



Allergy & Anaphylaxis Australia[®]

7 September 2023

Email: TGA.Scientific@health.gov.au

Dear Therapeutic Goods Administration,

RE: Australian medicine labelling rules – Targeted consultation on priorities for future improvements to TGO 91 and TGO 92

- Do we need to update more medicine labelling rules in the short term to support medicine safety before we conduct a broader review?

Yes, Allergy & Anaphylaxis Australia (A&AA) believes that an update is required in the short term to the “Declaration of Substances”, with respect to the food allergens that must be declared. It is vital that information on medicine labels is clear, accurate and comprehensive for people with allergy, their carers, and health professionals to enable them to make informed decisions about the suitability and safety of prescribed and non-prescribed medicines if they have a food allergy.

- What are the priorities for future updates to medicine labelling rules to support the safe and quality use of medicines?

Our suggestions for issues to be considered as a priority within the section ‘Declaration of Substances’ are:

1. A&AA recommends that all medicines containing food ingredients be clearly labelled regardless of the route of administration. This is important as even topical medications can cause an allergic reaction if they contain the food allergen the person is allergic to, particularly if applied to broken skin. There is also evidence that application of food containing topical medications can increase the risk of developing an allergy to that food.
2. The current requirement for prescription medicines is that substances must be declared on either the label on the pack or in the Consumer Medicine Information (CMI) leaflet. A&AA strongly believes that all food ingredients should be listed on the label of prescription medicines, as well as over the counter and listed medicines. A&AA is concerned that if this information is not on the label, people with food allergy may not understand that information for prescription medicines is also contained in the CMI leaflet and could mistakenly assume a food ingredient is not present.
3. Currently the list of allergens in Schedule 1: ‘[Substances or Groups of substances present in medicines that are required to be declared on the label of medicines](#),’ is not consistent with the [Food Standards Australia New Zealand \(FSANZ\) allergen labelling](#) requirements for food. For example, mollusc does not appear on the TGA list of substances to be declared, but it is required with the soon to be mandatory (February 2024), Plain English Allergen Labelling legislation progressed by FSANZ. It is important that all common food allergens, that contribute to 90% of food allergic reactions, are included.

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- a) It is important for gluten to be labelled for people with Coeliac Disease and gluten intolerance. The reference to gluten does not address the need for people with wheat allergy who may be a risk of a severe allergic reaction (anaphylaxis) to small amounts of wheat. Gluten free does not mean 'wheat free' as people with wheat allergy may react to wheat proteins other than gluten. A&AA propose that there be a requirement for wheat to be listed as 'wheat' regardless of the quantity to be consistent with FSANZ.
- b) Milk and milk products must be listed in the TGA Schedule 1 "Substances or Groups of substances present in medicines that are required to be declared on the label of medicines", but it does not make it clear in the examples that ALL animal milks should be listed. People with cow's milk allergy are also likely to be allergic to other milk, such as goat, horse, camel, sheep.
- c) Mollusc is not included in TGA Schedule 1. While we do not have accurate data on the incidence of mollusc allergy in Australia and New Zealand, it is listed as a separate common food allergen by FSANZ. In the FSANZ Safety Risk assessment document, "FSANZ's Food Allergy and Intolerance Scientific Advisory Group (FAISAG) has advised FSANZ that mollusc allergy is of clinical significance in the two countries." A&AA recommends that mollusc be included to be consistent with FSANZ.
- d) Tree nuts defined in TGA Schedule 1 include almond, Brazil, cashew, macadamia, almond, chestnut and walnut. A&AA recommends that the list of tree nuts be consistent with FSANZ: almond, Brazil, cashew, pistachio, walnut, pecan, macadamia, hazelnut, pine nut. Note that this list from FSANZ does not include chestnut.
- e) A&AA feels that a priority to ensure the safety and quality of medicines is to ensure the medicine labelling information is clear (plain English) and comprehensive. In the Plain English Allergen Labelling legislation, foods must be listed by their common name to make it easier for people with food allergy to understand. For example, the term almond should be used rather than the botanical name, *Prunus dulcis*.
- f) A&AA recommends that not only should the common food allergens be labelled, but all food should be labelled. This would mean that ingredient information would also be available to the remaining 10% of people who are allergic to other foods, such as corn, mammalian meat (gelatin), rice. People with food allergy, including health professionals prescribing medications, do not always consider food content in medication so having the medication labelled if it does have any food content would increase safety for those with food allergy.

Yours faithfully,

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