all ingredients in proprietary ingredient mixes. Thus for example the declaration of gelatine (for people with mammalian meat allergy) and corn (for people with non IgE mediated food allergy) would obviate the need for further enquiries.

A&AA considers that the TGA should consider mandating the declaration of other substances requiring declaration in Food Standard 1.2.3 in all therapeutic goods. The Food Standards Australia New Zealand (FSANZ) Food Standards Code (FSC) has added lupin as a common allergen. A&AA encourages the TGA to add lupin to the list of common allergens that must be declared for consistency.

We also encourage the TGA to make contact with FSANZ in regard to expected changes as a result of Proposal 1044 Plain English Allergen Labelling (PEAL). A final public consultation period is expected in October/November 2019.

A&AA encourages the TGA to list wheat for those with wheat allergy (as opposed to those with coeliac disease needing to avoid gluten).

A&AA urges the TGA to communicate the importance of not placing sticky labels over the allergen information on medication, biologicals and other therapeutic goods. If the allergen information is on the Consumer Medicine Information leaflet, the message on pack directing people to the CMI must remain visible

Questions (see page 8 of discussion paper)

Q1 A&AA prefers option 1A because it represents a substantial improvement on the current availability of information, and addresses the growing prevalence of allergic disease. Option 1A saves the consumer (or carer) with internet access some time in obtaining the information they need. They will no longer have to rely on the manufacturer of the medication or the TGA or their doctor or pharmacist to research the required information and get back to them, unlike the consumer who does not have internet access.

Q2 For option 1, the risks are that a) not all people have internet access or the ability to utilise internet access, b) the option does not address the presence of non-prescribed allergens in proprietary ingredient mixes, and c) the risk that consumers will assume the information provided is comprehensive, and will fail to independently check the composition of the proprietary ingredient mixes.

For option 1, the benefits are improved access to safety information for those with an allergy and for those providing support for or treating people with an allergy or coeliac disease

For option 2, the risk is a perceived failure by Government in addressing a recognised problem for those with an allergy or with coeliac disease

For option 2, for those with an allergy or coeliac disease, and for those providing support for or treating people with an allergy or coeliac disease, there are no benefits.

Q3 If option 1A or 1B were implemented, A&AA would be most interested in collaborating with the TGA to share information and therefore increase public safety.

The below request was put in an email to A&AA members:

"A&AA will be putting in a submission on this issue. You can directly email us with your opinion so that your voice can also be heard in our submission."

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Members have sent us the below information for inclusion in this submission. We ask the TGA to consider their individual concerns.

1) *I have a reaction to hydroxybenzoate preservatives. The presence of preservatives is often not on the packaging or even available online for the chemist to access easily for common painkillers such is paracetamol and ibuprofens. It would be good for this information to be clearly available.*

2) *I have responded to your survey but I was not happy with any of the options. I have a life threatening anaphylaxis reaction to anything mammal (AlphaGal/ Mammalian Meat Allergy) and the most difficult thing for me is knowing what medicines, vaccines and products used in medical and dental procedures are safe for me. No one can help. Doctors, dentists and pharmacists can't tell me if the products they use contain mammal. Even when I phoned the makers of the flu vaccine I was told this information was not available to the public and my doctor would need to make the inquiry. I reacted badly to a prolia injection which resulted in a painful case of shingles at the injection site. I have delayed an overdue colonoscopy as it is impossible for me to find out what products are used in the procedure (anaesthetics included).*
   So for me to safe when taking medicines I need to know the source of ALL ingredients including coatings and flavourings. Gelatine, glycerin, Vitamin D, magnesium stearate, dairy, carrageenan all have the potential of causing anaphylaxis.
3) *Thank you for contributing to this submission! I have long felt that it is unsatisfactory that medication packaging does not have full disclosure of common allergens and that it is often impossible to find that information online, even by a pharmacist. Sometimes this information is on the Consumer Medicine Information leaflet, however, if one is provided, it is usually sealed inside the packet and therefore inaccessible until after purchase. The information is not always up to date online. I am a Coeliac and extremely sensitive to even small traces of gluten and my son is anaphylactic to dairy products, so it is always essential for our family to have access to this kind of information.*
   I would like to request that the TGA not only implements greater transparency on their website concerning excipient ingredients, but that the common allergens also be declared on the packaging.
4) *The TGA didn't give us OPTION D - show both what's mentioned in OPTION A and OPTION B. In other words, we still won't have info about all ingredients. People who want organic products or wish to avoid certain things need to know **everything** in products.*
5) I think it's a great idea to provide allergen information on medicines.

We thank you for the opportunity to provide input on changes being made to improve access to excipient ingredient information that impacts consumer safety.

Yours faithfully,

[redacted]

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